Public Comment Summary Report

Project Title:

Development of Long-Term Care Hospital (LTCH) Ventilator Weaning Quality Measures

Dates:

- The Call for Public Comment ran from May 19, 2016 to June 9, 2016. One comment came in after the deadline and was accepted.
- The Public Comment Summary was last edited on November 28, 2016.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with RTI International to develop new candidate ventilator weaning quality measures for long-term care hospitals (LTCHs). The contract name is Development and Maintenance of Symptom Management Measures. The contract number is HHSM-500- 2013-13015I. As part of its measure development process, CMS has requested interested parties to submit comments on the candidate or concept measures that may be suitable for this project.

Project Objectives:

To develop new measures that assess LTCH quality of care. Development of measures includes conducting statistical testing to determine the specifications for the numerator and denominator, to identify exclusion criteria, and to adjust for patient characteristics associated with outcomes.

Toward achieving these objectives, CMS and RTI International solicited public comments on the following candidate ventilator weaning quality measures:

- Ventilator Weaning (Liberation) Rate
- Compliance with Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of the LTCH Stay

In addition to general feedback, RTI requested stakeholder input on:

- Utility of each candidate measure and variation across providers
- Potential unintended consequences of each measure as currently specified
- Feasibility of determining invasively mechanically ventilated patient initial status as weaning or non-weaning by the end of Day 2 of the LTCH stay, where Day 1 is

the day of admission. (It is understood that weaning status may change during the course of patient stay.)
- Importance of risk adjustment to the Ventilator Weaning (Liberation) Rate outcome measure
- Feasibility and utility of including partial weaning at discharge as an outcome

Information About the Comments Received:

- Web site used: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html
- Public comments were solicited by
  - Email notification to relevant stakeholders and stakeholder organizations
  - Email notification to Technical Expert Panel members
  - Posting on CMS Public Comment website
  - Email notification sent to original recipients as a reminder a week before the deadline, and forwarded to the Medicare Learning Network (MLN) for broader distribution.
- 9 responses were received on this topic. These comment letters all contained more than one comment, and were submitted by a range of stakeholder types, including providers and clinicians in LTCH settings, and patient advocacy groups.

Stakeholder Comments—General and Measure-Specific

This report provides a summary of public comments received, and CMS's responses to the public comments. CMS would like to thank all commenters for sharing their comments, concerns, and suggestions. In general, CMS received considerable support for the ventilator weaning measures concepts. We appreciate concerns shared by commenters, and have provided responses and clarifications regarding these concerns. Several commenters provided suggestions for measure modifications, which we carefully considered, making relevant measure updates where appropriate and feasible. At the end of the report, we provide a table containing the verbatim text of all public comments received.

1. Measure Utility/Clinical Importance

Summary: Several commenters noted the general importance of quality measures related to ventilation and ventilator weaning in the LTCH setting, and supported the development and implementation of CMS's candidate ventilator weaning quality measures. One commenter emphasized that unnecessary prolonged ventilation of patients must be avoided. Another commenter suggested that the measures may even be appropriate for skilled nursing facilities (SNFs) in the future, thus providing standardization across multiple post-acute care settings.

Four commenters explicitly supported the Ventilator Weaning (Liberation) Rate outcome quality measure. Two of these commenters stated that there is currently no common definition or consistent measurement of successful ventilator weaning, and that this measure provides the tools needed to assess this important area of clinical concern. Two commenters noted that standardization of ventilator weaning (liberation) rate at discharge will make it possible to effectively compare the performance of separate LTCHs based on this important clinical outcome. Two commenters supported CMS's decision to require documentation if a patient is not appropriate for weaning, with one of these commenters voicing support that documentation be conducted by a physician or a respiratory therapist.

Regarding the process measure, Compliance with Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of the LTCH Stay, one commenter explicitly supported the measure and stated that it provides a consistent analysis of quality in post-acute care between sites.

Response: CMS appreciates the commenters' support for the clinical importance of the quality measure concept and the goals of measurement in this domain. We concur that measurement of weaning liberation and standardization of definitions are important and useful for providers, patients, and their families. These measures allow for comparison of weaning processes and outcomes across LTCHs, and could lead to increased use of evidence-based ventilator weaning/liberation guidelines and improved health outcomes.

2. Measure Specifications

2.1 Measure time frame: Determining Weaning Status by Day 2

Summary: Determination of weaning status by Day 2 of the LTCH stay pertains both to the process measure, where it defines the measure assessment window, and to the outcome measure, where it is used as the window of time for determining measure exclusion criteria.

Three commenters agreed that it is feasible to categorize patient weaning status as weaning or non-weaning by Day 2 for patients on invasive mechanical ventilation upon admission, where Day 1 is the day of admission. One commenter said that it is their facility's practice to attempt weaning on all ventilated patients, and therefore there is no issue with determining weaning status by Day 2. Another commenter stated that by requiring a narrow and specific set of exclusions for non-weaning, the measures are specific enough

that there should be a high expectation of the ability to determine weaning status and perform an SBT by Day 2 for these patients.

However, several commenters expressed concern that requiring an assessment for weaning status to be completed and weaning efforts to begin by Day 2 of the LTCH stay was problematic.

Three commenters stated that it may not be feasible in all instances to have a clinical assessment completed by the end of Day 2. They further stressed that a comprehensive clinical assessment is necessary to determine whether a patient is stable enough to undergo SBT, and that collection and integration of all the appropriate information may not be achievable by Day 2. One commenter suggested that LTCH admission patterns, where patients are typically admitted in the late afternoon or evening, contributes to the difficulty in assessing weaning status by Day 2. One commenter expressed concern that nearly every patient admitted on a ventilator may be documented as medically unready for SBT if the determination is required by Day 2.

Two commenters suggested that requiring determination of weaning status by Day 2 would increase the administrative burden on providers, and one commenter stated that the specific time frame may force providers to make a clinical judgment in cases where there is not yet a true "yes" or "no" answer by Day 2 (i.e., weaning status is still unclear). Though this commenter agreed clinical records should always be accurate and timely, they further noted that the process could result in an unintended focus on documentation rather than on patient care delivery.

Two other commenters asked for clarity on the "by Day 2" language, and suggested that the assessment time frame be based on hours (i.e., 48 hours) so there is no room for confusion.

Two commenters addressed the Jubran et al., 2013 paper cited as supporting documentation for the measure. Both commenters noted that this study tested whether LTCH patients could breathe unassisted within the first 5 days, not by Day 2. One commenter stated that the Jubran study population was limited to a single LTCH and that the results are not generalizable to all LTCHs.

One commenter requested that LTCHs would not be unfairly penalized for patients on mechanical ventilation for whom weaning is expected once the patient stabilizes, but for whom weaning is not expected within the 2-day time period.

Response: The aim of the process quality measure, Compliance with Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of the

LTCH Stay, is to encourage implementation of evidence-based weaning guidelines as early during LTCH patient stays as is beneficial to patients, in order to decrease LTCH patient exposure to adverse ventilator-associated morbidity and mortality. Based on care providers' clinical judgment and assessment of readiness for SBT, patients on invasive mechanical ventilation on admission may receive a SBT by Day 2 of the LTCH stay.

CMS appreciates the commenters' concern regarding the collection and interpretation of a complete clinical assessment within the proposed timeframe. Additionally, CMS recognizes there are some conditions or clinically significant issues that may affect patients' abilities to wean off the ventilator, or to begin SBTs by Day 2, which is why mechanically ventilated patients who are not expected or anticipated to undergo weaning attempts during their stay are being considered for exclusion from the measure.

