Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock: V5.4 Measure Updates

Questions and Answers

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Webinar attendees asked the following questions and subject matter experts provided the responses. Questions and answers may have been edited for grammar.

Crystalloid Fluid Administration

Question 1: **Can normal saline (NS) 10 cc intravenous push (IVP) to flush a line also be used to count towards the crystalloid fluid volume?**

No, it cannot. The *Crystalloid Fluid Administration* data element excludes fluids that are given to flush intravenous (IV) lines.

Question 2: **Slide 37. "Start abstracting at the crystalloid fluid administration date/time." Does this mean start at the initial fluid time or the start time of the second bag that meets the target fluid volume?**

If multiple orders are written that total the target ordered volume, use the start date of the crystalloid fluid infusion that completes the target ordered volume.

Question 3: **We have been told in the past that we cannot include fluid from IV antibiotics unless they run at a rate greater than 125 milliliters (mL)/hour (hr). Has this changed?**

No, this has not changed. If the crystalloid fluids are used to dilute medications, they would need to be run at a rate greater than 125 mL/hr to be included for abstraction.

Question 4: **Are we allowed to use bicarbonate IV infusions if the rate is greater than 125 mL per hour?**

Only crystalloid solutions may be used toward the target ordered volume of crystalloid fluids. Fluids that are not crystalloid solutions (e.g., bicarbonate) may not be used to meet this data element.

Question 5: **Are we required to utilize the antibiotic fluids when determining end time if there is enough bolus fluids already ordered without the antibiotic fluids?**

Yes, crystalloid fluids used to dilute medication would be used toward the target ordered volume. Please note that IV line flushes are not included in the target ordered volume.

Question 6: **Can we use crystalloid fluid volumes used to dilute any medication or only specific medications?**

Crystalloid fluids used to dilute any medications that are ordered and administered at a rate greater than 125 mL/hr are acceptable.

Question 7: **Can you calculate the crystalloid fluid first; and then, if the volume is not enough, then calculate the amount of intravenous fluid (IVF) used to dilute antibiotics?**

Crystalloid fluids used to dilute medication would be used toward the target ordered volume if they are administered at the same time as other fluids.

Question 8: **Does the end time for fluids have to be documented to count the fluids?**

In order to determine the fluids to be infused, a rate, duration, or end time must be documented.

Question 9: **Can't the provider use ideal body weight (IBW) to calculate crystalloid fluids for patients with a body mass index (BMI) greater than 30?**

Yes, if the IBW is used, it must be documented clearly, and the clinician must indicate that IBW will be the weight used to determine the target ordered volume.

Question 10: **Have there been any changes in exclusion criteria for fluids, such as congestive heart failure (CHF), end stage renal disease (ESRD), or elevated brain natriuretic peptide (BNP)?**

No exclusions based on comorbidity were added to the *Specifications Manual for National Hospital Inpatient Quality Measures*, version 5.4, located at https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228776364473.

Question 11: **If crystalloids are given at 125 mL per hour along with antibiotics, and is given during the same time as the fluid bolus, is it an additive? For example, 500 mL/hr lactated ringers (LR) bolus plus 125 mL/hr NS = 750 mL/hr. As long as the fluids are given during the time the bolus is given, will they count?**

Each crystalloid fluid infusion must be infusing at a rate greater than 125 mL/hr to be used toward the target ordered volume. If the crystalloid fluid is infusing at a rate greater than 125 mL/hr during the time the bolus is given, it will count toward the target ordered volume.

Question 12: **If there are multiple orders for crystalloid fluid administration (CFA), will we still abstract the start time of the last one as the CFA start time? This may have huge impact on the initial hypotension.**

Yes, if crystalloid fluids are administered via multiple physician/advanced practice nurse (APN)/physician assistant (PA) orders, the start time of the infusion that completes the target ordered volume would be abstracted for the *Crystalloid Fluid Administration Time*.

Question 13: **If patient requires a total of 2100 mL and receives 1,000 at 0900; 1,000 at 1000; and 250 mL Zosyn at 1100, would the start of fluid administration be 1100?**

Yes, since multiple fluid orders are used to meet the target ordered volume, the start time of the infusion that completes the target ordered volume (1100) would be abstracted.

