

# Tobacco Treatment Public Comment Summary Report

## Project title

Hospital Inpatient and Outpatient Process and Structural Measure Development and Maintenance

## Dates

- ◆ The call for public comment ran from Thursday, November 5, 2015, to Friday, December 4, 2015.
- ◆ The public comment summary was submitted to the Centers for Medicare & Medicaid Services (CMS) on Friday, December 18, 2015.

## Project overview

CMS has contracted with Mathematica Policy Research and its partners to develop, electronically specify, and maintain process and structural clinical quality measures for five CMS hospital quality programs. The programs are the Hospital Inpatient Quality Reporting Program, Hospital Outpatient Quality Reporting Program, Ambulatory Surgical Center Quality Reporting Program, Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program, and Electronic Health Record (EHR) Incentive Program for Eligible Hospitals. The name of the contract is Hospital Inpatient and Outpatient Process and Structural Measure Development and Maintenance (Hospital-MDM). The contract number is HHSM-500-2013-130111/HHSM-500-T0003. As part of its measure development process, CMS has asked interested parties to submit comments on the TOB (Tobacco Treatment) measures.

## Project objectives

The project's primary objectives are:

- ◆ Conducting an environmental scan to identify gaps in existing hospital quality reporting programs where new measures will be useful and important
- ◆ Developing, specifying, and testing new hospital electronic clinical quality measures (eCQMs) for implementation in CMS's quality reporting programs in the areas identified during the environmental scan
- ◆ Retooling existing measures to facilitate reporting using data extracted from an EHR
- ◆ Maintaining previously developed hospital measures currently in the five CMS programs named above by monitoring their validity and effectiveness and recommending any needed improvements

## Information about the comments received

The project team used extensive outreach methods to notify stakeholders and the general public about the comment period:

- ◆ Email sent to CMS listserv groups, including the IQR Listserv and eHealth provider and vendor work groups (eCQI Resource Center)

- ◆ Email sent to The Joint Commission stakeholder list, including hospitals currently submitting the TOB chart-abstracted measures
- ◆ Email sent to TOB Technical Advisory Panel
- ◆ Email sent to TOB eCQM Task Force
- ◆ Email sent to EHR vendor contacts
- ◆ Email sent to CDC Office on Smoking and Health
- ◆ Health IT Policy Committee Quality Measures Workgroup
- ◆ Email sent to stakeholders and stakeholder organizations:
  - Action on Smoking and Health
  - American Academy of Addiction Psychiatry
  - American Academy of Family Physicians
  - American Association of Nurse Practitioners
  - American Academy of Physician Assistants
  - American Association for Respiratory Care
  - American Board of Surgery
  - American Board of Internal Medicine
  - American College of Cardiology
  - American College of Obstetricians and Gynecologists
  - American College of Physicians
  - American Head and Neck Society
  - American Lung Association
  - American Lung Association of DC
  - American Medical Association
  - American Medical Group Association
  - American Medical Student Association
  - American Medical Women's Association
  - American Nurses Association
  - American Osteopathic Association
  - American Pharmacists Association
  - American Psychiatric Nurses Association
  - American Public Health Association
  - American Society for Reproductive Medicine
  - American Society of Addiction Medicine
  - American Society of Preventive Oncology
  - American Thoracic Society
  - Association of Clinicians for the Underserved
  - Association for the Treatment of Tobacco Use and Dependence
  - DC Tobacco Free Families Campaign
  - Healthcare Information and Management Systems Society (HIMSS) Electronic Health Record Association
  - Institute for Healthcare Communication
  - Institute for Healthcare Improvement
  - Lung Cancer Alliance
  - National Committee for Quality Assurance

- National Hispanic Medical Association
- National Latino Council on Alcohol and Tobacco Prevention
- National Tobacco Cessation Collaborative
- North American Quitline Consortium
- Partnership for Prevention
- Pharmacists Planning Service Inc
- Pharmacy Council on Tobacco Dependence
- Pharmacy Partnership for Tobacco Cessation
- Society of Behavioral Medicine
- Society of General Internal Medicine
- Society for Research on Nicotine and Tobacco
- Tobacco Free Nurses
- University of Wisconsin Center for Tobacco Research and Intervention
- Youth Tobacco Cessation Collaborative
- Dr. Larry Dent, School of Pharmacy and Allied Health Sciences, University of Montana
- ◆ Facilitators of the following groups were asked to announce the public comment period during periodic meetings:
  - eMeasures Issue Group Work Group
  - Weekly governance call for measure developers
- ◆ Announcement on the eCQI Resource Center website
- ◆ Announcement through the IQR Support Contractor Listserv
- ◆ Posting on the CMS Public Comment website

We received twenty-nine (JIRA) comments, many with multiple comments embedded, in addition to 3 comments via email from the following during the public comment period:

- ◆ Six hospital/health systems (West Georgia Health, Kaiser Foundation Hospitals–Roseville, Maple Grove Hospital/North Memorial Health Care, Mayo Clinic, Memorial Hermann Health System, Baylor Scott and White Health)
- ◆ One EHR vendor (Cerner)
- ◆ Two professional societies (American Association of Orthopaedic Surgeons [AAOS], American Lung Association)
- ◆ One health information technology (IT) consulting company (Encore Health Resources)
- ◆ One group made up of academic institutions and professional societies (University of Wisconsin Center for Tobacco Research and Intervention [UW-CTRI], Altarum Institute Center for Prevention, American Cancer Society Cancer Action Network, American College of Preventive Medicine, American Lung Association, ClearWay Minnesota, Mayo Clinic, National Association of State Mental Health Program Directors [NASMHPD])
- ◆ One academic institution (University of Kansas)
- ◆ Six individuals (organizations not provided)

## Stakeholder comments—general and measure-specific

### Support

*Six commenters* supported the measure overall.

**Response:** Thank you for your support for the current approach, including the changes made to the previously chart-abstracted Tobacco Treatment measures.

### Measure intent

*Four commenters* recommended expanding the list of tobacco products to include other common forms of smoking, including e-cigarettes, marijuana, and hookah.

**Response:** Thank you for your comment. The forms of tobacco included in the TOB measures are based on recommendations from our clinical advisory panel. At this point in time, the body of evidence is not strong enough to support cessation interventions for hookah use and e-cigarette use since these are new and emerging forms of tobacco or non-tobacco products. The TOB measures focus on tobacco products, and marijuana is not included in the measures because it does not contain tobacco. We will consider the suggestion to clarify these items.

*Two commenters* said that TOB-2/2a and TOB-3/3a are very similar and should be combined for simplicity.

**Response:** Thank you for your comment. TOB-2/2a and TOB-3/3a were designed and endorsed as distinct measures because they have different intents. TOB-2/2a is intended to ensure the patient is offered tobacco cessation interventions while hospitalized, whereas TOB-3/3a is intended to ensure the continuity of cessation interventions after hospital discharge. These are two distinct processes which both contribute to patient success in quitting tobacco use.

*Four commenters* made remarks about refusal exclusions, specifically why TOB-2a and TOB-3a do not account for patient refusal.

**Response:** Thank you for your comment. TOB-2 and TOB-2a and TOB-3 and TOB-3a are paired measures which should be viewed together. Both rates should be reviewed to better understand the hospital's performance. The goal is to narrow the difference in rates over time. TOB-2 and TOB-3 are evaluating all patients who either accepted or refused practical counseling or referral and cessation medication or prescription if applicable. TOB-2a and TOB-3a are intended as public health measures, and evaluate all patients who actually received practical counseling or referral and cessation medication or prescription, if applicable.

We believe that reporting of these measures will yield information that provides meaningful distinctions in the quality of care provided across hospitals. Because tobacco use cessation treatment (counseling and medication if indicated) is considered an essential step in the care process for patients, we believe that it is critical for patients, their families and caregivers, to have accurate available information on whether hospitals integrate this into their care processes.

## Measure specifications

*Six commenters* expressed a desire to revise the way in which the amount of tobacco use is captured, including:

- ◆ *Three commenters* expressed the need to align the thresholds for “heavy” and “light” smokers with the meaningful use (MU) smoking status data element.
- ◆ *One commenter* expressed concern regarding the fact that the differentiation of light versus heavy tobacco users does not account for multi-form users (users of multiple forms of tobacco).
- ◆ *One commenter* recommended removing the categories of “heavy” and “light” users to simplify the measure.
- ◆ *One commenter* recommended adding categories for “current use,” “past use,” and “no history of use.”

**Response:** Thank you for your comments. The TOB measures have been developed to define light user as an individual who uses fewer than 5 cigarettes or 1/4 pack per day, while a heavy tobacco user is defined as one who uses 5 or more cigarettes, or 1/4 or more packs, per day. The recommended treatment for light and heavy users will differ for both TOB 2/2a and TOB 3/3a.

The TOB measure definition of light versus heavy cigarette user is grounded in the latest clinical evidence, which suggests cessation medications benefit those smoking 5–10 cigarettes per day (Baha and Le Faou 2010; Krupski, Cummings et al. 2013; Shiffman 2005). In addition, such smokers appear to be increasingly common (CDC 2014; Kotz, Fidler, and West 2012). In order to minimize redundant data capture related to amount of cigarette use, the TOB eCQMs model this concept as a numeric field. This allows for (1) a single source of data to support both the TOB measures and mapping to MU required SNOMED-CT codes and (2) robust data capture, without any required changes if the threshold changes in the future. We recognize the challenges associated with reconciling MU requirements with the TOB measures. We will review and consider the suggestions with CMS and our measure development team and will continue to look for ways to align the requirements for the TOB eCQMs and MU.

*Six commenters* recommended alignment with MU requirements and other tobacco measures, including tobacco usage, time frames for collecting tobacco use information, and the age cutoff for the initial population.

**Response:** Thank you for your comments. We recognize the challenges associated with reconciling the meaningful use (MU) requirements with the TOB measures. When re-specifying the TOB measures as eCQMs, we made every effort to align with the MU requirements. There are, however, areas or concepts we are unable to fully reconcile with MU requirements. For example, it is correct that the time frame used in the TOB-1 eCQM is different from the time frame allowed for tobacco use screening in the chart-abstracted measure. There are a couple of reasons for this:

- ◆ The time frame for screening within three days prior to admission is intended as a timing approximation to account primarily for events that may occur after hospital arrival but prior to inpatient admission (for example, when the patient is in the emergency department [ED] or in observation status). In the chart-abstracted measure, this is modeled as guidance to the abstractor.
- ◆ The time frame for screening within one day after admission was an intended departure from the chart-abstracted measure, however the same modification is expected to be made to the chart-abstracted measure in the future.

Regarding the 18-years-old and older initial population, there is no evidence to support the use of cessation medications in adolescents (under 18), and the TOB clinical advisory panel recommended restricting the measures' population to adults. Nevertheless, this should not preclude facilities from screening and providing cessation counseling to adolescent patients.

Please refer to the previous response for discussion surrounding the alignment of tobacco usage with MU.

We will, however, review and consider the suggestions with CMS and our measure development team.

*Six commenters* commented on the use of the impaired cognition concept in the measure, including suggestions to simplify the related logic and the use of the Glasgow Coma Scale, concerns about the many options for modeling the concept, difficulty in capturing impaired cognition, and overall clarification of the concept.

**Response:** Thank you for your comments. We included multiple options for modeling the concept of impaired cognition to allow for flexibility in the implementation of the exclusion. It is not expected that all possible options are implemented at a single site, but that facilities choose those that are more appropriate for their current workflow.