CMS would like to clarify that this measure is designed to encourage recommended actions for assessing and weaning patients who enter the facility on invasive mechanical ventilation, and to support safe discontinuation of invasive mechanical ventilation soon after being admitted to the LTCH. This ventilator weaning process measure, as posted for public comment, does not specify that an SBT be performed by Day 2. TEP feedback suggested that patients who are deemed not ready for SBT should have documentation of the reason(s) that they were deemed not ready; patients who are deemed ready for SBT by Day 2 should receive an SBT by Day 2. CMS will work to clarify the measure specifications and instructions in written documents, communication with providers, and educational material.

CMS appreciates commenters' concerns that few patients may be deemed medically ready for SBT in by the end of Day 2. This concern was included in the pilot test design and analysis, and CMS will take the findings into consideration during measure development.

CMS understands the concern over use of the "by Day 2" timeframe rather than "48 hours." The TEP discussed this issue at length, and questions were posed to the pilot testing sites. Based on feedback received during TEP meetings and from pilot test participants, the timeframe of "by Day 2" has been confirmed as appropriate for the LTCH setting. This timeframe imposes less burden on providers because it does not require providers to count hours. Furthermore, clinician action by Day 2 of the LTCH stay, where Day 1 is the day of admission, was shown to be feasible during pilot testing of the measures, even for patients admitted late on Day 1.

With respect to the Jubran article, longstanding clinical guidelines support SBT as soon as it is safe for patients. Therefore, although Jubran et al. (2013) found that one-third of ventilated patients admitted to their LTCH were

weaned within the 5 day window following admission, the TEP judged that assessment for patient readiness for SBT should begin much sooner after arrival; they did not think it appropriate to include patients in the measure numerator who were not assessed for readiness to begin SBT until Day 5 of the LTCH stay.

2.2 Including a Partial Weaning Status Response at Discharge

Summary: A few commenters supported the feasibility and utility of including a partial weaning response item on the discharge assessment. The commenters noted that there are a range of possible weaning outcomes, and that partial weaning is a definition of "success" for many patients. Another commenter also suggested that the inclusion of a partial weaning response may help providers understand how often this occurs, in order to provide benchmarks for comparison and improvement.

Conversely, one commenter did not support the inclusion of partial weaning as an outcome at discharge, and pointed to the logistics of counting hours on ventilation at discharge as potentially problematic, resulting in submission of inaccurate data to CMS. The commenter also felt that a partial weaning option increased the possibility of patient miscategorization, would not add clinically meaningful information to the measure, and that the impact of partial weaning on patient quality of life is limited. The commenter strongly encouraged restricting the outcome measure to reporting the percentage of fully weaned patients at discharge.

Response: CMS understands that it is important to assess various aspects of weaning outcomes, and that being fully liberated from invasive mechanical ventilation is not the care goal for some patients. Feedback from pilot testing participants was mixed with respect to the impact of partial liberation on patient quality of life and the utility to providers of measuring partial weaning status on discharge. CMS appreciates the commenters' support for including a partial weaning response item on the discharge assessment, but also understands the burden of counting hours on a ventilator at the time of discharge would impose on providers. Furthermore, in order for partial weaning as a discharge status to have any meaning, questions about the extent of ventilation treatment patients are receiving on admission would need to be added to the Admission Assessment. Pilot testing participants indicated that collecting this baseline data is burdensome or not feasible to capture from prior settings as it may be unreliable or incomplete. Given these concerns, and the limited benefits of including partial liberation as a liberation outcome, CMS has elected to focus the measure only on patients who are fully weaned at discharge.

2.3 Item wording

Summary: As mentioned briefly above, several commenters asked for a change to the "by Day 2" language of the process measure Compliance with Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of the LTCH Stay. Two commenters asked that the time frame be based on 48 hours instead of 2 days, one commenter recommended a change to either 72 or 96 hours, and two commenters recommended a more significant change to "by Day 5," citing the Jubran et al. (2013) paper.

One commenter also recommended revising the language of O0200A, response 0, to read "No, Not on invasive mechanical ventilation on admission" in order to prevent any confusion with the meaning of non-weaning.

Response: CMS understands the concerns regarding the wording of the timeframe. However, the selection and wording of the timeframe was made to meet both clinical and administrative needs, while minimizing burden. Although hours do provide a more specific timeframe, they were found during pilot testing to be more difficult for providers to count than calendar days. As the admission date is always known, it was decided to use the language "by Day 2." With respect to the suggestion of a 72- or 96- hour time frame, the TEP did not think it appropriate to include patients in the measure numerator who were not assessed for readiness for SBT until Day 3 or 4 of the LTCH stay, given that the evidence-based weaning guidelines specify that patients should be assessed as soon as possible after admission.

3. Unintended Consequences

While one commenter saw no unintended consequences from the measures, seven commenters expressed concern over the effect of the measure on patient safety, patients who opt for therapy withdrawal, LTCH processes and policies, and readiness for SBT.

3.1 Patient Safety

Summary: Two commenters were concerned that a patient may experience respiratory arrest if the SBT is performed incorrectly or too quickly, or if he or she is unable to wean. One of these commenters stated that patients may experience physical and psychological trauma if they need to be reintubated while awake and alert. The commenter further recommended that patient safety education regarding risks of SBT should be a required component of the protocol.

Response: CMS acknowledges the commenters' concerns regarding patient safety if providers assess weaning status within the proposed time frame and inappropriately perform an SBT on the patient. The measure is not intended to require providers to perform an SBT in situations where it is difficult to determine readiness for SBT or an SBT is contraindicated due to the patient's medical condition at the time of the assessment. CMS agrees that patient safety should come first, and that clinicians use their medical knowledge and clinical judgement in assessing a patient's readiness for SBT and ventilator liberation.

3.2 Patients Opting for Therapy Withdrawal

Summary: One commenter stressed the importance of honoring patient and family decisions, such as to seek therapy withdrawal if treatment fails. They recommended that patients who opt for therapy withdrawal be excluded from the measure. The commenter felt that retaining this group of in the measure could result in unintended consequences; for example, LTCHs might delay discussion of planned withdrawal of ventilator therapy in the hope that the patient would be successfully weaned, thus increasing their score on the outcome measure.

Response: CMS understands that planned withdrawal of ventilator support is an important and appropriate course of treatment for some LTCH patients, and acknowledges the potential for unintended consequences of the measure. However, based on consultation with pilot sites and the TEP, CMS concluded that exclusion of this category of patients from the measure could foster additional unintended consequences. As such, these patients will be included in the measure if they were admitted to the LTCH for weaning. CMS is committed to supporting quality end of life care, and will continue to consider these issues going forward.

3.3 LTCH Processes and Policies

Summary: A few commenters expressed concern that the quality measure may have a negative influence on provider policies and processes. Two commenters believed providers may be able to artificially increase facility scores, for example, by altering the admission policy to favor patients with the best weaning prognosis in order to improve liberation statistics. One of these commenters further believed that patients who are categorized as "non-weaning" for the purposes of the exclusion criteria may not be given the opportunity to wean, and that LTCHs with larger weaning programs may be at a disadvantage. Another commenter believed that the added pressure on the system and individual providers to document non-weaning status with increased specificity and timeliness would detract from patient care delivery.

Response: CMS appreciates the commenters' concern about the unintended policy and/or process changes that may occur in the LTCH if these measures are implemented. CMS is cognizant of the impact of quality measures on provider burden. We strive to create meaningful measures that are not unnecessarily burdensome to providers, and this includes conducting pilot testing to ensure that the collection of these items is feasible. CMS evaluation of pilot test results and TEP feedback included assessment of the feasibility of data collection, provider burden, and potential unintended policy and/or process changes. These findings will be taken into consideration during finalization of measure specifications.