Question 14: **If the physician orders the crystalloid fluids as a bolus with no infusion duration or rate of infusion, and only a start time is documented in the medication administration record (MAR), could we answer "Yes" to** *Crystalloids Fluid Administration***? Or, would it be "No" because we have no idea of how much fluids were administered?**

In this example, Value "2" (No) would be selected for *Crystalloid Fluid Administration* because in order to determine the fluids to be infused, a rate, duration, or end time must be documented.

Question 15: **Is it required to include specific antibiotics, such as vancomycin, when calculating fluid totals, even if they have also given a total bolus based on weight, or is it optional?**

Crystalloid fluids given to dilute medications that are ordered, documented as administered, and infused at a rate greater than 125 mL/hr would be used toward the target ordered volume.

Question 16: **Is there a minimum volume of crystalloid fluids used to dilute medications in order to count crystalloid fluids towards total fluid administration?**

The guidance does not specify a minimum fluid volume for antibiotic dilution to count toward the target ordered volume. However, please note the fluids must be infused at a rate greater than 125 mL/hr to be used toward the target ordered volume.

Question 17: **When documenting fluid administration, does documentation need to say "infused" or "completed," or does the word "stopped" count?**

To determine if the target ordered volume was completely infused, one of the following must be documented (written in the order or documented by nursing):

- Infusion rate
- Infusion duration or time over which to infuse
- Infusion end or completion time

Question 18: **What about medications diluted in dextrose five percent in water (D5W) that run at greater than 125 mL/hr?**

The only fluids that are acceptable to satisfy the target ordered volume are crystalloid or balanced crystalloid solutions.

Question 19: **When providers document why they are not giving fluid boluses, for example, the patient is already in fluid overload, why can this not be accepted especially when refusal of treatment is acceptable?**

The patient maintains the right to refuse treatment. However, evidence has demonstrated the effectiveness of crystalloid fluid resuscitation in this patient population. The physician/APN/PA retains clinical judgment authority and may decide in some outlier cases to not administer fluids; CMS is aware of this and does not expect all cases to meet the requirements.

Question 20: **If we are to abstract the pre-arrival vital signs from the emergency medical services (EMS), we should be able to abstract EMS fluids without all the hospital-given requirements. It seems unreasonable to ask EMS to give us a start time and end time of fluids given when the time the patient is actually in the ambulance is normally less than an hour. If we were even able to use the start time and end time of the ride itself, as EMS is trained to document those times. Not the actual start and end time of fluid.**

Thank you for the comments. Given that each case/scenario is different, accepting times other than the actual administration documentation potentially poses issues. For example, rural areas often have EMS transport times greater than one hour. As a result, using the EMS ride times does not accurately reflect fluid administration. As a reminder, along with the documented start time, a documented rate, duration, or end time is required.

Question 21: **When would crystalloid administration for initiating bolus versus completion of bolus be accepted?**

The *Crystalloid Fluid Administration Date* and *Time* data elements provide guidance for the abstraction of the initiation of crystalloid fluids. The target ordered volume completion time is determined upon reaching the *Persistent Hypotension* data element in order to determine if hypotension persists following the infusion of the target ordered volume of crystalloid fluids.

Question 22: **Is the fluid measure not met if the total volume is not infused before a vasopressor is started to address the hypotension?**

No, the time frame for acceptable crystalloid fluids is not based on *Vasopressor Administration*. The time frame for acceptable fluids is based on *Initial Hypotension* or septic shock, whichever comes first.

Question 23: **Patients with a history of ventricular assist device (VAD) are excluded from the sepsis measure. What is the status of excluding transcatheter aortic valve replacement (TAVR) patients? Prior communication was that these patients were being considered, as well. Is there any update on the status of excluding this patient population?**

At this time, CMS has no further updates regarding an exclusion of patients with a TAVR at the *Crystalloid Fluid Administration* data element.

Question 24: **Slide 24. Do I need a rate or time frame in order to use fluids from IV antibiotics?**

Yes, in order to consider the crystalloid fluids used to dilute IV antibiotics infused, a rate, duration, or end time must be documented.

Question 25: **Slide 24. Does this only include volumes greater than 250 mL, or is it any volume, if given at a rate greater than 126 mL/hr?**

Any crystalloid fluid used to dilute a medication given at a rate greater than 125 mL/hr is acceptable.