Our alpha testing findings indicate that the majority of testing sites (seven out of eight) have both Glasgow Coma Total and Component Scores available as structured data in their electronic health records systems. We included the individual components of the Glasgow Coma Scale (GCS) as well as the total; the intent was to allow for implementers that may already have this documentation in place to use such scores to exclude patients who may be unable to respond to screening questions. We understand, however, how the use of the GCS may complicate the logic of the impaired cognition exclusion.

We will consider your suggestions to simplify the impaired cognition exclusion, including the potential removal of the Glasgow Coma Scale, as we make revisions to the eCQM specifications.

*Six commenters* asked questions about the time frame specified for data collection in the measures and recommended adjusting the time frame and setting for the data collection. This included questions regarding the time frame for the screening as well as the recommendation to allow one day post-discharge for referrals.

**Response:** The TOB eCQM specifications have been designed to exclude patients with a length of stay (LOS) of one day or less. The current logic is designed to cover data gathered in the facility the patient has been admitted to, but prior to the inpatient admission, including data gathered in the ED and outpatient settings, as well as data captured while a patient is in observation status. There is no expectation that the facility would source data from other facilities; however, we want to ensure that facilities that have other data sources accessible are able to use these data for the measures.

We will, however, review and consider the suggestions made, particularly regarding the allowance for one day post-discharge, with CMS and our measure development team.

*Three commenters* commented about referrals, including asking clarification of the data to be captured, suggesting an adjusted time line for referrals for one day through discharge, and regarding the overall difficulty in the referral workflow.

**Response:** We recognize that the "Communication, Provider to Provider" data type does not provide sufficient detail on the intent of the referral data element. The original data element in the chart-abstracted measure requires that the patient has a follow-up appointment or that the hospital facilitates

the patient's contact with a quitline. We plan to revisit the logic associated with this data element to make it clearer. We will also review and consider the recommendation made to allow more time post discharge for a referral to occur.

*One commenter* asked about the need to add a “Medication, Order not done for medical reason” exclusion.

**Response:** Using the latest chart-abstracted data available, we have found that the medical reasons exclusion is very seldom used. However, we will review and consider your suggestion with CMS and our measure development team.

### Value sets

*Three commenters* asked about the availability of value sets and their naming. Specifically:

*Two commenters* asked questions related to the availability of value sets during the public comment period and including a mechanism for the public to provide feedback on empty value sets.

**Response:** The value sets used in the TOB eQMs were published in the Value Set Authority Center (VSAC) and were available for review throughout the public comment period. Instructions on how to access the value sets in the VSAC were included with the TOB eQm specifications and other materials provided in the public comment announcement. Only two value sets were not published with the TOB eQm specifications; this was due the fact there were no appropriate codes available in LOINC® to represent the intended data elements. We have requested these codes and are awaiting their approval. To mitigate the lack of availability of these two value sets, we included information about the intent and content of these value sets in a companion document published with the eQm specifications and other public comment materials.

*One commenter* asked whether the name of a value set (Risk Category Assessment: Frequency of Tobacco Use) could be changed to more accurately reflect the data element for which the value set is used.

**Response:** Thank you for your comment. We would like to clarify that while the TOB eQm logic only requires that the frequency of tobacco use is documented for pipe and/or cigar smokers, it does not necessarily need to be specific to these types of tobacco products (when used in other measures).

### Measure logic

*Six commenters* asked for clarity or recommended changes to the measure logic. Specifically:

*One commenter* said the measure logic was too complex, recommending the logic be simplified.

**Response:** We recognize the measure specifications seem complex. This is due, in part, to the limitations of the expression language associated with the Quality Data Model (QDM), which does not allow us to express conditional logic. In addition, some of the complexity arises from our attempt to provide sufficient flexibility in the specifications to accommodate variability in data capture and workflows, and therefore lower the burden of implementation across multiple facilities and EHR system implementations.

*One commenter* recommended allowing for alphanumeric fields for capturing the frequency of tobacco use in addition to the existing option of capturing this data as a numeric value with two decimal points.

**Response:** Thank you for your comment. The eCQM logic is not intended to require capturing the volume of cigarette use as a decimal number, and that mapping alphanumeric fields to a number would be acceptable, as stated in eCQM guidance. We understand that alphanumeric fields may be in use today, however we have found that the documentation varies across sites (for example, <1/2 pack, <=1/2 pack, 1–2 packs, 1/2 pack), which would make it difficult to create thresholds that would work for all implementers and therefore still require mapping. We will consider including additional guidance in the eCQMs to minimize the burden of mapping from alphanumeric fields to the numeric fields included in the logic.

*Three commenters* asked questions regarding the data sources for capturing cognitive impairment. Specifically, one asked for more clarification; another suggested cognitive impairment status be captured from only one data source in order to simplify the logic.

**Response:** Thank you for your comment. Both clinical diagnoses and coded diagnoses would be acceptable for capturing cognitive impairment. We included multiple options for modeling the concept of impaired cognition to allow for flexibility in the implementation of the exclusion. It is not expected that all possible options are implemented at a single site, but rather that facilities choose those that are more appropriate for their current workflow.

However, we appreciate your input on the expected level of effort to implement these exclusions. We will review and consider your suggestion with CMS and our measure development team.

*One commenter* recommended the streamlining of a temporal element within the logic.

**Response:** Thank you for your detailed review of the eCQM specifications. We will review and consider your suggestions with CMS and our measure development team.

*One commenter* said that the “Medication, Order not done: Patient Refusal” for “Tobacco Use Cessation Pharmacotherapy Ingredient Specific” construct is not compliant with the recent QRDA I & III Implementation Guide, and requested that ingredient-specific reference related to contraindications be removed from all negation constructs.

**Response:** Thank you for your comment. The medication, order logic is provided to allow for flexibility and minimize the burden of implementation. We recognize different implementers may embed patient refusal within different workflows and want to ensure the measure specifications support these different workflows. We also recognize that there have been recent updates to the reporting of negation in the HL7 Quality Reporting Document Architecture (QRDA). We will review and consider your suggestions with CMS and our measure development team.

### Concerns and challenges

*Nine commenters* submitted comments related to concerns about the value and effectiveness of the measures and health care in general, additional burden on hospitals, and government’s role in health care. Specifically:

*Two commenters* said the government should not dictate patient decisions regarding smoking (and a patient’s refusal for treatment should not penalize the hospital) and they do not want the government to have access to collect personal information on U.S. citizens.

**Response:** Thank you for your comments. Americans certainly have the right to purchase and smoke cigarettes as well as refuse counseling or treatment. TOB-2 and TOB-3 are evaluating all patients who

either accepted or refused practical counseling or referral and cessation medication or prescription if applicable, thus, patient refusal will not count against a hospital. TOB-2a and TOB-3a are intended as public health measures and will be used for research purposes.

We believe that reporting of these measures will yield information that provides meaningful distinctions in the quality of care provided across hospitals.

*Three commenters* said that these measures would create a burden on hospitals by forcing them to reconfigure EHRs and workflows.

**Response:** Thank you for your comments. We recognize the implementation of the measures may be more difficult for hospitals lacking the infrastructure and/or EHR workflows to support tobacco screening and cessation interventions. Part of assessing the feasibility of this measure includes obtaining feedback on the extent to which a hospital's enterprise EHR system can capture the data that is required. We will review your comments with CMS and our measure development team when discussing challenges and opportunities associated with future measure implementation.

*Three commenters* said they had concerns regarding the effectiveness and value of the measures and appropriateness of the measures in the inpatient setting.

**Response:** Thank you for your comments. All three TOB measures are based on previously developed chart-abstracted tobacco measures designed for the inpatient setting and endorsed by the National Quality Forum (NQF) in 2014. We would like to clarify that the TOB measures are not focused on patients admitted to inpatient care due to tobacco-related illnesses. The measures were developed with the general adult inpatient population in mind. In addition, the U.S. Department of Health and Human Services Public Health Service Clinical Practice Guideline, Treating Tobacco Use and Dependence 2008 Update emphasizes that a hospitalization presents a unique opportunity to promote tobacco cessation and urges such evidence-based interventions be delivered to every hospitalized tobacco user.

- During hospitalization, patients are not allowed to use tobacco, are in contact with many health professionals, and may be more willing to accept assistance in quitting
- Many tobacco users quit, unaided, following hospitalization
- Those who receive intensive treatment during hospitalization and outpatient follow-up treatment for at least one month are more likely to quit than smokers receiving no treatment

## Preliminary recommendations

We will review the commenter suggestions with CMS and our measure development team to improve the alignment between CMS programs. We will also consider ways to simplify the eCQM logic to minimize the burden of implementation. Finally, we will consider the suggestions regarding the measure concepts and intent with our clinical advisory panel for future iterations of the measures.

Any updates to the measure specifications will be disseminated to the public when the measure testing is complete.

## **Overall analysis of the comments and recommendations**

Feedback received on the TOB-1, TOB-2/2a, and TOB-3/3a measures was highly constructive. Many commenters raised valid concerns about the alignment of these TOB measures with MU requirements, which many hospitals have implemented. A number of commenters were concerned about the lack of a patient refusal exclusion for the paired measures (TOB-2a and TOB-3a). Comments on measure logic largely focused on the timing of certain data elements. Commenters also provided important feedback on their current workflows and EHR capabilities and configurations as they pertain to this measure, including specific remarks on the feasibility of capturing information regarding refusals and referrals, which are needed to calculate the measure. We thank commenters for providing their unique perspectives on this measure.

## Public Comment Verbatim Report

Item #	Date posted	Text of comment	Name and organization of commenter	Email address	Type of organization	Final response
1	11/16/15	<p>I would like to leave a comment about the Tobacco Measures and the way they are written by the Joint Commission. When a patient refuses counseling or treatment, the case fails. There is no exclusion written into these measures. The last time I checked, Americans still have Civil Liberties and a Bill of Rights that allow them to refuse things such as care and treatment. Americans have the RIGHT to make bad decisions. Americans have the right to purchase and smoke cigarettes, drink alcohol and many other things that are not healthy. Hospitals cannot force patients to listen to counseling and accept treatment or help and hospitals should not be punished for the rights of Americans. The measures are written in a very confusing methodology and basically hold no importance to physicians or the medical community when they are written so poorly and do not exclude situations out of our control. They become "so what" numbers and do nothing to improve the quality of care. God Bless America, I can refuse your control over my decisions for my health care.</p>	Not available	Not available	Not available	<p>Americans certainly have the right to purchase and smoke cigarettes as well as refuse counseling or treatment. TOB-2 and TOB-2a and TOB-3 and TOB-3a are paired measures which should be viewed together. Both rates should be reviewed to better understand the hospital's performance. The goal is to narrow the difference in rates over time. TOB-2 and TOB-3 are evaluating all patients who <i>either</i> accepted or refused practical counseling or referral and cessation medication or prescription if applicable. Either will pass the measure. TOB-2a and TOB-3a are intended as public health measures, and evaluate all patients who actually received practical counseling or referral and cessation medication or prescription if applicable. Only cases where the patient actually received the practical counseling or referral and cessation medication or prescription if indicated will pass the measure.</p> <p>We believe that reporting of these measures will yield information that provides meaningful distinctions in the quality of care provided across hospitals. Because tobacco use cessation treatment (counseling and medication if indicated) is considered an essential step in the care process for patients, we believe it is critical for patients, their families, and caregivers to have accurate information on whether hospitals integrate this into their care processes. Facilities may be able to identify opportunities to increase their rate of uptake of tobacco cessation treatment by reporting TOB-2a and TOB-3a.</p>