4. Patients Inappropriately Deemed Unready for SBT

Summary: Several commenters questioned whether the measure's definition of non-weaning and the requirement to make this determination by Day 2, fails to account for certain patient populations. Three commenters noted that the requirement to complete the assessment and determination of weaning status by Day 2 may falsely increase the number of patients "deemed medically unready" for SBT, thus limiting the measure and its intent. Since the definition of "non-weaning" does not account for patients who are not ready to wean at the time of admission, but for whom weaning attempts are expected or anticipated once the patient has stabilized, the rates of non-weaning patients may be higher than expected in LTCHs. One of these commenters further explained that inaccurate numbers of non-weaning patients may render comparisons of performance across facilities ineffective because frailer and sicker patients who are not ready for SBT by Day 2, would be excluded from the outcome measure.

Response: CMS understands these concerns, but would like to emphasize that the measure specifications posted for public comment do not exclude patients deemed medically unready for SBT by Day 2; rather, all patients who are admitted to the LTCH on invasive mechanical ventilation, for whom weaning attempts are expected or anticipated (e.g. patients admitted for weaning), are included in the outcome measure even if weaning does not begin by Day 2. CMS encourages providers to use the non-weaning category to indicate patients for whom no weaning attempts are expected or anticipated during the patient stay (e.g. a chronically ventilated patient who is admitted for treatment of another condition).

5. Risk Adjustment

5.1 Support for Risk Adjustment

Summary: Several commenters supported risk adjustment for the outcome measure, and one commenter noted that risk adjustment was especially important considering the LTCH PPS payment and admission criteria for chronically, critically ill patients that were implemented as of October 2015. Commenters particularly mentioned support of a risk adjustment model that would include patients on dialysis and/or receiving vasoactive medications, patients with metastatic cancers and neuromuscular disease, and post-transplant patients.

Response: CMS appreciates commenters' support of risk adjustment for the outcome measure, Ventilator Weaning (Liberation) Rate. At this time, CMS is testing the use of risk adjustors for patients on dialysis and/or vasoactive medications, patients with metastatic cancers and neuromuscular disease, or post-transplant patients. CMS will review the data and consider their use in the future.

5.2 Risk Adjustor: Dialysis

Two commenters recommended that the item O0100J, Dialysis be refined to include patients who require dialysis during the current admission. One commenter suggested the item include those patients with chronic kidney disease. One commenter felt that this risk adjustor needs to be collected on discharge, and not on admission, to reflect the treatments provided during the entire hospital stay.

Response: Patients with chronic kidney disease will be included in the risk adjustment model through the dialysis item, O0100J. CMS agrees that these patients represent a more difficult population to wean. Currently, the instructions on the LTCH CARE Data Set v. 2.01 Admission Assessment for Item O0100J, Dialysis, indicate that this item should be checked only if dialysis is part of the patient's treatment plan on admission. With respect to collecting this information at the time of discharge instead of admission, the TEP noted that risk factors must be present prior to the weaning/liberation outcome. CMS agrees that dialysis is an important risk factor and that patients could receive this treatment at any time during a patient's stay. However, adding this item to the discharge assessment could result in the capture of dialysis status for patients who are weaned, and subsequently undergo dialysis prior to discharge, negating the usefulness of dialysis as a risk factor.

5.3 Risk Adjustor: Vasoactive Medications

Two commenters suggested that the intent of O0100H1, Vasoactive Medications be clarified. Specifically, the commenters recommended that the interpretation of vasoactive medications include: vasoactive pressors, intravenous vasopressors, inotrophs, and vasodilators. One commenter added that continuous medication for pulmonary edema could merely be the ongoing use of diuretics and that this language should be removed from the definition because it could inappropriately risk adjust for certain patients. One commenter felt that this risk adjustor needs to be collected on discharge, and not on admission, to reflect the treatments provided during the entire hospital stay.

Response: CMS will further clarify the wording of the vasoactive medications item. With respect to collecting this information at the time of discharge instead of admission, the TEP noted that risk factors must be present prior to the weaning/liberation outcome.

5.4 Risk Adjustor: Transplant Patients

Two commenters recommended that CMS clarify the proposed assessment item, "I7100. Lung, Heart, Liver, Kidney, or Bone Marrow Transplant" to have a qualifier such as "recent" or "in the previous 12 months" so providers do not inadvertently risk adjust for patients who have survived many years since transplant and could be weaned from the ventilator.

Response: CMS will consider identifying a time frame for transplant patients. The original intent of this proposed assessment item was to capture post-transplant patients.

5.5 Risk Adjustor: Severe Left Systolic/Ventricular Dysfunction

One commenter stated that coding of "Severe Left Systolic/Ventricular Dysfunction" may be confusing for some facilities when a patient has Left Ventricular Failure (LVF) but does not require a device.

Response: This item was included in a pilot test of patient-level data collection for the ventilation weaning (liberation) quality measures. During the pilot test, CMS received similar feedback from pilot participants regarding the potential of this item to be confusing. Based on recommendations from the Ventilator Weaning (Liberation) Technical Expert Panel (TEP), CMS will consider editing this item for clarity and to improve reliability. CMS will provide further guidance in written documents, communication with providers, and educational material.

5.6 Further Development of Risk Adjustment

A few commenters suggested that the risk adjustment variables were not adequately capturing differences in patients' clinical characteristics. They asked that additional testing be completed, and suggested the following variables: multiple organ failures, opioid dependence, severe wounds, and various pulmonary conditions. One commenter felt that the categories, such as "Progressive Neuromuscular Disease," lacked sensitivity and specificity, and would be burdensome for "LTCHs with manual systems in place."

Finally, one commenter who supported risk adjustment for the outcome measure requested that it should not affect the overall wean rate of a facility. The commenter clarified that they recommended a wean rate for facility A be measured identically to facility B and stated that risk stratification that may skew comparisons.

Response: CMS appreciates the suggestions for additional risk factors, and would like to confirm that the steps for calculation of weaning rates are identical across all facilities. This measure is still in the development phase. We are considering testing additional variables for the risk adjustment model of this measure as part of future measure refinement. During pilot testing, "progressive neuromuscular disease" was found to be feasible to collect, even for LTCHs with manual systems in place.

6. Public Reporting Minimum Denominator

Summary: One commenter noted that for both measures, those LTCHs that have fewer than 20 patient stays in the denominator would not be included in public reporting. The commenter supported the inclusion of a minimum sample size for these measures, but also strongly recommended that the size be determined by the number of patient stays required to yield reliable measure scores.

Response: CMS appreciates the commenter's support for including a minimum reporting requirement when publically reporting these quality measures. CMS strives to produce valid and reliable measures, and will take the commenter's recommendation into consideration. We are considering basing the measure calculations on one year of data, in order to obtain a sufficient number of patient stays to yield reliable measure scores.

7. Additional Measures for Ventilated Patients

Summary: One commenter recommended adding a measure for individuals who are admitted to the LTCH without mechanical ventilation support, but later need ventilator assistance. The commenter further noted that the measure

does not address or document certain ventilator patient populations such as those who needed to be reintubated after weaning attempts were made, and patients on prolonged mechanical ventilation. Outcomes for these patients may be different, and the commenter recommends ventilation measures that address quality of care for these populations.

Response: CMS acknowledges the commenter's request for additional quality measures related to invasive mechanical ventilation, and appreciates the importance of this aspect of clinical care for patients. The Technical Expert Panel that convened to support CMS in developing and refining these measures did consider other ventilator liberation-related measure concepts, but felt that the data collection needed to track some groups (e.g. patients who are liberated and later reintubated), would be difficult and burdensome to providers at this time. CMS will consider these suggestions in future measure revisions and or development of new measures.

Preliminary Recommendations

CMS and the measure development contractors appreciate the comments received for the Ventilator Weaning (Liberation) quality measures for LTCHs. The general comments about the measures, as well as the specific input we received with respect to time frames, item wording, unintended consequences, and risk adjustors, were informative to the development of these two measures.

Overall Analysis of the Comments and Recommendations

The comments and feedback received provided useful input for the development of the Ventilator Weaning (Liberation) measures. We appreciate the comments and will take them into consideration as we complete measure development.