Question 26: **Slide 25. Must the antibiotic run at greater than 125 mL/hr? The example on the slide was vancomycin 1 gram (gm)/250 mL NS over 60 minutes, which passed.**

Yes, the crystalloid fluids used to dilute the medication must be infused at a rate greater than 125 mL/hr.

Question 27: **Slide 25. Do you need to know the exact time fluids were completed? Can you explain the formula used to figure this out?**

Yes, in order to consider the crystalloid fluids to be infused, a rate, duration, or end time must be documented. Using the documented rate, duration, or end time, provides the actual completion time of the fluid administration in order to determine the full amount was administered within the required time frame.

Question 28: **Slide 25. When calculating for the target ordered volume, can we use the minimum volume [within 10 percent lower than the 30 mL/kilogram (kg)] as the target volume to determine when the fluids were completely administered?**

No, **only** crystalloid fluid volumes **ordered** by the physician/APN/PA that are within 10 percent lower than the 30 mL/kg total volume are acceptable. The 10 percent lower volume may not be assumed.

Question 29: **Slide 25. Is blood and blood products included in the crystalloid fluid amount if it meets all of the other guidelines (fast enough rate, start and stop time)?**

No, at this time, the only acceptable fluids are crystalloid or balanced crystalloid solutions.

Question 30: **Slide 25. In the example, where are you getting "20.87"?**

The 20.87 mL per minute is the combined mL per minute of infusions #2 and #3 in the example on slide 25. Since these two infusions are running simultaneously, the mL per minute infusing is combined to determine the total fluid volume infused.

Question 31: **Slide 25. Previously, abstraction guidelines explicitly directed not to use crystalloid solutions used to flush lines or given with medications (i.e., antibiotics). Is this a change?**

Yes, including the crystalloid solutions used to dilute antibiotics is a change, which was implemented starting in manual version 5.3a.

The *Crystalloid Fluid Administration* data element continues to maintain the Exclusion Guidelines for Abstraction, which excludes crystalloid solutions that are given to flush other medications or IV lines.

Question 32: **Slide 25. Shouldn't the total volume to be divided include the 250 mL with the vancomycin instead of 100 mL?**

Per the example on slide 25, the total volume to be divided includes the 250 mL of NS used to dilute the vancomycin, which is used toward the target ordered volume. The example does not use 100 mL of NS with the vancomycin infusion.

Please review the information on the slide again; if you have any additional questions, please follow-up via the *QualityNet* online question-and-answer (Q&A) tool available at https://cms-ocsq.custhelp.com/app/utils/login_form/redirect/ask.

Question 33: **Slide 26. Does this also include an IBW?**

IBW may be used in any instance where actual or estimated weight is acceptable provided the IBW is properly documented by the physician/APN/PA per the abstraction guidance.

Question 34: **Has any consideration been given to whether the CFA should be given to patients with significant cardiac history? Our cardiologists think this should be excluded.**

Yes, the evidence available has been reviewed and CMS, the measure stewards, and the measure writers continue to review new evidence regarding CFA in severe sepsis patients. Currently, the measure stewards have no plans to update the data element with an exception for patients with cardiac comorbidities.

Blood Culture Collection

Question 35: **Slide 19. In version 5.3, we were only able to look back at antibiotics less than 72 hours prior to time zero. Will that still be the same for this version? What does that do if the patient was on antibiotics greater than 72 hours, as we won't be able to accurately capture the cultures?**

Slide 19 references the time frame for the abstraction of an acceptable blood culture based on an IV or intraosseous (IO) antibiotic received within 24 hours before the *Severe Sepsis Presentation Time*.

For the *Broad Spectrum or Other Antibiotic Administration Date* and *Time* data elements in manual version 5.4, if one or more antibiotic was administered within the 24 hours before the *Severe Sepsis Presentation Time*, then the earliest dose of that same antibiotic within 72 hours before the *Severe Sepsis Presentation Time* would be abstracted.

If the *Broad Spectrum or Other Antibiotic Administration Date* and *Time* are greater than 24 hours before the *Severe Sepsis Presentation Time*, the case will be excluded prior to reaching the *Blood Culture Collection* data element in the algorithm. If the *Broad Spectrum or Other Antibiotic Administration Date* and *Time* are within the 24 hours prior through three hours after the *Severe Sepsis Presentation Date* and *Time*, blood cultures would still be drawn per the abstraction guidance.