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2	11/25/15	<p>1.Measuring the electronic tobacco use and cessation counseling can be useful by making the staff more cognitive of the need to address the options for quitting the tobacco habit. As a result of the core measure abstraction we have seen more patients receiving the counseling and cessation medications.</p> <p>2.The burden of capturing and documenting the data elements that are required to calculate the measure is the difference in definitions of measures between meaningful use and the core measure. Some examples are: for meaningful use the definition of a light smoker is &lt; 10 daily while the definition of a light smoker for core measures is &lt; 4 daily. Another example is the definition of current smoker in meaningful use is tobacco use within the last 12 months, while the core measure definition is tobacco use in the last 30 day. These differences leads to redundancy in abstraction and confusion. It seems these definitions should be aligned with each other.</p>	Janet Geter, West Georgia Health	geterj@wghealth.org	Hospital/Health System	<p>1. Thank you for your support for collecting the tobacco treatment measures electronically.</p> <p>2. We recognize the challenges associated with reconciling the meaningful use requirements with the TOB measures. When re-specifying the TOB measures as eQMs, we made every effort to align with the meaningful use (MU) requirements. For example, we have included SNOMED-CT codes used to capture/report the MU smoking status data element in the TOB eCQM value sets used to identify whether a patient is a user of tobacco and how frequently a patient uses smoking tobacco. There are, however, areas or concepts we are unable to fully reconcile with MU requirements, specifically:</p> <ul style="list-style-type: none"> <li>• <u>Lookback period for the determination of the "currency" of tobacco use:</u> We are unaware of any defined time frame for the determination of whether a patient is a current or former smoker in the context of the meaningful use smoking status data element. The 30-day time frame used in the TOB measures provides (1) a clear and objective time frame against which tobacco screening can occur and (2) an opportunity to continue cessation interventions for patients who may be in the process of quitting. Evidence shows those who receive intensive treatment during hospitalization and outpatient follow-up treatment for at least one month are more likely to quit than smokers receiving no treatment. Therefore, while patients may indicate they are ex-smokers, if they have quit recently (during the previous 30 days), they are at greater risk for relapse, and cessation interventions during this period</li> </ul>

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						<p>have been shown to improve cessation rates.</p> <ul style="list-style-type: none"> <li>• <u>Definition of light versus heavy smoker:</u> the TOB measure definition of light versus heavy cigarette user is grounded in the latest clinical evidence, which suggests cessation medications benefit those smoking 5–10 cigarettes per day (Baha and Le Faou 2010; Krupski, Cummings et al. 2013; Shiffman 2005). In addition, such smokers appear to be increasingly common (CDC 2014; Kotz, Fidler, and West 2012). To minimize redundant data capture related to amount of cigarette use, the TOB eQMs model this concept as a numeric field. This allows for (1) a single source of data to support both the TOB measures and mapping to meaningful use required SNOMED-CT codes and (2) robust data capture, without any required changes if the threshold changes in the future.</li> <li>• We will strive to incorporate additional guidance in the TOB eCQM specifications to streamline the fulfillment of the TOB and MU requirements.</li> </ul>
3	11/25/15	<p>3. Data our data is already captured in an EHR which is structured and codified .</p> <p>4. Concerns: the outpatient counseling referral is difficult to achieve because most patients refuse the counseling. TOB 2a and Tob 3a reflect only those patients who have received the counseling and medications. It is as if the hospital is being held responsible for the patient’s actions.</p> <p>The exclusion of those patients who are discharged on day 3 or before also has a negative effect on our scores as well. We do have patients who have accepted the outpatient referral but are not included due to length of stay.</p>	Janet Geter, West Georgia Health	geterj@wghealth.org	Hospital/Health System	<p>Thank you for your comments.</p> <p>We are happy to learn that capturing the data required to support electronic reporting of the TOB measures would be straightforward.</p> <p><u>Regarding your comment on TOB-2a and TOB-3a:</u> TOB-2 and TOB-2a and TOB-3 and TOB-3a are paired measures which should be viewed together. Both rates should be reviewed to better understand the hospital's performance. The goal is to narrow the difference in rates over time. TOB-2 and TOB-3 are evaluating all patients who <i>either</i> accepted or refused practical counseling or</p>

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						<p>referral and cessation medication or prescription if applicable. Either will pass the measure. TOB-2a and TOB-3a are intended as public health measures, and evaluate all patients who actually received practical counseling or referral and cessation medication or prescription if applicable. Only those cases where the patient actually received the practical counseling or referral and cessation medication or prescription if indicated will pass the measure. We believe that reporting of these measures will yield information that provides meaningful distinctions in the quality of care provided across hospitals. Because tobacco use cessation treatment (counseling and medication if indicated) is considered an essential step in the care process for patients, we believe that it is critical for patients, their families, and caregivers to have accurate available information on whether hospitals integrate this into their care processes. Facilities may be able to identify opportunities to increase their rate of uptake of tobacco cessation treatment by reporting TOB-2a and TOB-3a.</p> <p><u>Regarding the three-day length of stay exclusion:</u> We recognize the three-day threshold on the length of stay (LOS) exclusion may cause a large number of patients to fall off the measure population. The TOB eCQM specifications have been designed to only exclude patients with a length of stay of one day or less, which should address your concerns. We expect to carry this modification of the LOS exclusion to be incorporated in the chart-abstracted measure specifications in the future.</p>
4	12/3/15	Thank you of the opportunity to comment on these measures while they are in development. These measures are complex and difficult to understand. We would like to see them simplified.	Not available	Not available	Not available	<p>Thank you for your comments.</p> <p><u>Regarding the complexity of the specifications:</u> We recognize the measure</p>

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		<p>We do not have any information on the value set details which limits our understanding of concept definitions especially for tobacco use and impaired cognition. We would like to remind developers that MU has existing requirements for reporting smoking status codification. These measures are focused on tobacco use in general and MU is focused on smoking status. In the past TJC defined light and heavy smoker as less than 5 cigarettes for light and 5 or more cigarettes for heavy. UMLS defines light as 1-9 cigs/day and heavy as 20-39 cigs/day. The concepts are not aligned and there is potential for conflicting reporting requirements.</p> <p>Tob 1: Is it possible to simplify the logic for impaired cognition? Without insight into example codes it is difficult to make specific recommendations. The expectations for 3 components of the Glasgow Coma scale to be reported will require separate capture, codification and extraction of each result. This makes this build complex. Is it possible to limit this logic to just the total or is impaired cognition enough to satisfy the exclusion? Depending upon how impaired cognition is defined, a patient with a Glasgow Coma score of &lt;=8 would probably have impaired cognition. Is Glasgow Coma Scale widely used?</p> <p>Tob 2: There is no Medication, Order not done for medical reason. This numerator is looking for patients who received or refused practical counseling to quit. We would like clarification if there should be the ability to document situations in which cessation medications are not ordered due to medical reasons.</p> <p>Tob 3: For Communication, Provider to Provider what is the required data to be captured?</p>				<p>specifications seem complex. This is due, in part, to the limitations of the expression language associated with the Quality Data Model, which does not allow us to express conditional logic. In addition, some of the complexity arises from our attempt to provide sufficient flexibility in the specifications to accommodate variability in data capture and workflows, and therefore lower the burden of implementation across multiple facilities and electronic health records (EHR) system implementations.</p> <p><u>Regarding the availability of value sets:</u> We would like to clarify that the value sets used in the TOB eQMs were published in the VSAC and were available for review throughout the public comment period. Instructions on how to use access the value sets in the VSAC were included along with the TOB eQm specifications and other materials provided in the public comment announcement.</p> <p><u>Regarding alignment with meaningful use (MU) requirements:</u> We recognize the challenges associated with reconciling the MU requirements with the TOB measures. When re-specifying the TOB measures as eQMs, we made every effort to align with MU requirements. For example, we have included SNOMED-CT codes used to capture/report the MU smoking status data element in the TOB eQm value sets used to identify whether a patient is a user of tobacco and how frequently a patient uses smoking tobacco. There are, however, areas or concepts we are unable to fully reconcile with MU requirements, specifically:</p> <ul style="list-style-type: none"> <li>• <u>Definition of light versus heavy smoker:</u> The TOB measure definition of light versus heavy cigarette user is grounded</li> </ul>

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						<p>on the latest clinical evidence, which suggests cessation medications benefit those smoking 5–10 cigarettes per day (Baha and Le Faou 2010; Krupski, Cummings et al. 2013; Shiffman 2005). In addition, such smokers appear to be increasingly common (CDC 2014; Kotz, Fidler, and West 2012). To minimize redundant data capture related to amount of cigarette use, the TOB eQMs model this concept as a numeric field. This allows for (1) a single source of data to support both the TOB measures and mapping to MU required SNOMED-CT codes and (2) robust data capture, without any required changes should the threshold change in the future. Specifically, documenting the average number of cigarettes or number of packs smoked per day would allow sufficient detail to map to some of the codes allowed in the MU smoking status data element.</p> <ul style="list-style-type: none"> <li>• <u>Smoking tobacco versus all forms of tobacco (smoking and smokeless)</u>: TOB measures cover both smoking tobacco and smokeless tobacco products (chewing tobacco) as recommended by Tobacco Use and Dependence clinical practice guidelines (<a href="http://www.ncbi.nlm.nih.gov/books/NBK63952">http://www.ncbi.nlm.nih.gov/books/NBK63952</a>). Patients who use smokeless forms of tobacco should be able to benefit from tobacco cessation interventions.</li> </ul> <p>Regarding your comments on specific measures:</p> <p><u>TOB-1</u>: We included the individual components of the Glasgow Coma Scale as well as the total. However, there is no expectation that a new workflow is created to document the score of each</p>

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						<p>individual component; the intent is to allow for implementers who may already have this documentation in place to use such scores to exclude patients who may be unable to respond to screening questions. Our alpha testing findings indicate that the majority of testing sites (seven out of eight) have both Glasgow Coma Total and Component Scores available as structured data in their EHR systems.</p> <p><u>TOB-2:</u> Using the latest chart-abstracted data available, we have found that the medical reasons exclusion is seldom used. However, we will review and consider your suggestion with CMS and our measure development team.</p> <p><u>TOB-3:</u> We recognize that the "Communication, Provider to Provider" data type does not provide sufficient detail on the intent of the referral data element. The original data element in the chart-abstracted measure requires that the patient has a follow-up appointment or that the hospital facilitates the patient's contact with a quitline. Given the anticipated implementation challenges associated with this concept and the "Communication" data type, we plan to revisit the logic associated with this data element.</p>
5	12/3/15	<p>Please see attached letter fully supporting the three Tobacco Treatment electronic clinical quality measures (eCQMs) from multiple organizations.</p> <p>Thank you. Attachment –</p> <p>On behalf of the University of Wisconsin Center for Tobacco Research and Intervention (UW-CTRI), Altarum Institute Center for Prevention, American Cancer Society Cancer Action Network, American</p>	<p>Rob Adsit, University of Wisconsin Center for Tobacco Research and Intervention</p>	<p>ra1@ctri.wisc.edu</p>	<p>Academic Institution; Comment submitted on behalf of group of academic institutions and professional societies</p>	<p>Thank you for your comment and your full support of these measures. We greatly appreciate your feedback.</p>