Public Comment Verbatim Report

The following table details the verbatim comments received. We did not make any changes or edits to the content.

Public Comment Verbatim Report

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
6/7/2016	Ventilator Weaning Quality Measures for use in LTCHs	Re: CMS Quality Measures for Long-Term Care Hospital (LTCH) Ventilator Management Dear Sir or Mdm., I am writing to comment upon the proposed CMS quality measures. These do not correspond well to the work flow, patient population or principles of medical care in the Long-Term Acute Care Hospital. I list my concerns followed by suggestions. 1. The requirement that weaning efforts begin on "day two" does not recognize the admission pattern to LTCH's. Virtually all admissions arrive in the late afternoon or evening. Therefore, "day two" is actually the first day of evaluation with full staffing. Ventilator dependent patients are generally seen by a Pulmonology consultant on that day. Information is usually incomplete at that time. Almost always, the LTCH receives a discharge summary dictated by a medical resident with little understanding of mechanical ventilatory support in the ICU setting. Further information such as previous consultations, x-ray images, discussion with the referring Pulmonologist and other data is sought. It is critically important that diagnosis including the previous clinical course be known before initiating weaning maneuvers. Seldom is all of this information available immediately. 2. LTCH patients by their nature are medically complex. Ventilator support does not exist in isolation. Other consultations including Cardiology, Infectious Disease and Nephrology are part-and-parcel of constructing a therapeutic approach. It is not feasible to have all of these accomplished and integrated by the first day (day two by your criteria). 3. Patients referred to LTCH's almost invariably have failed weaning efforts. Multiple other medical issues are often paramount including narcotic analgesia, surgical drains, treatment of active infection, congestive heart failure, malnutrition or resolution of pneumonia or pleural effusion. On a clinical basis, it may be obvious that the patient is not in a situation to have a reduction in mechanical ventilatory support.	Jerome L. Slate, M.D. FCCP, Pulmonologist Medical Acute Care Unit Hebrew Rehabilitation Center, Boston, MA	JeromeSlate@HSL.Harvard.edu	Individual provider

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
		4. Hypercapneic respiratory failure causes desperate air-hunger and fear. A Spontaneous Breathing Trial in a patient with major respiratory insufficiency that will predictably result in CO2 retention is inherently cruel. A Spontaneous Breathing Trial in a patient unable to ventilate runs a serious risk of major complications including death. LTCH's are not intensive care units with 1:1 nursing. Other issues on a ward may prevent early recognition and intervention in a rapidly failing trial. I suggest that anyone recommending this trial without evaluation including measurement of Pulmonary Mechanics (VC, IF, RSBI) and a clinical assessment of appropriateness should first themselves undergo a CO2 rebreathing trial and maintain that trial until their End-Tidal pCO2 reaches 50 mmHg, a common result when there is a failure of weaning. I can guarantee that no subject will voluntarily reach that point. The cruelty of this maneuver, unto itself, makes it an unconscionable requirement.(Of course, the clever Pulmonologist, to skirt this CMS Quality Measure, will simply use a meaningless high level CPAP trial, let the patient breath rapidly for a few moments and declare it a failure.) 5. Ventilator Liberation Rate implies that success is defined by this parameter. In fact, the patient mix to an LTCH is easily divided into three groups with different liberation rates. For example, previously healthy postsurgical patients have a good prognosis. Patients with underlying lung disease will not do as well. Patients with neuromuscular disease do poorly. Using the Ventilator Liberation Rate as a quality parameter will skew the admission policy toward the patient with the best prognosis in order to improve Ventral Liberation statistics. Patients with poorer prognoses will be underserved. 6. Some CMS prescriptive therapeutic maneuver requirements have a history of poor results. Several years ago, a CMS Quality Measure required early administration of antibiotics in the treatment of pneumonia. This resulted in a lack of appropriate cultures, poor diagnostic accuracy and inappropriate antibiotic treatment. Ultimately, after an embarrassing outcry from the medical community, this recommendation was rescinded.			

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
		When physicians perform a therapeutic maneuver in order to satisfy a Quality Measure, as seen in the above, adverse consequences occur. In the case of a Spontaneous Breathing Trial, because of the logistics of the typical LTCH setting, there will be cruelty and there may be deaths related to this attempt to satisfy a CMS Quality Measure. Ironically, the quality parameter may reduce quality. I suggest that quality measures for the first few days be restricted to assessment parameters. These could include factors such as Pulmonary Consultation, measurement of Pulmonary Mechanics (VC, IF, RSBI), appropriate gathering of other medical background information, direct conversation with the referring consultant (Intensivist or Pulmonologist) and a formal written plan of care for the patient's mechanical ventilator support. Prescriptive therapeutic maneuvers pose both danger and cruelty to patients unable to support them. Thank you very much for your consideration.			
6/8/2016	Ventilator Weaning Quality Measures for use in LTCHs	SPAN & Family Voices-New Jersey comments on the Centers for Medicare and Medicaid Services candidate proposed Long-term Care Hospital (LTCH) ventilator weaning quality measures Mar June 9, 2016 Thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services proposed LTCH ventilator weaning quality measures. The Statewide Parent Advocacy Network (SPAN) is NJ's federally designated Parent Training and Information Center. Family Voices (FV) is a national network that works to "keep families at the center of children's healthcare." The NJ State Affiliate Organization for FV is housed at SPAN, which is also the home of the Family-to-Family Health Information Center. The Family Voices Coordinator also serves as NJ representative for the Caregiver Action Network, addressing caregiver issues across the lifespan. Our comments regarding ventilator weaning quality measures follow.	Lauren Agoratus, M.A., State Coordinator-Family Voices NJ @ SPAN	familyvoicesnj @aol.com CC:diana.autin @spannj.org; pkinsell@span nj.org	Patient advocacy association

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
		LTCH Ventilator Weaning Quality Measures DRAFT Data Elements: Planned Discharge, Unplanned Discharge, and Expired Assessments for Public Comment 01. Fully weaned at discharge (i.e., patient did not require any invasive mechanical ventilation support for at least 2 consecutive calendar days immediately prior to discharge) There is no measure of if an attempt was made to wean the patient from mechanical ventilation but they needed to be reintubated. Sometimes patients on ventilators long term can have complications such as laryngospasm in which they suffer respiratory distress and require resuscitation and reintubation, then gradual weaning. This has important implications for possible future complications such as procedures requiring breathing tube extubation. Specifications S.11. Denominator Exclusion Details Patients are excluded from the target population (i.e., denominator) for all three measure components if they meet either of the following criteria: (a) Admission Assessment item O0200A. Invasive Mechanical Ventilator = 0, No (i.e., No Ventilation Support on Admission), OR There needs to be measures of individuals who are admitted and later need ventilator assistance. Outcomes for these individuals can be if they require long term ventilation, were weaned off ventilation (or reintubated,) were readmitted for complications or died. In addition, there must be documentation if there was prolonged ventilation for administrative convenience for multiple procedures over a period of time, which increases risk.			

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
		1b.1. Briefly explain the rationale for this measure Discontinuation of invasive mechanical ventilation, known as weaning or liberation, is feasible for many ventilated patients, and is associated with improved health outcomes. We strongly agree with this and would suggest other measures and ventilation as last resort due to risks. As stated above, unnecessary prolonged ventilation for multiple surgical procedures which could be spread out over time, must be avoided. Again, ventilator weans must be done carefully and gradually to avoid unnecessary complications. Call for Public Comments: Special Topics for Consideration Special Topics for Consideration and Feedback: • Potential unintended consequences of each measure as currently specified • Feasibility of determining invasively mechanically ventilated patient initial status as weaning or non-weaning by the end of Day 2 of the LTCH stay, where Day 1 is the day of admission. (It is understood that weaning status may change during the course of patient stay.) The unintended consequences could be respiratory arrest if the wean is performed incorrectly or too quickly. Physical and psychological trauma result when the patient must be reintubated while awake, alert, and aware (e.g. bleeding or tissue tears.) Here again, there must be documentation if the patient needed reintubation, not merely documentation of total ventilation time during the hospital stay. This will help providers avoid future complications, preventable medical errors, and improve patient safety. Finally, we also think that it is important to have patient/safety education regarding risks as a required component of the protocol. Thank you again for the opportunity to comment on the proposed CMS ventilator weaning quality measures.			