Question 36: **Slide 20. The example of 03/01/2018 is not a good example since this does not go into effect until 07/01/2018.**

Thank you for your comment. The dates provided in the example were for demonstration purposes only.

Question 37: **Can we use the blood culture and sensitivity lab results to determine appropriate antibiotics or is actual physician/APN/PA documentation required? If my blood culture results show a list of susceptible antibiotics, can I still use it to determine if the antibiotic is appropriate?**

The *Broad Spectrum or Other Antibiotic Administration Selection* data element requires documentation from the physician/APN/PA for lab sensitivity and acceptable antibiotics. The abstractor may not use the culture and sensitivity lab results to infer the susceptible antibiotics.

Question 38: **Can you use the actual blood culture report to determine the date of the culture and susceptibility result instead of physician/APN/PA documentation?**

The *Broad Spectrum or Other Antibiotic Administration Selection* data element requires documentation from the physician/APN/PA for lab sensitivity and acceptable antibiotics. The abstractor may not use the culture and sensitivity lab results to infer the susceptible antibiotics.

Question 39: **Does the blood culture collection time refer to a one-time dose of an antibiotic not being continued or is it related to the severe sepsis or the antibiotic started for severe sepsis?**

The *Blood Culture Collection Time* is based on when IV or IO antibiotic administration is started in relation to the *Severe Sepsis Presentation Time*.

If the patient does not receive an IV or IO antibiotic within 24 hours before the *Severe Sepsis Presentation Time* but received an IV or IO antibiotic within three hours after the *Severe Sepsis Presentation Time*, the *Blood Culture Collection* time frame would be 24 hours prior through three hours after the *Severe Sepsis Presentation Time*.

If the patient received an IV or IO antibiotic within 24 hours before the *Severe Sepsis Presentation Time*, the *Blood Culture Collection* time frame would be 24 hours before the IV or IO antibiotic through three hours after the *Severe Sepsis Presentation Time*.

Question 40: **If there is a positive culture drawn within three hours of *Severe Sepsis Presentation* and susceptibility is noted in report, there now needs to be a physician documentation link?**

Yes, the *Broad Spectrum or Other Antibiotic Administration Selection* data element requires documentation from the physician/APN/PA for lab sensitivity and acceptable antibiotics.

Broad Spectrum Antibiotics

Question 41: **Slide 21. Does this indicate that a copy of the culture results documented by the physician in the electronic health record (EHR), at the time of severe sepsis presentation, is no longer required to be in the medical record? Is the physician documentation of the result sufficient?**

A copy of the culture results does not have to be in the EHR. There must be physician/APN/PA documentation referencing the result of a culture done within five days prior to the antibiotic start time. The physician/APN/PA documentation must identify the date of the culture results, identify the causative organism, and identify the organism's antibiotic susceptibility.

Question 42: **Slide 21. How can the IV antibiotic administered date and time data elements be abstracted for oral (PO) vancomycin given for *Clostridium difficile* (*C. difficile*) patients to pass the algorithm? The first question is administration of "any IV antibiotics" before the selection data element. How can the abstractor select "Yes" for PO vancomycin given for *C. difficile* under the IV antibiotic selection element if the first data element of "any IV antibiotics given" question is answered "No" already and the algorithm doesn't allow continuing?**

For severe sepsis patients reaching inpatient care, an IV antibiotic is part of the recommended treatment. Therefore, if an IV antibiotic was not given in the 24 hours prior through three hours after *Severe Sepsis Presentation Time*, Value "2" (No) would be selected for the *Broad Spectrum or Other Antibiotic Administration* data element. The exception for *C. difficile* provided in the *Broad Spectrum or Other Antibiotic Administration Selection* data element is available for severe sepsis patients with *C. difficile* who generally receive an IV antibiotic (e.g., IV Flagyl) not on Table 5.0 or Table 5.1 and also receive PO vancomycin.

Question 43: **Slide 21. Do you mean the date of the result (e.g., when the report was updated with results) or when the culture was drawn?**

Physician/APN/PA documentation must include the date of the culture result from within five days prior to the antibiotic start time. It is not the documentation of when the culture was drawn.