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		<p>College of Preventive Medicine, American Lung Association, ClearWay Minnesota, Mayo Clinic, National Association of State Mental Health Program Directors (NASMHPD), we thank you for the opportunity to provide comments regarding the Centers for Medicare and Medicaid Services <b>Hospital Inpatient and Outpatient Process and Structural Measure Development and Maintenance (Hospital-MDM) Electronic Specification for Three Re-engineered Tobacco Treatment (TOB) Measures.</b></p> <p><b>We fully support the inclusion of the three National Quality Forum- (NQF) endorsed Joint Commission tobacco cessation performance measures<sup>1</sup> as electronic clinical quality measures (eQMs) across multiple Centers for Medicare and Medicaid Services (CMS) quality reporting programs: (TOB-1) Tobacco Use Screening; (TOB-2) Tobacco Use Treatment Provided or Offered During Hospitalization; and, (TOB-3) Tobacco Use Treatment Management at Discharge.</b></p> <p>The rationale for including tobacco dependence interventions during a hospitalization is compelling. Tobacco use is the leading cause of premature disease and death in the United States, responsible for almost half a million deaths and approximately \$150 billion in added healthcare costs each year.<sup>2</sup> Moreover, it is a primary driver of hospitalizations for cancers, stroke, cardiovascular and respiratory diseases, and pregnancy and newborn complications. Finally, tobacco use interferes with recovery and contributes to delayed bone and wound healing, infection, and other post-operative complications.</p> <p>Hospitalizations are an ideal time to assist smokers to quit. Every hospital in the United States must provide a smoke-free environment if it is to be accredited by The Joint Commission. And, hospitals across the nation are increasingly implementing smoke-free campus policies. As a result, every hospitalized smoker is temporarily housed in a</p>				

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		<p>smoke-free environment. In this environment, they may be more motivated to quit than at any other time and that motivation may be enhanced because their hospitalization was caused or made worse by smoking.</p> <p>In addition, if a hospitalized smoker receives counseling and is offered and uses cessation medication to manage withdrawal symptoms and has a positive experience, s/he may be more likely to continue using that medication to permanently quit after discharge.</p> <p>Importantly, the U.S. Department of Health and Human Services Public Health Service Clinical Practice Guideline, <i>Treating Tobacco Use and Dependence 2008 Update</i><sup>3</sup> (The Guideline) emphasizes that a hospitalization presents an unequalled opportunity to promote tobacco cessation and urges such evidence-based interventions be delivered to every hospitalized smoker. The Guideline provides specific actions regarding assisting hospitalized patients who smoke to quit.</p> <p>Tobacco users have higher hospitalization rates than those who do not use tobacco and higher rates of readmission post-discharge. However, most hospitals have not placed a high priority on systematically identifying smokers, recording their smoking status, offering evidence-based assistance in quitting, and following up after discharge. These proposed CMS eCQMs have the potential to help address, facilitate, and promote inpatient evidence-based tobacco cessation interventions.</p> <p>Thank you for the opportunity to comment on these tobacco cessation eCQMs.</p>				
6	12/3/15	<p>The burden of capturing and documenting data elements for multiple programs increases when the measures are not aligned. For example, the TOB-2/2a and TOB-3/3a logic criteria for light (&lt;5 and &lt;0.25) and heavy (&gt;=5 and &gt;=0.25) cigarette smokers does not align with the Meaningful Use mappings for CCD and will require extra mapping effort and report logic, especially if the amount is</p>	Lynne Daise, Cerner Corporation	lynne.daise@cerner.com	EHR Vendor	<p>Thank you for your comment. We recognize the challenges associated with reconciling the meaningful use (MU) requirements with the TOB measures. While we made every effort to align with the MU smoking status data element requirements, we were unable to fully reconcile some concepts. Specifically, the TOB measure definition of light versus</p>

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		only captured as numeric values. We request that the measures be aligned across the requirements to streamline data collection and reduce redundant data documentation.				<p>heavy cigarette user is grounded in the latest clinical evidence, which suggests cessation medications benefit those smoking 5–10 cigarettes per day (Baha and Le Faou 2010; Krupski, Cummings et al. 2013; Shiffman 2005). In addition, such smokers appear to be increasingly common (CDC, 2014; Kotz, Fidler, and West 2012).</p> <p>To minimize redundant data capture related to amount of cigarette use, the TOB eQMs model this concept as a numeric field. This allows for (1) a single source of data to support both the TOB measures and mapping to MU use required SNOMED-CT codes and (2) robust data capture, without any required changes if the threshold changes in the future. Specifically, documenting the average number of cigarettes or number of packs smoked per day would allow sufficient detail to map to some of the codes allowed in the MU smoking status data element.</p> <p>We will consider including additional guidance in the eQMs to minimize the burden of mapping from alphanumeric fields to the numeric fields included in the logic.</p>
7	12/3/15	The TOB-2/2a and TOB-3/3a logic evaluates the Average Number of Cigarette Packs Smoked per Day result as <0.25 and >=0.25 requiring the Average Number of Cigarette Packs Smoked per Day to be collected as a numeric value with two decimal positions rather than a whole number or to map alpha responses representing pack amount to numeric fields for reporting the measure. Although this information can be captured, it will require extra mapping effort and report logic or a workflow change. We suggest that a value set option be provided in addition to the two-decimal numeric option.	Lynne Daise, Cerner Corporation	lynne.daise@cerner.com	EHR Vendor	Thank you for your comment. The eQCM logic is not intended to require capturing the volume of cigarette use as a decimal number, and mapping alphanumeric fields to a number would be acceptable, as stated in eQCM guidance. We understand that alphanumeric fields may be in use today, however we have found that the documentation is variable across sites (for example, <1/2 pack, <=1/2 pack, 1–2 packs, 1/2 pack), which would make it difficult to create thresholds that would work for all implementers and therefore still require mapping.

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						We will consider your suggestion as we make revisions to the eCQM specifications.
8	12/3/15	In light of the statement: "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 without warranty.", we recommend TOB 2a and 3a be removed from the measure. Patient refusal should not be counted against the organization's performance, as long as appropriate interventions have been addressed/performed by the provider. Refusal of treatment is a patient right.	Elena Varakuta, Kaiser Foundation Hospitals - Roseville	elena.v.varakuta @kp.org	Hospital/Health System	<p>Thank you for your comment. TOB-2 and TOB-2a and TOB-3 and TOB-3a are paired measures which should be viewed together. Both rates should be reviewed to better understand the hospital's performance. The goal is to narrow the difference in rates over time. TOB-2 and TOB-3 are evaluating all patients who <i>either</i> accepted or refused practical counseling or referral and cessation medication or prescription if applicable. Either will pass the measure. TOB-2a and TOB-3a are intended as public health measures, and evaluate all patients who actually received practical counseling or referral and cessation medication or prescription if applicable. Only those cases where the patient actually received the practical counseling or referral and cessation medication or prescription if indicated will pass the measure.</p> <p>We believe that reporting of these measures will yield information that provides meaningful distinctions in the quality of care provided across hospitals. Because tobacco use cessation treatment (counseling and medication if indicated) is considered an essential step in the care process for patients, we believe that it is critical for patients, their families and caregivers, to have accurate available information on whether hospitals integrate this into their care processes. Facilities may be able to identify opportunities to increase their rate of uptake of tobacco cessation treatment by reporting TOB-2a and TOB-3a.</p>
9	12/3/15	The TOB-1 Guidance section states the following data source for capturing cognitive impairment: "A problem list or coded diagnosis indicative of impaired cognition." We request clarification regarding the interpretation of the Diagnosis,	Lynne Daise, Cerner Corporation	lynne.daise@cern er.com	EHR Vendor	Thank you for your comment. Both clinical diagnoses, including admitting and working diagnoses, in addition to coded diagnoses, such principal or other diagnoses as assigned by a coder, would be acceptable. We will

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		Active: Cognitive and Psychiatric Disorders Indicative of Impaired Cognition logic criteria, and more specifically whether including clinical diagnoses (e.g. admitting, working) may be used or if it is only intended to be the principal or other ICD-10 diagnosis as it is with the HIQR tobacco measure set.				consider your suggestion as we make revisions to the eCQM specifications.
10	12/3/15	<p>The following comments received outside of JIRA are copied and pasted verbatim along with the commenter's initials.</p> <p>"I do not smoke. I am very pleased that smoking is prohibited in restrants. I also feel that you are butting into Americas right to privacy My health records etc is my business the Gov. has no right to collect personal information on any U.S citizen. " -- M.H.</p> <p>"I would like to find out what would be needed to submit these measures electronically for our facility." -- C.M.</p> <p>"My comment is , why are we considered failed if the patient refuses counseling ? We can't force them to listen or watch a video." V.C.</p>	Not Available	Not Available	Not Available	<p>Comment 1: Thank you for your comment. These measures are being retooled from previously developed and approved chart-abstracted tobacco treatment measures for electronic specification. Quality measures such as these currently exist to provide the Centers for Medicare and Medicaid Services (CMS) quality and performance information for hospitals. Information collected by CMS as a part of this measure is not used by the government to target patients for any reason.</p> <p>Comment 2: The Tobacco Treatment eCQMs are currently under development and will undergo further testing in 2016. It is anticipated that the eCQM specifications will undergo further revisions before being included in any reporting program. CMS will release the specifications once they are ready for implementation.</p> <p>Comment 3: Thank you for your comment. TOB 2 and TOB 3 do take into account patient refusal so that the hospital is not penalized if the patient refuses counseling or treatment. TOB-2 and TOB-2a and TOB-3 and TOB-3a are paired measures which should be viewed together. Both rates should be reviewed to better understand the hospital's performance. The goal is to narrow the difference in rates over time. TOB-2 and TOB-3 are evaluating all patients who <i>either</i> accepted <i>or</i> refused practical counseling or referral and cessation medication or prescription if applicable.</p>

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						<p>Either will pass the measure. TOB-2a and TOB-3a are intended as public health measures, and evaluate all patients who actually received practical counseling or referral and cessation medication or prescription if applicable. Only those cases where the patient actually received the practical counseling or referral and cessation medication or prescription if indicated will pass the measure.</p> <p>We believe that reporting of these measures will yield information that provides meaningful distinctions in the quality of care provided across hospitals. Because tobacco use cessation treatment (counseling and medication if indicated) is considered an essential step in the care process for patients, we believe that it is critical for patients, their families, and caregivers to have accurate available information on whether hospitals integrate this into their care processes. Facilities may be able to identify opportunities to increase their rate of uptake of tobacco cessation treatment by reporting TOB-2a and TOB-3a.</p>
11	12/3/15	<p>In response to the question of if there will be EHR effort to capture data in a structured format, we feel that reason for not ordering something (Tobacco Use Cessation Pharmacotherapy) is difficult to obtain and likely will require additional workflow for provider as well as EHR builds. However, there is value to capturing patient refusal of the cessation medication, so despite the additional effort of this data element, we believe it should remain as part of the measure.</p>	Barbara Doyle, Encore Health Resources, A Quintiles Company	bdoyle@encorehealthresources.com	Health IT Consulting	<p>Thank you for your comment. We understand that capturing data related to why an intervention was not performed may not be a part of regular workflow or electronic health record configurations. However, as you indicated, it is important to capture the reason a treatment was not performed to avoid unfairly penalizing a hospital due to circumstances outside of the hospital's control. We appreciate your support for retaining patient refusal elements in the TOB measures.</p>
12	12/3/15	<p>The value of measuring both patients who received or refused AND those who only received intervention is questionable. Whether received or refused, the healthcare providers have performed appropriate interventions. We recommend the part</p>	Barbara Doyle, Encore Health Resources, A Quintiles Company	bdoyle@encorehealthresources.com	Health IT Consulting	<p>Thank you for your comment. TOB-2 and TOB-2a and TOB-3 and TOB-3a are paired measures which should be viewed together. Both rates should be reviewed to better understand the hospital's performance. The</p>