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
6/8/2016	Ventilator Weaning Quality Measures for use in LTCHs	Dear Contract Management Team: This letter is respectfully submitted on behalf of Kindred Healthcare, the nation's largest provider of integrated care for people with post-acute and chronic care needs delivers care and services to more than one million patients each year in 2,700 post-acute care locations throughout 46 states. Kindred's 95 Transitional Care Hospitals, certified by Medicare as long-term acute care hospitals (LTCHs), deliver quality patient outcomes for the most difficult to treat, chronically, critically ill and medically complex patients who require specialized and aggressive interventions over an extended recovery period. Kindred Healthcare believes that LTCHs are an essential component to a successful and complete post-acute care (PAC) continuum. In particular, patients are frequently discharged from short-term acute hospitals' Intensive Care Units (ICUs) to LTCHs for successful weaning from prolonged mechanical ventilator support. In order to treat patients with an acute diagnosis on top of multiple chronic illnesses, multi-organ system failure, or who require a lengthy reliance on a ventilator, we have established clinical programs, condition-specific pathways and outcome measures to support optimal clinical outcomes. Our interdisciplinary teams, led by physician specialists, coordinate care to assure appropriate lengths of stay and help improve outcomes and recovery for LTCH patients. As one of the nation's leading LTCH providers, we appreciate the opportunity to comment on the proposed new candidate quality measures for use in the Center for Medicare and Medicaid Services' (CMS') LTCH Quality Reporting Program. We commend RTI International and CMS for recognizing the importance of tracking Ventilator Weaning (Liberation) as a vital quality metric across LTCH locations. Based upon our clinical experience, we believe there are minor changes to the proposed measures that would elicit a more appropriate and comprehensive capture of a LTCHs Liberation rate. We look forward to working with RTI International and CMS in continuing to refine and improve the LTCH Quality Reporting Program. If you have any questions about these recommendations, please contact me at 502.596.7175 or Sean.Muldoon@Kindred.com. Sincerely, Sean R. Muldoon, M.D., M.P.H., F.C.C.P. Chief Medical Officer, Kindred Hospital Division	Susan Feeney | Senior Director, Communications & Public Policy | 202.607.0315 (direct)	susan.feeney@kindred.com	LTCH provider

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
		I. OVERVIEW The population of older Medicare-eligible beneficiaries in America is growing rapidly, many of whom have multiple chronic conditions, resulting in increased medical utilization, higher readmissions, and increased costs. These trends stress the need for effective care management and integrated services that link acute and post-acute care (PAC) though careful coordination across settings. As the nation's largest provider of post-acute care, Kindred is developing the capability to provide care in a seamless way, creating a better patient experience with higher quality at lower lowers costs. Kindred Healthcare's focus is on delivering innovative solutions through expanded care management capabilities across its integrated PAC network, data-driven insights, and 24/7 direct consumer assistance and support. We believe that appropriate Quality Reporting Programs for care settings across the continuum will improve outcomes, ensure cross-setting comparisons and contribute to an enhanced patient experience. We commend RTI International and CMS for recognizing the importance of tracking Ventilator Weaning (Liberation) as a vital quality metric across LTCH locations. At present, while many LTCHs track their ventilator weaning rates, there is no common definition or measurement of Ventilator Weaning, making it impossible for physicians, referring facilities or patients to effectively compare the performance of separate LTCHs in this important clinical outcome. We believe there are minor adjustments to the collected data elements that would improve on the proposed Ventilator Wean Rate measure. In order to treat patients who require a lengthy reliance on a ventilator, we have established clinical programs, condition-specific pathways and outcome measures to support optimal clinical outcomes. This has contributed to a nearly 8% improvement in our internally-tracked Ventilator Wean rates from 2011 through 2015. However, we have limited concern with the proposed process Quality Measure: Compliance with Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of the LTCH Stay. We believe that through documentation of patients being "non-weaning" this measure will quickly become an ineffective tool to compare facility performance.			

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
		II. Ventilator Weaning (Liberation) Rate Proposed Quality Measure CMS has proposed a measure to capture facility-level Ventilator Weaning (Liberation) Rate for patients admitted to a LTCH for patients who require invasive mechanical ventilation support, and where weaning attempts were expected upon admission. A patient is considered fully weaned if he or she does not require any invasive mechanical ventilation support for at least 2 days prior to the date of discharge. The following three components will be reported separately: the percentage of patients who are fully weaned at discharge (alive), the percentage of patients who are not fully weaned at discharge (alive), and the percentage patients who died. Kindred Response – Kindred appreciates the standardization of a Ventilator Weaning Rate for LTCHs as we believe it will provide physicians, referring hospitals and consumers with the tools to assess this important clinical outcome and to more appropriately compare hospitals. We also support that documentation for this proposed Quality Measure may be conducted by either the physician or respiratory therapist, as it supports appropriate clinical knowledge for documentation. a. Admission Assessment Data Components, Section 1. Active Diagnoses – Data collection on comorbidities and co-existing conditions was designed to help identify those LTCH invasively mechanically ventilated patients as non-weaning at the time of admission to an LTCH. Patients who may be considered non-weaning include patients who are consideredchronically ventilated as defined by evidence-based guidelines for ventilator liberation or patients with an acute or chronic medical conditions that negates at admission any expectation or anticipation of weaning attempts. Kindred Response – While Kindred supports the exclusion of truly non-weanable patients from being including in the denominator used to determine LTCH Ventilator Weaning Rates, we believe the data collection may exclude patients that could potentially be weaned from a ventilator. Specifically, the proposed assessment includes “I7100. Lung, Heart, Liver, Kidney, or Bone Marrow Transplant.” Kindred believes that for Liver, Kidney or Bone Marrow Transplant patients, a qualifier of “recent” or “unstable” should be added. Patients who had one of these types of transplants in the past may be quite stable and could successfully weaned from a ventilator.			

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
		b. Admission Assessment Data Components, Section O. Special Treatments, Procedures, and Programs – Data collection includes identification for treatments at admission, such as dialysis and vasoactive medications. Kindred Response – Kindred supports the identification of patients requiring dialysis and vasoactive medications. However, we believe that minor adjustments to the assessment will improve the tool. Specifically, for component "O0100J. Dialysis" we believe that the assessment of requiring Hemodialysis, Continuous Renal Replacement Therapy, or Peritoneal Dialysis upon admission to the LTCH should be expanded to include those patients who will require dialysis after admission. By simply inserting the phrase "ongoing or imminent" prior to the word Dialysis would capture this patient subset. Additionally, for "O0100H1. Vasoactive Medications" the intent of the component could be clarified with minor edits. Rather than the proposed definition of "pressors, dilators, continuous medication for pulmonary edema" we believe a more accurate definition should be "vasoactive pressors, inotrophs, vasodilators." Continuous medication for pulmonary edema could merely be the ongoing use of diuretics and the use of the term could inappropriately exclude patients from being included in the Ventilator Weaning Rate. III. Compliance with Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of the LTCH Stay Proposed Quality Measure CMS proposes a process Quality Measure to assess compliance with a Spontaneous Breathing Trial (SBT) for patients on invasive mechanical ventilator support by their second day in an LTCH. The proposal seeks to identify the minor subset of patients who can be taken off ventilator support sooner than expected. For the purpose of this measure, SBT is a trial of unassisted breathing for a certain period of time during the day and full ventilator support at night, administered to patients with endotracheal tubes. Kindred Response – Kindred believes this process measure represents an unnecessary administrative burden on physicians and respiratory therapists and will not produce the results desired. Until a full clinical assessment is done, which may not be complete by the day after admission, it is not known how many patients are too unstable to undergo SBT. We believe an assessment on or before Day 2 will unnecessarily increase the documentation of "deamed medically unready", weakening the value of the measure. While supporting documentation			