Question 44: **Slide 21. Regarding cultures. If an antibiotic not on the monotherapy or dual therapy list is found to be appropriate as a result of a blood culture drawn two hours after severe sepsis presentation time, will that meet the measure? The sensitivity is obviously not known at the time the antibiotic was ordered.**

The culture would have to be done within five days prior to the antibiotic start time and there would have to be physician/APN/PA documentation when the culture resulted and identify the causative organism and its antibiotic susceptibility. If this is present and a susceptible antibiotic was given in the three hours after *Severe Sepsis Presentation Time*, selecting Value "1" (Yes) would be appropriate. Unless sensitivity is known, an appropriate antibiotic cannot be ordered to meet the requirements of the measure.

Question 45: **Slide 22. What happens if the patient refuses the comfort care?**

Slide 22 is referencing the *Broad Spectrum or Other Antibiotic Administration Selection* data element. Documentation of the refusal of comfort care is applicable throughout the measure and would exclude the case. However, this particular slide is addressing the antibiotic selection.

Question 46: **Slide 22. How specific must the date documentation be? Is it acceptable for the licensed independent practitioner (LIP) to document phrases that indicate time, such as "yesterday" or "two days ago," to meet the criteria?**

Since the physician/APN/PA documentation includes a reference to the date (e.g., yesterday, two days ago) that is within five days prior to the antibiotic start time, this documentation is acceptable.

Question 47: **Slide 22. What if you have the culture, but the physician/APN does not state why they are using the antibiotic, but it is a susceptible antibiotic per the sensitivity on culture on record within five days prior to severe sepsis?**

There must be physician/APN/PA documentation referencing a result of a culture done within five days prior to the antibiotic start time. The physician/APN/PA documentation must identify the date of the culture results, identify the causative organism, and its antibiotic susceptibility.

Question 48: **Slide 23. Do both bullet points need to be met?**

Yes, both bullet points on slide 23 must be met to choose Value "1" (Yes).

Question 49: **Slide 23. What if they give IV vancomycin only and not oral?**

Administration of IV vancomycin alone is not sufficient to meet the *Broad Spectrum or Other Antibiotic Administration Selection* data element for a patient with *C. difficile*.

Question 50: **Slide 23. Is it appropriate to document and accept suspicion of *C. difficile*? In the emergency department (ED), results from testing are not provided that quickly.**

Documentation of suspicion of *C. difficile* would not be sufficient to meet the *Broad Spectrum or Other Antibiotic Administration Selection*. Unless the clinician reviews and documents definitive culture results for *C. difficile*, only antibiotics from the monotherapy and combination therapy would be acceptable to meet the requirements of the SEP-1 measure.

Question 51: **If a patient was on an antibiotic for more than 24 hours, why isn't the patient excluded in the new version?**

If the patient was on an IV antibiotic in the 24 hours prior to *Severe Sepsis Presentation Time* and also received that same IV antibiotic more than 24 hours prior, the case would be excluded upon reaching the *Broad Spectrum Antibiotic Time* calculation in the SEP-1 algorithm.

Question 52: **Will doxycycline ever be added to the 5.1 acceptable antibiotic therapy table?**

At this time, there are no plans to add doxycycline to the combination antibiotic table (Table 5.1).

Question 53: **What if the antibiotics were administered greater than 24 hours prior to time zero or severe sepsis presentation? Will the patient be excluded from the measure?**

If the patient was on an IV antibiotic in the 24 hours prior to *Severe Sepsis Presentation Time* and also received that same IV antibiotic more than 24 hours prior, the case would be excluded upon reaching the *Broad Spectrum Antibiotic Time* calculation in the SEP-1 algorithm.

Question 54: **What if the patient has been diagnosed on a previous stay to have extended-spectrum beta-lactamase (ESBL) in their urine? The admitting physician determines that the patient most likely has a urinary tract infection (UTI)/ESBL again. The physician does not select the antibiotics from either of the two lists but orders an antibiotic therapy that has worked in the past (cultures are still drawn but not resulted when antibiotics are selected). Is this still a "Yes" for *Broad Spectrum or Other Antibiotic Administration Selection*?**

There must be physician/APN/PA documentation referencing a result of a culture done within five days prior to the antibiotic start time. The physician/APN/PA documentation must identify the date of the culture results, identify the causative organism, and its antibiotic susceptibility.