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		of the numerator definition measuring just patients who received intervention be removed.				<p>goal is to narrow the difference in rates over time. TOB-2 and TOB-3 are evaluating all patients who <i>either</i> accepted or refused practical counseling or referral and cessation medication or prescription if applicable. Either will pass the measure. TOB-2a and TOB-3a are intended as public health measures, and evaluate all patients who actually received practical counseling or referral and cessation medication or prescription if applicable. Only those cases where the patient actually received the practical counseling or referral and cessation medication or prescription if indicated will pass the measure.</p> <p>We believe that reporting of these measures will yield information that provides meaningful distinctions in the quality of care provided across hospitals. Because tobacco use cessation treatment (counseling and medication if indicated) is considered an essential step in the care process for patients, we believe that it is critical for patients, their families, and caregivers to have accurate available information on whether hospitals integrate this into their care processes. Facilities may be able to identify opportunities to increase their rate of uptake of tobacco cessation treatment by reporting TOB-2a and TOB-3a.</p>
13	12/3/15	For TOB-2 and TOB-3, please consider updating requirements to capture information gathered in the ED versus “after hospital arrival but prior to inpatient admission”. Until technology is fully interoperable capturing data prior to admission is very difficult to obtain and places a burden on facilities.	Barbara Doyle, Encore Health Resources, A Quintiles Company	bdoyle@encorehealthresources.com	Health IT Consulting	Thank you for your comment. The current logic is designed to cover data gathered in the facility the patient has been admitted to, but prior to the inpatient admission, including data gathered in the ED, but also outpatient data, as well as data captured while a patient is in observation status. There is no expectation that the facility would source data from other facilities, but we want to ensure that facilities that may have other data sources accessible are able to use this data for the measures.

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14	12/3/15	Recommend combining TOB-2 and TOB-3 to capture intervention during hospital admission or at discharge to simplify measure calculation and interpretation. We believe this captures appropriate clinical workflow.	Barbara Doyle, Encore Health Resources, A Quintiles Company	bdoyle@encorehealthresources.com	Health IT Consulting	Thank you for your comment. TOB-2/2a and TOB-3/3a were designed and endorsed as distinct measures because they have different intents. TOB-2/2a is intended to ensure the patient is offered tobacco cessation interventions while hospitalized, whereas TOB-3/3a is intended to ensure the continuity of cessation interventions after hospital discharge. These are two distinct processes which both contribute to patient success in quitting tobacco use.
15	12/3/15	In response to the question of the level of effort required to collect required data in a structured format we feel that EHRs will likely need to make updates to incorporate the documentation of the following items in structured format: <ul style="list-style-type: none"> <li>• Cognitive Impairment assessment performed</li> <li>• Cognitive impairment assessment results</li> <li>• Reason for not doing tobacco assessment due to cognitive impairment</li> <li>• # cigarettes smoked per day</li> <li>• # packs of cigarettes smoked per day</li> <li>• Smokeless tobacco non-user</li> </ul>	Barbara Doyle, Encore Health Resources, A Quintiles Company	bdoyle@encorehealthresources.com	Health IT Consulting	Thank you for your comment. We appreciate your feedback. We agree that hospitals may need to work with their vendors to incorporate certain functionality or update configurations within their electronic health record (EHR) system to collect data at the level that is required for these tobacco measures.
16	12/3/15	Consider changing timeframe to match current measures. Change from “3 days prior through 1 day after” to “within first 3 days of admission” to be consistent with other tobacco measures.	Barbara Doyle, Encore Health Resources, A Quintiles Company	bdoyle@encorehealthresources.com	Health IT Consulting	Thank you for your comment. You are correct that the time frame used in the TOB-1 eCQM is different from the time frame allowed for tobacco use screening in the chart-abstracted measure. There are a couple of reasons for this: <ul style="list-style-type: none"> <li>• The time frame for screening within three days prior to admission time frame is intended as a timing approximation to primarily account for events that may occur after hospital arrival but prior to inpatient admission (when the patient is in the emergency department or in observation status, for example). In the chart-abstracted measure, this is modeled not as a timing constraint, but as guidance to the abstractor.</li> </ul>

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						<ul style="list-style-type: none"> <li>The time frame for screening within one day after admission was an intended departure from the chart-abstracted measure, however the same modification is expected to be made to the chart-abstracted measure in the future.</li> <li>We will review and consider your suggestion with CMS and our measure development team.</li> </ul>
17	12/3/15	<p>We recommend that "Impaired Cognition" be captured solely from "Diagnosis, Active". If documentation is in place for impaired cognition via coma scale or other and noted in physician documentation, it will be included in the clinical or billing diagnoses. Patients with impaired cognition is a very small part of the population, and is a denominator exclusion. The requirements are very complicated for what will ultimately have a small impact on the measure.</p> <p>We recommend the following requirements be removed:</p> <ol style="list-style-type: none"> <li>Capturing codified results (result: Impaired Cognition) is challenging in an EHR. Workflow must be created to document the result, and the result must be mapped to the value set.</li> <li>Capturing reasons not done (Risk Category Assessment not done: Impaired Cognition) is challenging in an EHR. Workflow must be created to document the reason, and Healthcare providers need to remember to document it. If it is to be included, please allow it as a "medical reason" from current "medical reason" value set versus creating a net new value set.</li> </ol>	Barbara Doyle, Encore Health Resources, A Quintiles Company	bdoyle@encorehealthresources.com	Health IT Consulting	<p>Thank you for your comment. We included multiple options for modeling the concept of impaired cognition to allow for flexibility in the implementation of the exclusion. It is not expected that all possible options are implemented at a single site, but rather that facilities choose those that are more appropriate for their current workflow. However, we appreciate your input on the expected level of effort to implement these exclusions. We will review and consider your suggestion with CMS and our measure development team.</p>
18	12/3/15	<p>Please consider updating requirements to capture information gathered in the ED versus "after hospital arrival but prior to inpatient admission". Until technology is fully interoperable this data is very difficult to obtain, and places a burden on facilities.</p>	Barbara Doyle, Encore Health Resources, A Quintiles Company	bdoyle@encorehealthresources.com	Health IT Consulting	<p>Thank you for your comment. The current logic is designed to cover data gathered in the facility the patient has been admitted to, but prior to the inpatient admission, including data gathered in the emergency department, but also outpatient data, as well as data captured while a patient is in observation status. There is no expectation that the facility would source data from other facilities, however we want to ensure</p>

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						that facilities that may have other data sources accessible are able to use this data for the measures.
18	12/3/15	Add clarification that e-Cigarettes are NOT included in the measure. OR, consider including e-Cigarettes and expanding definition to include nicotine.	Barbara Doyle, Encore Health Resources, A Quintiles Company	bdoyle@encorehealthresources.com	Health IT Consulting	Thank you for your comment. The TOB measures focus on tobacco products, and e-cigarettes are not included in the measures because these products do not contain tobacco. Details surrounding individual data elements are included in value set definitions, which are available in the Value Set Authority Center, along with value set content. We will consider your suggestion to clarify, in the context of the measures' header, that e-cigarettes are not included in the measures.
20	12/3/15	<p>The measures appear to be unduly complicated, or repetitive, and we suspect resistance to the following:</p> <ul style="list-style-type: none"> <li>• Trying to capture data up to 3 days prior to admission timeframe</li> <li>• The difference in timing for the interventions from current manually abstracted measures (1 day after admission in eMeasure and up to 3 days after admission in manually abstracted measure)</li> <li>• The cognitive impairment exclusions.</li> <li>• The omission of eCigarettes needs to be explicitly called out, OR the measure should be updated to include nicotine as well as tobacco.</li> <li>• Tobacco 2 and 3 are very similar and suspect they could be combined in one measure. The value of "at discharge" versus during admission is questionable.</li> <li>• The value of the sub "a" measures is questionable as it is outside the provider's control whether or not a patient refuses treatment. The standard measure of "receive or refuse" measures the providers' interventions to try have their patients quite smoking or smokeless tobacco.</li> </ul>	Barbara Doyle, Encore Health Resources, A Quintiles Company	bdoyle@encorehealthresources.com	Health IT Consulting	<p>Thank you for your comments. We recognize the measure specifications seem complex. This is due, in part, to the limitations of the expression language associated with the Quality Data Model, which does not allow us to express conditional logic. In addition, some of the complexity arises from our attempt to provide sufficient flexibility in the specifications to accommodate variability in data capture and workflows and therefore lower the burden of implementation across multiple facilities and electronic health record system implementations. We will review and consider your suggestions with CMS and our measure development team.</p> <p>In response to your specific comments:</p> <ul style="list-style-type: none"> <li>• Trying to capture data up to three days prior to admission and differences in timing for the interventions from current manually abstracted measures: Please see response to Item #16.</li> <li>• Cognitive impairment exclusions: Please see response to Item #17.</li> <li>• Omission of e-cigarettes: Please see response to Item #9.</li> </ul>

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						<ul style="list-style-type: none"> <li>• Similarity between TOB-2/2a and TOB-3/3a: Please see response to Item #14.</li> <li>• Value of TOB-2a and TOB-3a: Please see response to Item #12.</li> </ul>
21	12/1/15	<p>After review of the Tobacco Measure Set in our eCQM Steering Committee, our health system does not feel that the Tobacco Measure Set would be of benefit to inpatient reporting via IPPS IQR eCQM requirements.</p> <p>One hospital within our system is performing chart abstraction on TOB-1 and TOB-2 for the HBIPS population. Our IT leadership has shared that there are no technical concerns with obtaining the requirements for the Tobacco e-measures from discrete fields within our EMR. However, our concerns stem from the operations of "why and how" we ask these questions to patients. It seems that the Tobacco Measure Set is being suggested for review for inpatient eCQMs to align with PQRS and the EP side of Meaningful Use. While alignment of measures in the different realms of care is nice, these performance metrics do not bring meaningful processes or measurements to an acute inpatient care where it may not be appropriate to address the patient's tobacco use. This measure may give CMS population prevalence of smoking in all hospitals, however, "checking the box" of providing tobacco cessation counseling and referrals to outpatient counseling does not get at the root cause of smoking issues and we do not feel that this specific process measure will impact outcomes.</p>	Linnea Huinker, Maple Grove Hospital / North Memorial Health Care	Linnea.Huinker@maplegrovehospital.org	Hospital/Health System	<p>Thank you for your comment. We appreciate your perspective. All three TOB measures are based on previously developed chart abstracted tobacco measures designed for the inpatient setting and endorsed by the National Quality Forum in 2014. In addition, the chart-abstracted measures are currently available for hospital reporting in The Joint Commission's ORYX program.</p> <p>The U.S. Department of Health and Human Services Public Health Service Clinical Practice Guideline, Treating Tobacco Use and Dependence 2008 Update emphasizes that a hospitalization presents a unique opportunity to promote tobacco cessation and urges such evidence-based interventions be delivered to every hospitalized tobacco user:</p> <ul style="list-style-type: none"> <li>• During hospitalization, patients are not allowed to use tobacco, are in contact with many health professionals, and may be more willing to accept assistance in quitting.</li> <li>• Many tobacco users quit, unaided, following hospitalization.</li> <li>• Those who receive intensive treatment during hospitalization and outpatient follow-up treatment for at least one month are more likely to quit than smokers receiving no treatment.</li> </ul>
22	12/4/15	TOB-1: The temporal comparison operator for Diagnosis, Active: Cognitive and Psychiatric Disorders Indicative of Impaired Cognition can be reduced to "starts before or concurrent with end of Occurrence A of \$EncounterInpatient."	Not available	Not available	Not available	Thank you for your detailed review of the eCQM specifications. We will review and consider your suggestions with CMS and our measure development team. Regarding your comment on the Frequency of Tobacco Use