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
		for this measure includes a ventilator weaning study by Jubran and colleagues, the study was limited to one LTCH and we do not believe that the conclusions are applicable to all LTCHs. At a minimum, the test on the second day is significantly sooner than the Jubran study, which tested if LTCH patients on invasive mechanical ventilation were able to breathe unassisted on the 5th day after admission. We believe that for nearly every patient on a ventilator, the physician or respiratory therapist will be documented as "deemed medically unready for SBT by Day 2 of the LTCH Stay." This would render the measure ineffective as it provides no new comparative data if all hospitals receive a 100% compliance score. IV. CONCLUSION As one of the nation's leading LTCH providers, Kindred appreciates the opportunity to comment on the proposed new candidate quality measures for use in the Center for Medicare and Medicaid Services' (CMS') LTCH Quality Reporting Program. We commend RTI International and CMS for recognizing the importance of tracking Ventilator Weaning (Liberation) as a vital quality metric across LTCH locations. Based upon our clinical experience, we believe that the minor changes documented above may elicit a more appropriate and comprehensive capture of a LTCHs Liberation rate. In terms of the Compliance with SBT By Day 2 of the LTCH Stay process Quality Measure, it is inconsistent with the outcomes elicited in the Jubran study published in 2013 and will fail to provide meaningful information that will impact earlier weaning of LTCH patients. We remain committed to working with CMS and the Department of Health and Human Services to ensure that systems that impact LTCHs and other PAC settings supports transparency and the capability of providers to deliver care in a seamless way, creating a better patient experience with higher quality at lower lowers costs.			

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
6/9/2016	Ventilator Weaning Quality Measures for use in LTCHs	Re: Development of Long-Term Care Hospital (LTCH) Ventilator Weaning Quality Measures Dear Measure Development Team, The National Association of Long Term Hospitals (NALTH) is pleased to submit comments on the candidate measures, Ventilator Weaning (Liberation) Rate and Compliance with Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of the LTCH Stay. NALTH is the only hospital trade association in the national that is devoted exclusively to the needs of patients who require services provided by long term care hospitals (LTCHs). NALTH is committed to research, education and public policy development that furthers the interests of the very ill and often debilitated patient populations who receive services in LTCHs throughout the nation. NALTH's membership is composed of the nation's leading LTCHs, including free-standing, hospital-within-hospital, for-profit, and non-profit LTCHs. On behalf of our member hospitals, we wish to express our gratitude for the opportunity to share our comments on the draft specifications for the ventilator weaning quality measures. We have carefully reviewed the draft specifications for two candidate measures, Ventilator Weaning (Liberation) Rate and Compliance with Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of the LTCH Stay, and have identified several concerns regarding the utility of these measures. We discuss these concerns below. General Comments LTCHs are highly specialized acute care facilities that treat complex and often critically ill patients who require hospital-level care for an extended period of time. As such, an LTCH must meet Medicare's conditions of participation for acute care hospitals and have an average length of stay of more than 25 days. Like short-term care hospitals (STCHs), LTCHs treat patients requiring critical, acute, or sub-acute levels of care and discharge patients that no longer require such high levels of care. Patients requiring invasive mechanical ventilation support may transition from a STCH to other care settings. In many cases, these patients transition to LTCHs to continue their care and receive ventilator weaning services offered by these hospitals.	Lane Koenig, PhD President, KNG Health Consulting Phone: 240 403 0154, Cell: 301 385 9869	lane.koenig@knghealth.com	Hospital association

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
		Definition of "Non-Weaning" Patients On page 1 of both measure specifications (brief description of measure), "non-weaning" patients are defined as "patients on invasive mechanical ventilation upon admission to the LTCH, for whom at the time of admission weaning attempts are NOT expected or anticipated (e.g., patients who are chronically ventilated in the community or a facility, or have progressive neuromuscular disease such as amyotrophic lateral sclerosis, or irreversible neurological injury or disease or dysfunction such as high (C2) spinal cord injury). Consideration of a patient as non-weaning must be based on documentation found in the patient's medical record at admission." The definition of "non-weaning" patients do not account for patients that are not ready for weaning at the time of admission, but for whom weaning attempts are expected or anticipated once the patient has stabilized. For example, consider a septic patient requiring mechanical ventilation that is discharged from a STCH to an LTCH. Weaning may be possible for the patient, but the patient must first be treated for sepsis and stabilized before weaning is attempted. These types of cases are often admitted to LTCHs. As a result, rates of non-weaning patients may be high for LTCHs. We ask the measure development team and CMS to ensure that LTCHs are not unfairly penalized for patients on mechanical ventilation for whom attempted weaning is not expected or anticipated at the time of admission, but for whom weaning attempts are expected or anticipated once the patient is stabilized. Definition of Day 2 of the LTCH Stay The measure specifications define Day 2 of the LTCH Stay (page 1 for both measures) "as the second day of the patient's LTCH stay, where Day 1 is the day of admission." The measures require patients to be assessed by Day 2 of the LTCH stay. The definition is unclear as to whether the assessment needs to be completed by the second midnight following admission to an LTCH or within 48 hours. For example, if a patient is discharged to the LTCH at 11:59 pm, it is unclear whether the LTCH has until 11:59pm of the next day or 48 hours after admission. If the measure specifications indicate that an assessment must be done by Day 2 of the LTCH stay, NALTH believes that the definition of Day 2 should be defined as 48 hours after admission to the LTCH. However, we request that the measurement team consider a 72 or 96 hour period to allow more time for stabilization and assessment of LTCH patients.			

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
		Ventilator Weaning (Liberation) Rate Risk Adjustment In comparing between LTCH facilities, we are concerned that the risk adjustment variables are not adequately capturing patient differences. Without sufficient risk adjustments, differences in ventilator weaning rates may be due to differences in patients' clinical characteristics and may not be attributed to differences in care quality across providers. We note the set of variables listed in the measure specification will be used for early testing efforts (page 5); however, the list fails to capture many of the comorbidities found within the LTCH patient population, such as patients with multiple organ failures, opioid dependence, or severe wounds. We ask the measure development team to test for additional variables associated with clinical outcomes for ventilator weaning and to provide more information on the variables used for risk adjustment. If you have any questions about these comments, please contact Lane Koenig, PhD, NALTH Director of Research and Policy, at lane.koenig@knghealth.com.			
6/9/2016	Ventilator Weaning Quality Measures for use in LTCHs	Comments on LTCH Ventilator Weaning Quality Measures The Federation of American Hospitals (FAH) supports the development and implementation of these measures for use in long-term care hospitals (LTCH). We have several comments on each measure that will further ensure that the measures are used appropriately and improve patient care. Ventilator Weaning (Liberation) Rate Several clinical factors are included in the potential variables to be tested in the risk adjustment model. Additional specificity around the timing and clinical details for three of these factors should be considered. First, it can be difficult to successfully wean patients who recently underwent a transplant (Item I7100, Lung, Heart, Liver, Kidney, or Bone Marrow Transplant). For this reason, we support including transplantation in the risk adjustment model but recommend that the data element be further specified to those patients who received a transplant in the previous 12 months. This modification would capture those patients for whom weaning may be more challenging. Second, we recommend	Heidi Bossley, Federation of American Hospitals	hbossley@gmail.com, jchambers@fah.org	Hospital association