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		<p>TOB-2 and TOB-3: The differentiation of light versus heavy tobacco users in the Numerator sections does not account for multi-form tobacco users. A Risk Category Assessment for tobacco users could indicate that an individual is a light cigarette smoker (2 cigarettes/day) and a heavy cigar smoker (smokes tobacco daily). In such a situation, the individual would pass the numerator logic as a light tobacco user and would not required the documentation of cessation medication as necessitated for heavy tobacco users. In order to indicate that an individual is a light tobacco user, the logic must indicate that they are a light tobacco user AND NOT a heavy tobacco user.</p> <p>All TOB: The value set for "Risk Category Assessment: Frequency of Tobacco Use" has not yet been posted on the Value Set Authority Center. Since this data element should be only documented in relation with pipe and cigar tobacco usage, can the name of the value set be changed to reflect this dependency? For example, changing the name to "Risk Category Assessment: Frequency of Cigars/Pipe Tobacco Use".</p>				<p>value set, we would like to clarify that while the TOB eCQM logic requires only that the frequency of tobacco use is documented for pipe and/or cigar smokers, it does not necessarily need to be specific to these types of tobacco products.</p>
23	12/3/15	<p>TOB-2: Please do not require hospitals to distinguish between "light" and "heavy" smokers in this reporting measure. There is no consistent way of defining these categories, and the treatments are the same for heavy and light smokers. It will add unnecessary complication and confuse health care providers.</p> <p>TOB-3: Please do not require hospitals to distinguish between "light" and "heavy" smokers in this reporting measure. In addition, it would be very helpful to permit hospitals to refer "3 days prior to admission through 1 day post-discharge". If we refer to the quitline prior to discharge, the quitline will start calling the patient while they are still in the hospital. If the patient provides his/her home phone number, they will miss the calls. It is difficult to estimate the day/time of discharge. It would be</p>	Kimber P. Richter, The University of Kansas	krichter@kumc.edu	Academic Institution	<p><u>Distinction between "light" and "heavy" smokers:</u> Thank you for your comment. The TOB measures have been developed to define light user as an individual who uses fewer than 5 cigarettes or 1/4 pack per day; a heavy tobacco user is defined as one who uses 5 or more cigarettes or 1/4 or more packs per day. The recommended treatment for light and heavy users will differ for both TOB 2/2a and TOB 3/3a. Although all tobacco users should receive cessation counseling, the measures require that only heavy users receive an FDA-approved cessation medication.</p> <p><u>Referrals through one day post discharge:</u> Thank you for your comment. We will review</p>

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		<p>good to give hospitals 1 day leeway post-discharge to make the referral. We are struggling with this now, because we are trying very hard to meet the Psychiatric tobacco measures. Our practice is to watch for the patient to be discharged, then immediately fax-refer to the quitline. When we do this, however, we are not meeting the measure because we are referring post-discharge.</p> <p>We run an inpatient bedside tobacco treatment program that treats over 1,000 inpatients per year. We love the idea behind the new measures, but a few tweaks will make them work better in hospital practice.</p>				and consider your suggestions with CMS and our measure development team.
24	12/4/15	<p>Please see attached comment letter on Tobacco Treatment Measures. Attachment –</p> <p><b>RE: Hospital Inpatient and Outpatient Process and Structural Measure Development and Maintenance (Hospital-MDM) Electronic Specification for One Set of Three Re-Engineered Tobacco Treatment (TOB) Measures</b></p> <p>Dear Sir or Madam:</p> <p>On behalf of the members of the American Association of Orthopaedic Surgeons (AAOS), we appreciate the opportunity to offer comments on the project entitled “Hospital Inpatient and Outpatient Process and Structural Measure Development and Maintenance (Hospital-MDM) Electronic Specification for One Set of Three Re-Engineered Tobacco Treatment (TOB) Measures,” and the Tobacco Treatment (TOB) measure set, in particular.</p> <p>The Centers for Disease Control and Prevention (CDC) estimates that tobacco-related diseases result in more than 435,000 deaths among adults in the United States each year, and is recognized as one of the major causes of preventable disease. While it’s commonly known that smoking is linked to heart and respiratory diseases as well as to several types of cancer, many people are unaware that smoking has serious negative effects on the musculoskeletal</p>	Jennifer Hersh, Kyle Shah, American Association of Orthopaedic Surgeons (AAOS)	hersh@aaos.org	Professional Society	Thank you for your comment and your support of the changes made to the measures. We greatly appreciate your feedback. We recognize the implementation of the measures may be more difficult for hospitals lacking the infrastructure and/or electronic health records (EHR) system workflows to support tobacco screening and cessation interventions. Hospitals may need to work with their vendors to incorporate certain functionality or update configurations within their EHR to collect data at the level that is required for these tobacco measures.

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		<p>system, leading to poor outcomes in post-operative orthopaedic patients. Such outcomes include increases in wound and fracture healing times and post-operative infections. In addition, smokers are at higher risk of developing osteoporosis; tobacco use is also associated with an increase in the incidence of low back pain and rheumatoid arthritis. Due to the severe and negative impact of smoking on the musculoskeletal system, the AAOS strongly recommends against the use of tobacco products and supports the proposed re-engineering of the three TOB measures by the Joint Commission. The proposed changes to the TOB measures (TOB-1, TOB-2, and TOB-3) would allow for TOB interventions for events post-arrival to the hospital – for example, when a patient is admitted to the emergency room or for observation – but within a three-day timeframe prior to an inpatient admission to account for the 2 hospital stay measure. Consequently, all admissions of at least one day would be included in the denominator, which varies for each TOB. These changes would increase the number of patients receiving tobacco use screening (TOB-1), tobacco use counseling/treatment provided or offered (TOB-2, TOB-2a), and/or tobacco use counseling/treatment provided or offered at discharge (TOB-3, TOB-3a). Previously, only those patients with a minimum three day length-of-stay were eligible for tobacco use screening, counseling, or treatment. It is important to note TOBs are classified as electronic clinical quality measures (eCQMs), which require a strong infrastructure and adequate analytics to support alignment between measure data elements. This may prove burdensome for those hospitals lacking adequate support and infrastructure, not to mention the additional burden on staff to report what may be a substantial increase in data due to the upsurge in the number of patients being screened.</p> <p>The proposed re-engineered Tobacco Treatment (TOB) measures have the potential to substantially increase the number of patients who receive anti-</p>				

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		<p>smoking interventions as current medical practice has reduced the number of patients with hospitalizations lasting three days or more and therefore would not be eligible for interventions under the current TOB measures. AAOS strongly believes the three TOB measures should be re-developed as outlined above and fully supports the Joint Commission in their efforts to implement measures to help decrease the incidence and prevalence of smoking among the inpatient population, thereby improving patient outcomes and ultimately, their overall health.</p> <p>Thank you for your time and attention regarding the American Association of Orthopaedic Surgeons' (AAOS') comments on re-engineering the three TOB measures as tobacco use remains a significant threat to our nation's public health. Should you have questions on any of the above comments, please do not hesitate to contact AAOS' Medical Director, William O. Shaffer, MD, at 202-548-4430 or via email at shaffer@aaos.org.</p>				
25	12/4/15	<p>On behalf of Mayo Clinic, thank you for the opportunity to provide comment on the electronic specifications for Tobacco Treatment. Mayo Clinic greatly appreciates efforts to align tobacco specifications across multiple programs.</p> <p>Mayo Clinic supports the following changes: modified length of stay to less than or equal to one day, included events occurring with 3 days prior to admission, broadened timeframe for interventions from within 3 days of inpatient admission to any time during hospitalization, removed exclusion of pregnant heavy tobacco users for cessation medications (due to small proportion of patients impacted), and removal of medical reasons for not administering or prescribing cessation medications (due to the small proportion of patients impacted). Mayo Clinic supports smoking cessation education and tobacco use cessation education being included in the Interactive Tobacco Use Cessation Counseling value set. Mayo Clinic supports adding "referral to tobacco cessation counseling program" and</p>	Bonnie Norris, Mayo Clinic	norris.bonnie@mayo.edu	Hospital/Health System	Thank you for your comment and your support of the changes made to the measures. The TOB eCQMs are derived from the previously developed chart-abstracted tobacco treatment measures and are intended to retain the same intent as the original measures. We will consider your suggestion regarding the distinction of light and heavy smokers in future iterations of the Tobacco Treatment measures.

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		<p>“referral to tobacco Quit Line” to the Referral for Tobacco Cessation Counseling value sets. When providing an opportunity for nicotine dependency subject matter experts to review the eQIM tobacco specifications, Dr. J. Taylor Hays and Mr. Michael Burke recommended streamlining TOB-2 and TOB-3 even further to promote improved understanding. As the definitions for light smoker and heavy smokers are older and smoking patterns have changed, their recommendation was to eliminate the associated tobacco amounts from the light/heavy designations and use less than daily smoking frequency for designation into the light smoker category and daily smoking frequency for designation into the heavy smoking category.</p> <p>Thank you again for the opportunity to provide feedback on these eQIM specifications. For more information, feel free to contact me at <a href="mailto:norris.bonnie@mayo.edu">norris.bonnie@mayo.edu</a>.</p>				
26	12/4/15	<p>It is obvious that a significant amount of work and thought went into developing these electronic versions of the clinical quality measurement. With that in mind, we appreciate the opportunity to give feedback to the committee that developed the specifications. We are posting a single response but will refer to all 3 measures in this response. We will start by providing general thoughts on the measures and attempt to address some of your specific questions.</p> <p>In general, we consider these measures to be more suited for the ambulatory setting. We believe that a primary care physician maintains a stronger, more personal influence on a patient in regards to smoking and treatment. Typically, a person does not enter the inpatient setting due to a smoking related illness without a referral from their primary care physician. In this case, we would expect that the PCP had already discussed treatment options and/or prescribed the appropriate medications. While we know, that a certain percentage of people use the emergency department as their primary</p>	Joseph Kunisch, Michael Mickan, Memorial Hermann Health System	Not available	Hospital, Health System	<p>Thank you for your comments. We appreciate your thoughtful and detailed review of the measures and their specifications. We will review and consider your suggestions with CMS and our measure development team.</p> <p><u>Regarding the TOB measure's appropriateness for the inpatient setting:</u> We would like to clarify that the TOB measures are not focused on patients admitted to inpatient care due to tobacco-related illnesses. The measures were developed with the general adult inpatient population in mind. In addition, the U.S. Department of Health and Human Services Public Health Service Clinical Practice Guideline, Treating Tobacco Use and Dependence 2008 Update emphasizes that hospitalization presents a unique opportunity to promote tobacco cessation and urges such evidence-based</p>

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		<p>care provider, we feel that requiring 100% screening and intervention is not feasible and wonder about the effectiveness of decreasing the rate of active smokers/tobacco users. In the study by Rigotti et al (2008) that is cited in your supporting references, their conclusion was that only when supportive contact is continued for 1 month after discharge, are the intra-hospitalization interventions effective. This supports evidence that the anti-tobacco interventions are more effectively managed in the ambulatory setting. While we believe that the practice guidelines are effective in decreasing the rate of tobacco users, we don't believe the guidelines will be as effective in the inpatient setting. If these measures are to be implemented, we would like to provide the following feedback specific to the measures:</p> <p>h4. All Measures;</p> <p>We suggest that when the empty value sets are created, that there is a mechanism in place for the public to provide feedback on the values. We have learned in our experience of implementing eCQMs that the value sets can be constricting thus making it difficult to capture and report specific data elements. Documentation practices can vary across institutions and forcing a clinician to change how they normally document is a significant burden on clinicians and implementers. Feedback to assure the value sets are broad enough to fit varying practices would be extremely helpful.</p> <p>h4. TOB-1 Use Screening</p> <ul style="list-style-type: none"> <li>Initial population is for all patients <math>\geq 18</math> y/o. This does not align with the meaningful use core object of recording smoking status which is all patients <math>\geq 13</math> y/o. It is easier for clinical staff to think of a single population, either using tobacco products or not. We recommend aligning one with the other for consistency.</li> <li>To make the Glasgow Coma Score (GCS) more efficient, we recommend removing all but "Physical Exam, Performed: Glasgow Coma Score Total" satisfies all: (result <math>\leq 8</math>). While we understand the purpose of the GCS granularity to</li> </ul>				<p>interventions be delivered to every hospitalized tobacco user:</p> <ul style="list-style-type: none"> <li>During hospitalization, patients are not allowed to use tobacco, are in contact with many health professionals, and may be more willing to accept assistance in quitting.</li> <li>Many tobacco users quit, unaided, following hospitalization.</li> <li>Those who receive intensive treatment during hospitalization and outpatient follow-up treatment for at least one month are more likely to quit than smokers receiving no treatment.</li> </ul> <p>We agree that continued support after discharge is essential, and that is precisely the focus of TOB-3/3a.</p> <p><u>Regarding a mechanism to comment on value sets not available at the time of public comment:</u> Only two value sets were not published along with the TOB eCQM specifications; this was due the fact there were no appropriate codes available in LOINC<sup>®</sup> to represent the intended data elements. We have requested these codes and are awaiting their approval. To mitigate the unavailability of these two value sets, we included information about the intent and content use of these value sets in a companion document published along with the eCQM specifications and other public comment materials.</p> <p>Regarding your TOB-1 comments:</p> <ul style="list-style-type: none"> <li><u>Initial population is for all patients <math>\geq 18</math> years old:</u> We appreciate your suggestion. However, there is no evidence to support the use of cessation medications in adolescents and the TOB clinical advisory</li> </ul>

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		<p>measure severity of the patient's condition, for this measure we question the purpose of including the individual values given that in our EHR and normal clinical practice, the GCS is always totaled. While leaving the more granular scores present may appear not to cause any additional burden, there is a level of mapping and maintenance involved for every data element. In addition, the more data elements the query has to look for, the more inefficient the algorithm becomes. We have learned this with the complex Venous Thromboembolism measures when the reports would take multiple hours to complete for a large healthcare system like ours.</p> <p>h4. TOB-2 &amp; 3</p> <ul style="list-style-type: none"> <li>• "Medication, Order not done: Patient Refusal" for "Tobacco Use Cessation Pharmacotherapy Ingredient Specific"</li> <li>• construct is not compliant with the recent QRDA I &amp; III Implementation Guide. I refer to Section 5.2.3.1 (Pg. 30) "Not Done with a Reason" copied below. I've bolded the applicable coding that shows when referring to a medication not given, the Value Set OID is to be referenced. The way the TOB algorithm is currently written, it references the "ingredient specific" medication. This forces a physician to select a specific medication that was refused, instead of the current proper way of stating "all of the medications were refused" using the value set OID. We request that ingredient specific reference related to contraindications be removed from all negation constructs.</li> <li>• {quote} For a QDM data element that is not done (when negationInd="true") with a reason, such as "Medication, Order not done: Medical Reason", an entryRelationship to a Reason (templateId: 2.16.840.1.113883.10.20.24.3.88") with an actRelationship type of "RSON" is required. This is specified in the section 3.4 Asserting an Act Did Not Occur with a Reason in the base HL7 QRDA-I, R3 Implementation Guide. To summarize, the</li> </ul>				<p>panel recommended restricting the measures' population to adults. Nevertheless, this shouldn't preclude facilities from screening and providing cessation counseling to adolescent patients. For the purposes of reporting the TOB measures, this is not a requirement.</p> <ul style="list-style-type: none"> <li>• <u>Glasgow Coma Score (GCS)</u>: We included multiple options for modeling GCS scores to allow for flexibility in the implementation of the exclusion. It is not expected that all possible options are implemented at a single site, and that facilities can choose to use the GCS total score only, without mapping the individual component scores, if that is more appropriate for their current workflow. However, we appreciate your input on the expected level of effort to implement these exclusions. We will review and consider your suggestion with CMS and our measure development team.</li> </ul> <p>Regarding your TOB-2 and TOB-3 comments:</p> <ul style="list-style-type: none"> <li>• <u>Medication, Order not done" and associated value sets</u>: The medication, order logic is provided to allow for flexibility and minimize the burden of implementation. We recognize different implementers may embed patient refusal within different workflows and want to ensure the measure specifications support these different workflows. We also recognize that there have been recent updates to the reporting of negation in QRDA. We will review and consider your suggestions with CMS and our measure development team.</li> <li>• <u>Screening logic and value sets</u>: We recognize that implementers may use</li> </ul>

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		<p>following steps shall be followed:</p> <ul style="list-style-type: none"> <li>• Set the containing act attribute negationInd="true"</li> <li>• Use code/[@nullFlavor="NA"]</li> <li>• Set code attribute code/sdtc:valueset="[VSAC value set OID]"</li> <li>• Use code/originalText for the text description of the concept in the pattern "None of value set: [value set name]"</li> </ul> <p>h4 Figure 16: Not Done Example</p> <p>&lt;!--Medication administered not done, patient refusal: Drug declined by patient - reason unknown. No "Antibiotic Medications for Pharyngitis" were administered --&gt;</p> <p>&lt;act classCode="ACT" moodCode="EVN" negationInd="true"&gt;</p> <p>&lt;templateId</p> <p>root="2.16.840.1.113883.10.20.24.3.42"</p> <p>extension="2014-12-01" /&gt;</p> <p>&lt;id root="517d5bbb-03a8-4400-8a78-754321641159" /&gt;</p> <p>&lt;code code="416118004"</p> <p>displayName="Administration"</p> <p>codeSystem="2.16.840.1.113883.6.96"</p> <p>codeSystemName="SNOMED-CT"</p> <p>&lt;statusCode code="completed" /&gt;</p> <p>&lt;entryRelationship typeCode="COMP"&gt;</p> <p>&lt;substanceAdministration classCode="SBADM" moodCode="EVN"&gt;</p> <p>&lt;manufacturedProduct classCode="MANU"&gt;</p> <p>&lt;templateId</p> <p>root="2.16.840.1.113883.10.20.22.4.23"</p> <p>extension="2014-06-09" /&gt;</p> <p>&lt;id root="37bfe02a-3e97-4bd6-9197-bbd0ed0de79e" /&gt;</p> <p>&lt;manufacturedMaterial&gt;</p> <p>*&lt;code nullFlavor="NA"*</p> <p>*sdtc:valueSet="2.16.840.1.113883.3.464.1003.196.12.1001"&gt;*</p> <p>*&lt;originalText&gt; None of value set: Antibiotic</p>				<p>different workflows for screening patients for tobacco use. The eCQM logic is designed to accommodate multiple forms and levels of granularity in data capture. The current logic was designed with the input from health information technology experts, who recommended modeling the details of tobacco use separately. However, we do not intend the eCQM logic to dictate data capture, as long as the data that is captured can be mapped to the data included in the value sets.</p>

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		<p>Medications*                      *for Pharyngitis* {quote}</p> <p>* In addition to the above, we strongly recommend removing all "Medication, Order not done: Patient Refusal" constructs from the algorithm and only keeping "Medication, Administered not done: Patient Refusal". Please review CQM-225 (<a href="https://jira.oncprojectracking.org/browse/CQM-225">https://jira.oncprojectracking.org/browse/CQM-225</a>) and related discussions for rationale.</p> <p>* For "Risk Category Assessment:" we recommend one category that combines the two into the following:                      * Light User: practical counseling during stay/referral to outpatient counseling at discharge                      ** Smokeless Tobacco: Any                      Cigar/Pipe: Some days                      Cigarette: &lt; 5 per day/&lt; 0.25 packs per day                      ** Heavy User: practical counseling AND cessation medications during stay /referral to outpatient counseling AND received prescription for cessation medications at discharge                      Cigar/Pipe: Every day                      Cigarette: &gt;= 5 per day/&gt;= 0.25 packs per day                      The above 5 categories would be combined into a value set called "Risk Category Assessment: Tobacco Type and Frequency" (Light and Heavy with the descriptions are major categories not to be included in value set).                      Rationale                      ** Significantly reduces cognitive burden for providers, as well as number of clicks to document the discrete data fields.                      ** Specific frequency unlikely to be accurate.</p> <p>* In conclusion, we recommend approving these measures for the ambulatory setting after reconfiguration. If the measures are approved for the inpatient setting, please consider the recommended changes to the algorithm to make the data capture and queries more efficient and</p>				

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		end-user friendly. We thank you for considering our recommended changes.				
27	12/5/15	<p>Please see the attached document. Thank you for the opportunity to comment on the Tobacco Electronic Clinical Quality Measure.</p> <p>Attachment – The Joint Commission’s goal to promote tobacco use screening and when this screening is positive, to offer counseling and pharmacotherapy is laudatory. For decades, tobacco use has ranked amongst the top preventable causes of morbidity and mortality. Healthcare intervention for tobacco use disorders has historically been ignored and not reimbursed. However, good clinical practice should not be lost as electronic algorithms define and incentivize priorities for patient care (assuming limited resources). “The Right Treatment at the Right Time”</p> <p>1) A nicotine or tobacco user’s stage of change needs to be assessed. Interventions geared towards a patient in precontemplation are different than those geared towards someone who is in the action phase and ready to quit. 2) It may be more helpful to distinguish between “current use,” “past use,” and “no history of use” instead of or in addition to the “light” and “heavy” smoker categories. a. A pregnant ex---smoker needs relapse prevention once she gives birth. 3) All forms of nicotine and tobacco use (present and future) should be included. E--- cigarettes exploit the loophole of not containing tobacco. Hookah and other forms of nicotine and tobacco use also exist. 4) Assessments need include important medical, psychiatric, and addiction co--- morbidities and socioeconomic factors. a. Personalized reasons to quit (whether the patient has asthma, congestive heart failure, bladder cancer, chronic pain, healing wounds, and/or is pregnant, etc) are helpful motivators. 5) Nicotine and other abused drugs are mood altering and share some of the same brain pathways. a. Alcohol and illicit drugs are often concomitant with tobacco use. Do we address nicotine and tobacco and ignore the alcohol when a patient only smokes</p>	Lori D. Karan, MD,	lori.karan@gmail.com	Individual	<p>Thank you for your comments. We appreciate your perspective. The TOB intervention measures were designed based on the Treating Tobacco Use and Dependence: 2008 Update and with input from guideline developers, who are part of our clinical advisory panel. We agree tobacco cessation interventions are complex and should be individualized. The TOB measures were designed to establish a baseline for tobacco screening and cessation interventions during hospitalization, as recommended by the guidelines, but also taking into account implementation burden.</p> <p>We will review and consider your suggestions with our clinical advisory panel.</p>