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
		that Item O0100J, Dialysis be refined to those patients with chronic kidney disease or those placed on dialysis during the current admission. Further specificity to O0100H1, Vasoactive Medications is needed and should include intravenous vasopressors, vasodilators, and inotropes. Compliance with Spontaneous Breathing Trial (SBT) by Day 2 We are concerned that the requirement that the trial be performed by Day 2 of the LTCH stay may lead to unintended consequences; specifically, that patients will be identified as unstable and unable to be considered as potential candidates for SBT due to the limited timeframe rather than true readiness to wean. Ensuring that both a comprehensive assessment by the clinician and trial are completed by the second day following admission may not be feasible in all instances. As a result, if patients are considered unstable, they will not be included in the measure even when they may be able to have an SBT performed at day 3, 4 or 5. We recommend that the measure developer revise the timeframe from 2 days to 5 days. We do not believe that it compromises patient care and if expanded there is the potential for more patients to be included in the measure. It is also consistent with the findings of the Jubran (2013) study cited under the rationale for this measure where more than 30% of patients were able to breath without ventilator assistance within the first 5 days. Minimum sample size requirement for both measures In the specification documents for both measures under S10. Denominator Exclusions, those LTCHs that have less than 20 patient stays in the denominator during the reporting period would not be included in public reporting. While we support the inclusion of a minimum sample size for these measures to ensure that the reliability of the measure scores is adequate, we strongly recommend that testing include the number of patient stays required to yield results that are reliable rather than setting a sample size without testing and analysis.			

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
6/9/2016	Ventilator Weaning Quality Measures for use in LTCHs	Thank you for the opportunity to provide public comment on the following two candidate LTCH quality measures: Ventilator Weaning (Liberation) Rate Compliance with Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of the LTCH Stay Spaulding Hospital for Continuing Medical Care Cambridge (SHC) is a 180-bed long-term acute care facility located on a 7-acre campus in Cambridge, MA. SHC is part of Partners Continuing Care, a non-profit post-acute care network which includes two Inpatient Rehabilitation Facilities (IRF), a Long Term Acute Care Hospital (LTCH), two Skilled Nursing Facilities (SNF) and a Home Health Agency (HH). We offer these comments in the spirit of constructive feedback. Specific to the special topics RTI has listed for consideration and feedback: Utility of each candidate measure and variation across providers: It is reasonable that upon admission to LTCH, patient would continue the practice from the Acute Care Hospital of assessing readiness for SBT Potential unintended consequences of each measure as currently specified: The "Compliance with SBT" measure puts additional pressure on the system and on individual providers to document with great specificity and timeliness, in order to meet coded field O0200D - Is there documentation of the reason(s)... that the patient was deemed medically unready for SBT by Day 2 of the LTCH Stay? We are always concerned that such focus on patient care documentation detracts from focus on patient care delivery. While the clinical record should always be accurate and timely, this very specific time frame may force a provider to make a clinical judgment in some patient cases when there is not yet a binary YES-or-NO answer. Further, if the provider's choice of wording is not explicit, the nurse completing the LASER tool will need to make outreach to confirm the intention. For the purpose of this measure, the term "documentation" indicates explicit physician or respiratory therapist documentation of the reason that a patient was not deemed ready for SBT (including TCT or CPAP breathing trial) within the given time frame. Documentation must be dated prior to Day 2 of the LTCH stay.	Karen S. Nelson, RN Vice President, Quality, Compliance & Regulatory Affairs Partners Continuing Care 300 First Avenue Charlestown, MA 02129 tel. 617-952-5880 Mary M. O'Quinn Director Quality & Compliance, Spaulding Hospital Cambridge Director Patient Safety & Risk Management, Spaulding Rehab Network 1575 Cambridge Street Cambridge, MA 02138 tel. 617-758-5538	KNELSON@PARTNERS.ORG, MOQUINN@PARTNERS.ORG	Healthcare provider network

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
		Feasibility of determining invasively mechanically ventilated patient initial status as weaning or non-weaning by the end of Day 2 of the LTCH stay, where Day 1 is the day of admission. (It is understood that weaning status may change during the course of patient stay.): Feasible, and is standard of care in ACH ICUs. Importance of risk adjustment to the Ventilator Weaning (Liberation) Rate outcome measure: Accurate risk adjustment is highly important, especially considering the CMS LTCH PPS payment criteria and narrow admission criteria for chronically, critically patients which began implementation as of Oct. 2015. The six variables listed, however, are not comprehensive enough and are not fully representative of the type of patients now being admitted to LTCH under the narrower PPS criteria. We strongly suggest adding other variables, particularly those related to various pulmonary conditions. Feasibility and utility of including partial weaning at discharge as an outcome: O0350. Ventilator Weaning (Liberation) Rate and related codes for Invasive Mechanical Ventilator: Weaning Status at Discharge: We concur that it is important to acknowledge the range of weaning outcomes, and the potential for partial weaning (codes 02 and 03). This is a definition of success for many patients and the hospitals which care for them and help them achieve partial weaning.			
6/9/2016	Ventilator Weaning Quality Measures for use in LTCHs	Thank you for allowing us to provide public comment on this initiative to CMS. Our responses to the suggested topics are indicated below: • Potential unintended consequences of each measure as currently specified Our facility recommends the following revisions on the CARE data set as follows: 1-O0200A - revising code 0 to say No, Not on invasive mechanical ventilation on admission >> end data collection for O0200; go to T-03.This would prevent confusion with non-weaning and minimize keystroke variance.	Michael Smith, RRT, RCP Manager | Respiratory Care Services	jmsmith@srhs.com	LTCH provider

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
		2- O0350A - revise code 01. Fully weaned at discharge to be based on 48 hours instead of 2 consecutive days. This would minimize confusion of time period and use the consistent measure metric as codes 02 through 09 in hours. • Importance of risk adjustment to the Ventilator Weaning (Liberation) Rate outcome measure Our facility recommends the need to include risk adjustment for the outcome measure. • Feasibility and utility of including partial weaning at discharge as an outcome Our facility recommends the need to include partial weaning at discharge as an outcome.			
6/20/2016	Ventilator Weaning Quality Measures for use in LTCHs	Comments from the American Association for Respiratory Care Measure Title: Ventilator Weaning (Liberation) Rate Special Topics for Consideration and Feedback: • The measure developer welcomes public feedback on all aspects of the two candidate ventilator weaning quality measures and on the draft item sets. Additionally, they would appreciate your input on the following topics: • Utility of each candidate measure and variation across providers- The measure provides a much needed consistent analysis of ventilator liberation in post-acute care from site to site. By requiring a narrow and very specific set of exclusions for non-weaning the measure has much more utility across the spectrum of LTACH providers. Additionally the exact formula can also be applied to ventilator weaning in the Skilled Nursing Facility arena. By virtue of this utility we can compare weaning effectiveness across 2 levels of care in the post-acute segment. • Potential unintended consequences of each measure as currently specified – We see no unintended consequences of this measure	Anne Marie Hummel, Director, Regulatory Affairs, Phone: 703-492-9764 Tom Kallstrom, Executive Directior, American Association for Respiratory Care	ashummel@aol.com, hummel@aarc.org	Health professional organization