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		<p>when they get high? b. As states decriminalize and legalize marijuana, we may find a prevalence of marijuana use that exceeds nicotine and tobacco use. This may already be the case in California and Colorado. It takes years to define quality metrics; marijuana is on the horizon. 6) Treatment planning should take into account the multidimensional assessments and be holistic. We need to get away from care silos. 7) The intervention and intensity of treatment should be tailored and not 'cookie cutter.' a. A patient with depression may need concomitant treatment of this diagnosis in order for an intervention about nicotine/tobacco use to be successful. b. As persons with tobacco use disorders of less severity have quit, co---morbid assessment and treatment are becoming increasingly important. If the only referral is to a quitline, this staff may not qualified to properly assess or address such co---morbidities. 7) There needs to be an allowance for longitudinal care, continuity of care, and follow---up. a. There may be more urgent needs that are the focus of the hospitalization b. The metrics proposed would penalize the following case despite better than average care: A patient who had a detailed assessment prior to hospital admission, is given motivational interviewing and periodic education over the next year. S/he is prescribed medication at a time s/he is ready to quit, and given relapse prevention skills building thereafter. The data capture, analysis, and reporting associated with this goal is no small feat. While I agree with the importance of addressing nicotine and tobacco use, I am unsure about the implementation and ramification of this (and other) quality measures. Medical care is both complex and needs to be streamlined. It should neither be unduly simplified (assessments that only contain type of tobacco and frequency &amp; amount of use) nor burdened (nominal interventions at inopportune times). Thank you for the opportunity to comment on this important electronic clinical quality measure. I am submitting these comments in my individual capacity as a</p>				

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		primary care and addiction medicine practitioner. Lori D. Karan, MD, FACP, FASAM12/04/15				
28	12/4/15	Our hospital's Tobacco Treatment data are currently captured in an electronic health record; however the information is not reported as structured data, and at this time a high level of effort would be required to collect it in a structured format. Our hospital supports CMS' efforts to advance implementation of eCQMs; however, the technological gap between information platforms utilized by hospitals throughout the United States may result in reporting of inconsistent data that is not indicative of actual care provided to patients.	Suzanne Parchment, RN,	suzannep@baptisthealth.net	Hospital/Health System	Thank you for your comment. We understand that capturing the data in a structured format may require a high level of effort and hospitals may need to work with their vendors to incorporate certain functionality or update configurations within their electronic health records system to collect data at the level that is required for these tobacco measures. We will share your comments with CMS and our measure development team.
29	12/4/15	The American Lung Association appreciates the opportunity to comment on the TOB eCQM Measure Set. Please see the attached document for our complete comments. Attachment -- <b>National President and CEO</b> Harold P. Wimmer <b>Board Chair</b> Kathryn A. Forbes, CPA <b>Board Vice-Chair</b> John F. Emanuel, JD <b>Secretary/Treasurer</b> Penny J. Siewert <b>Past Chair</b> Ross P. Lanzafame, Esq The American Lung Association appreciates the opportunity to submit comments regarding the Centers for Medicare and Medicaid Services (CMS) <i>Hospital Inpatient and Outpatient Process and Structural Measure Development and Maintenance (Hospital-MDM) Electronic Specification for Three Re-engineered Tobacco Treatment (TOB) Measures</i> . The American Lung Association supports the three tobacco treatment (TOB) measures being included as electronic clinical quality measures (eCQMs) for the many CMS quality-reporting programs. Including tobacco treatment measures at hospitals will encourage interventions during a time patients are more likely to quit and stay quit.	Anne DiGiulio, American Lung Association	anne.digiulio@lung.org	Professional Society	Thank you for your comments and your support.  <u>Regarding your comments on TOB-1:</u> The forms of tobacco included in the TOB measures are based on our recommendations from our clinical advisory panel. At this point in time, the body of evidence is not strong enough to support cessation interventions for hookah use and e-cigarette use since, as you indicated, these are new and emerging forms of tobacco or non-tobacco products.  <u>Regarding your comments on TOB-2/2a and TOB-3/3a:</u> The TOB intervention measures were designed based on the Treating Tobacco Use and Dependence: 2008 Update and with input from guideline developers, who are part of our clinical advisory panel. We will review and consider your suggestions with our clinical advisory panel.

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		<p>While the American Lung Association fully supports the inclusion of the three tobacco treatment measures as part of the electronic clinical quality measures (eQMs), the measures can and should be made more robust, to insure all patients have the tools to quit.</p> <p>In the eQM titled, "Tobacco Use Screening (TOB-1)," the numerator asks for a comprehensive tobacco use screening, however only lists four types of tobacco products to classify the use (cigarettes, smokeless tobacco, pipe tobacco, cigars). By limiting the types of tobacco products on this list, to categorize tobacco users, the screening is not comprehensive. The list omits new and emerging tobacco products including, but not limited to, e-cigarettes and hookah. These products and others are increasingly common, especially among young adults<sup>1,2</sup>. The Lung Association would encourage CMS to include "other tobacco products" and specifically list e-cigarettes in the list of tobacco products to be identified.</p> <p>1 The eQMs titled, "Tobacco Use Treatment Provided or Offered (TOB-2)/Tobacco Use Treatment (TOB-2a)" and "Tobacco Use Treatment Provided or Offered at Discharge (TOB-3)/ Tobacco Use Treatment at Discharge (TOB-3a)" track which patients, who use tobacco products, have been offered cessation treatment. The numerator, and thus clinicians' actions, should be based on the relevant U.S. Public Health Service guidelines, "Treating Tobacco Use and Dependence: 2008 Update." As such, it should be clear that light tobacco users are offered all three forms of counseling (individual, group and phone) and heavy tobacco users are offered all FDA-approved cessation medications and all three forms of counseling, both during the hospital stay and at discharge.</p> <p>The American Lung Association fully supports the inclusion of the three National Quality Forum endorsed Joint Commission tobacco cessation performance measures as eQMs. Their inclusion</p>				

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		<p>will encourage patients to quit, saving lives and money. Thank you for the opportunity to comment. Sincerely, Harold P. Wimmer National President and CEO</p>				
30	12/4/15	<p>We greatly appreciate the opportunity to comment on the proposed Tobacco Treatment eCQMs. Please see the attached document for our comments.</p> <p>Thank you.</p> <p>Attachment – We greatly appreciate the opportunity to provide input on the development of the electronic version of the Tobacco Use measures. Please see our responses to the specific areas requested below:</p> <ul style="list-style-type: none"> <li>• The usefulness of measuring, electronically, tobacco use and cessation counseling within hospitals <ul style="list-style-type: none"> <li>➢ Since tobacco use is known to have significant effects on the health and longevity of our nation’s population and is a complicating factor in the treatment of many diseases we feel these measures are extremely important in helping to care for our inpatient population by assisting in identifying patients who use tobacco products and in providing to them assistance in quitting.</li> </ul> </li> <li>• The level of burden associated with capturing and documenting the data elements required to calculate the measure <ul style="list-style-type: none"> <li>➢ While we feel the general level of burden in documenting and capturing the data elements required to capture the eTOB measures is worth the effort for the positive impact on the health of our nation, the documentation of frequency of use seems unnecessarily burdensome with little additional clinical value provided. More effort should be directed to streamline documentation of frequency and type of use as well as to</li> </ul> </li> </ul>	Cindy Sunderman, Baylor Scott and White Health	Cindy.Sunderman@BaylorHealth.edu	Hospital/Health System	<p>Thank you for your comment. We appreciate your feedback. With regard to the capture of frequency of tobacco use, we feel it is an important element to capture in order to recommend an effective treatment program. Frequency of tobacco use will dictate whether or not a patient receives counseling and/or FDA-approved cessation medication. We also understand the appropriate capture of information required to calculate the measure may require updated electronic health records system configurations and workflows and, while this is a process that may take some time, it is necessary in order for the measure to remain useful. For example, although it may not currently be a part of regular workflow to capture refusals, this is required in order to ensure that patients who refuse treatment do not count against the hospitals.</p>

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		<p>standardize across programs. .</p> <ul style="list-style-type: none"> <li>• If the data is already captured in an EHR, whether this information is reported as structured data rather than open text fields and, if not, the level of effort that will be required to collect it in a structured format               <ul style="list-style-type: none"> <li>➤ Our current documentation related to tobacco use assessment uses structured data with very few open text fields; however, the amount of use (number of cigarettes or PPD) is currently a free text field. We will need to change our current documentation of amount of use in order to comply with the current proposed version of the eTOB measures. The level of effort for this change is small.</li> <li>➤ The process for making the cessation counseling referrals is strictly a paper/fax process; we do not document the referral in any way in our EHR. The level of effort to add this documentation is moderate since a new workflow will need to be developed as well as the structured documentation added to our current EHR documentation.</li> <li>➤ In our health system tobacco cessation counseling is shared across disciplines. The documentation of such counseling is not consistent across disciplines as workflow varies greatly. Capturing this documentation across disciplines while be challenging.</li> <li>➤ Capturing data for the exclusion criteria of cognitive impairment, while possible, is complicated, requiring fairly complex configuration. A streamlined, targeted question could be added with little effort, but would increase the documentation burden of our clinicians.</li> <li>➤ We do not currently have a process in place to capture refusal of cessation medication at time of discharge (refusal of prescription); nor do we currently have structured documentation for refusal of counseling. Little</li> </ul> </li> </ul>				

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		<p>effort is required to add such documentation but requires new workflow and increased burden on our clinical staff.</p> <ul style="list-style-type: none"> <li>• If the data is captured as structured data in the EHR, whether it is codified using a standard terminology (SNOMED-CT, LOINC, RxNorm, ICD-10)               <ul style="list-style-type: none"> <li>➢ We currently have all of the structured data fields coded using standard terminology with the exception of the amount of use which is currently a free text field</li> </ul> </li> <li>• If the data is codified, whether the codes included in our value sets are appropriate               <ul style="list-style-type: none"> <li>➢ We feel the current value sets contain all codes appropriate for these measures</li> </ul> </li> <li>• Any foreseen resistance to or unintended consequences from the proposed measures               <ul style="list-style-type: none"> <li>➢ We have had feedback from our clinical staff that the number of questions required to document smoking status is too burdensome and does not provide additional clinical value. Although we have created our documentation to have indicators making these fields mandatory, no hard stops exist, only an indication that the document was saved as incomplete. We currently have compliance issues across our system with documenting the complete tobacco use assessment.                   <ul style="list-style-type: none"> <li>➢ We have great interest on the clinical side to automate the referral process for cessation counseling by integrating into the EHR. However, this project has very low priority with our IT department.</li> <li>➢ We do not foresee any unintended consequences from these proposed measures.</li> </ul> </li> </ul> </li> </ul>				