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
		• Feasibility of determining invasively mechanically ventilated patient initial status as weaning or non-weaning by the end of Day 2 of the LTCH stay, where Day 1 is the day of admission. (It is understood that weaning status may change during the course of patient stay.) Since the exclusions are narrow and specific there should be a high expectation of the ability to determine the status of weaning or non-weaning by Day 2 of the admission. • Importance of risk adjustment to the Ventilator Weaning (Liberation) Rate outcome measure – Statistical risk adjustment as described and anticipated in the future would be helpful in predicting individual weaning success however it should not affect the overall wean rate of a facility. That is to say that a wean rate for facility A must be measured identically to facility B. If the wean rate is adjusted due to risk stratification one could argue that the comparisons are skewed. • Feasibility and utility of including partial weaning at discharge as an outcome – It would be entirely feasible to have an additional subset to determine the rate of partial weaning success. Partial liberation would lead to an improved quality of life. An individual who is vent dependent only at night could be more productive while off the vent during the day. Additionally it would serve to determine how often this partial liberation occurs in order to provide benchmarking for comparison. Measure Title: Compliance with Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of the LTCH Stay Special Topics for Consideration and Feedback: The measure developer welcomes public feedback on all aspects of the two candidate ventilator weaning quality measures and on the draft item sets. Additionally, they would appreciate your input on the following topics:			

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
		• Utility of each candidate measure and variation across providers- The measure provides a much needed consistent analysis of quality in post-acute care from site to site. The measure would stimulate similar care patterns across the spectrum of sites. Additionally the exact formula can also be applied to ventilator care in the Skilled Nursing Facility arena. By virtue of this utility we can compare compliance effectiveness across 2 levels of care in the post-acute segment. • Potential unintended consequences of each measure as currently specified – We see no unintended consequences of this measure • Feasibility of determining invasively mechanically ventilated patient initial status as weaning or non-weaning by the end of Day 2 of the LTCH stay, where Day 1 is the day of admission. (It is understood that weaning status may change during the course of patient stay.) Since the exclusions are narrow and specific there should be a high expectation of the ability to determine the status of weaning or non-weaning by Day 2 of the admission. Additionally the determination of SBT tolerance can be made effectively. • Importance of risk adjustment to the Ventilator Weaning (Liberation) Rate outcome measure – Statistical risk adjustment as described and anticipated in the future would be helpful in predicting individual weaning success however it should not affect the overall outcome measure. • Feasibility and utility of including partial weaning at discharge as an outcome –NA			
9/12/16*	Ventilator Weaning Quality Measures for use in LTCHs	Comment: Two Candidate Long Term Care Hospital (LTCH) Ventilator Weaning Quality Measures. June 9, 2016 RML Specialty Hospital appreciates the opportunity to comment on the two candidate LTCH Ventilator Weaning quality measures. RML is very excited to be participating in the pilot study for these two measures.	Karen Finerty, RN, BSN, MBA Chief Quality Officer RML Specialty Hospital	KFinerty@rmlspecialtyhospital.org	LTCH provider

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
		RML supports the inclusion of ventilator weaning in the quality reporting program. RML applauds CMS/RTI's attempts to gather meaningful risk data. However, RML urges further study and clarification before proceeding with these proposed quality measures and LTCH CARE Data Set items due to the concerns outlined below. RML feels strongly and supports capturing risk adjustment factors. Multi-organ involvement, particularly patients requiring dialysis, metastatic cancers and neuromuscular disease clearly impact a patient's ability to wean. RML encourages CMS to explore other options for capturing the risk factor data. The current broad list of co-morbidities lack sensitivity and specificity. For example, "progressing neuromuscular disease" and "other spinal cord disorders or injuries" have hundreds of possible ICD 10 codes associated. For LTCHs that have manual systems in place, it would be extremely burdensome for a staff person to be able to determine whether or not to include that risk factor or not. Even for those LTCHs with electronic systems in place where data can be pulled based on codes, further clarification would be helpful. In reality, the risk factor elements may not be found in claims data via ICD 10 codes. LTCHs are treatment focused, not diagnosis focused. For example, RML cares for patients with Left Ventricular Assist Devices on a regular basis. For those patients, the ICD 10 code Z95.812 is used. However, RML also provides care for many other patients who also have Left Ventricular Failure (LVF) but do not require a device. Those codes are rarely captured because, again, the focus for the LTCH physician is treatment not diagnosis. He may document the patient's "heart failure" in the History and Physical or progress note, but not capture the details of the LVF for coding purposes. Again, that level of detail was most likely captured by the referring STACH hospital's physician. Additionally, the capture of special treatments, both the use of dialysis and vasoactive medications, needs to be done on discharge, not on admission. The wording of the query needs to reflect the patient's entire hospital stay, not just either the Admitting or Discharge Assessment Reference Date (ARD) range. Often these treatments may not be anticipated or started within the admission ARD. In fact, if a patient requires the use of vasoactive medications on the day of admission, chances are that patient should not have been transferred from the			

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
		referring hospital to the LTCH until he was more stable. Likewise, the renal insufficiency patients may take some time before "declaring" the need to go on dialysis. Some patients will be able to be supported with close conservative management, while others will go on dialysis, sometimes temporarily, sometimes on a permanent basis. It is RML's practice to attempt weaning on all patients who come to us on mechanical ventilation. Therefore, it is not an issue to determine the weaning status of the patient by the end of Day 2. However, this may not be the practice of other LTCHs. This may lead to an unintended consequence of some patients not being given the opportunity to try to wean, or "cherry picking" weaning patients. This would be particularly advantageous to LTCHs with smaller weaning programs, where the potential of having even one patient not wean would significantly adversely affect their weaning rate. Likewise, LTCHs in markets lacking appropriate discharge options for ventilated, or ventilated renal patients are going to be less likely to admit ventilated patients who have a questionable probability of weaning, as it may negatively affect their wean rate as well as leaving them with a patient they cannot discharge. These are significant unintended consequences and are extremely detrimental to those LTCHs with larger programs and in areas with high level Skilled Nursing Facilities. These factors, small weaning programs and markets lacking discharge options, need to be taken into consideration and accounted for in some manner. RML agrees with the timing of the initial spontaneous breathing trials and supports requiring documentation if the patient is not appropriate for the weaning trial. RML believes that including partial weaning at discharge as an outcome is problematic and not valid. From a logistical standpoint, the accuracy of data (less than 12 hours, or greater than 12 hours but less than 24 hours) would be questionable at best, given the number of staff members involved and methods of counting, and may be prone to gaming of the categories. Additionally, one can wean many patients who are confused, comatose or debilitated to partial ventilatory assist. However, it is clinically meaningless and further complicates their care once discharged from the LTCH. The rare exception is the patient with			

(continued)

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
		a neuromuscular disease or COPD patient that can take advantage of vent-free time for speech or mobility. These patients are generally not the patients weaning in the LTCH setting. RML does not see a difference in the quality of life or discharge destination of those patients who are partially weaned and those who fail weaning completely. RML believes strongly that a more meaningful approach to this indicator is to include any patient on any amount of mechanical ventilatory support on admission (denominator) and count only those who are completely liberated from mechanical ventilation at discharge (numerator). Lastly, RML firmly believes in giving patients every opportunity to wean but also respects the right of every patient to choose their course of treatment that is in accordance with their lifestyle and beliefs. Great strides have been made across the country to ensure patients are informed about their disease processes, prognosis and treatment options. Physicians and hospital staff have undergone hours of education to ensure patients' rights are respected and Goals of Care conversations occur with insight and compassion. This is particularly important to the LTCH patient. Often these patients will take the opportunity for continued aggressive treatment but if treatment fails, will seek therapy withdrawal. In RML's case, this group of patients represents 3%of total discharges (24% of expirations). This factor must be taken into account, and patients who opt for therapy withdrawal must be excluded from the measure completely. Not addressing the issue, will cause severe unintended consequences for both the LTCH and the patients. LTCHs may not offer this very important treatment option for fear of it affecting their wean rate adversely, thus, forcing the patient to remain tied to a ventilator with an unacceptable quality of life and causing undo stress and financial burden. RML Specialty Hospital appreciates the opportunity to share our thoughts and comments on this very important quality measure. We extend an open invitation to CMS and RTI to visit RML to see first-hand the patient population this measure affects. We welcome the opportunity to further discuss the critical factors associated with it. Thank you.			

*Due to a submission error, CMS received this comment late.