Directives for Comfort Care or Palliative Care

Question 55: **Slide 28. Does this mean we don't go by the time prior to or within three hours of presentation of severe sepsis when a palliative consult is documented?**

As long as the documentation of the order for a palliative consult, in the example, occurred within the time frame specified for the *Directive for Comfort Care* data elements, Value "1" (Yes) would be selected.

Question 56: **Slide 28. If there is documentation by the physician that a conversation of palliative care occurred, is this considered an exclusion?**

No, only physician/APN/PA documentation of an inclusion term (e.g., palliative care) in certain contexts (see data element) and within the allowable

time frame would be considered appropriate. Documentation that only notes a conversation of palliative care occurred would not suffice.

Question 57: **Slide 28. Can you please clarify palliative care consult?**

Physician/APN/PA documentation of an "order" for a palliative care consult within the allowable time frame would be acceptable to select Value "1" (Yes).

Question 58: **Slide 29. In the second example, what if the physician made the first reference and a mid-level practitioner made the second? Does the level of the documenter impact if one supersedes another?**

The "level" of the person documenting the inclusion term does not supersede one another.

Question 59: **Slide 29. Is hospice care just the inclusion term and even if they refuse it, you would still select Value "1"? Would this be true even if the patient does not change to a "comfort measures only" status during the stay? In this case, would you still select Value "1"?**

Use of the word hospice is the inclusion term. If there is initially a physician/ APN/PA order for hospice care within the time frame specified in the *Directive for Comfort Care* data elements and shortly thereafter the clinician cancels the order, selecting Value "1" (Yes) would still be appropriate because of the initial order that was entered into the medical record. This is still true even if the patient does not change to a "comfort measures only" status during their stay.

Question 60: **How do you handle delay of care due to the family being indecisive of comfort care? Especially when they initially deny care, then, within three hours, they decide they want to proceed with care.**

If there is appropriate physician/APN/PA or nursing documentation of a delay or refusal of care by the patient or authorized patient advocate, this would be addressed in the *Administrative Contraindication to Care* data element. If so, Value "1" (Yes) would be selected for the *Administrative Contraindication to Care* data element.

If there is physician/APN/PA documentation in one source that indicates the patient is comfort measures only (CMO) or palliative care, **and** there is

physician/APN/PA documentation in another source that indicates the patient is **not** CMO or palliative care, the source that indicates the patient is CMO or palliative care would be used and Value "1" (Yes) should be selected for the *Directive for Comfort Care or Palliative Care, Severe Sepsis or Septic Shock* data element.

Question 61: **I have been using palliative care "consult" orders already. Is this correct for the current abstraction period and is it excluded?**

An order for palliative care consult would be sufficient to select Value "1" (Yes) for manual versions 5.3 and 5.4 as long as documentation takes place in the allowable time frame.

Question 62: **If the note suggests that a palliative consult will follow up after discharge, can that be taken as a Value "1"?**

No, only physician/APN/PA documentation within the context specified in the data element that includes allowable time frames would be considered appropriate.

Question 63: **There is an order for palliative care within the time frame and the palliative nurse sees the patient and documents that "no palliative needs identified" also within the time frame. How do I answer the comfort care question?**

The physician/APN/PA order for palliative care, within the specified time frame, is sufficient to select Value "1" (Yes) for the *Directive for Comfort Care* data elements. The palliative care nurse documentation, after the fact, would not change the selection of Value "1" (Yes).

Question 64: **Can we consider "allow natural death" as an inclusion term for comfort measures?**

The *Directive for Comfort Care* data elements have the only acceptable inclusion terms listed in each data element. At this time, "allow natural death" is not included in the list of inclusions terms.

Question 65:	What if the palliative consult was done greater than six hours from severe sepsis, but the palliative care team is still seeing the patient and we only have the patient as a full code. Palliative care does not mean end of life, but more of a collaborative way to conduct the patient's care to get best outcome, it does not mean CMO.
	If there is an order for a palliative consult submitted within the time frame, selecting Value "1" (Yes) would be appropriate. Remember, clinicians always retain their clinical judgment. If the patient is listed as a full code, the team should continue to work collaboratively to provide the optimal care for the patient.

Hypotension

Question 66:	Slide 10. For initial hypotension, are we using the time of the second hypotension prior to the completion of the fluids or the first time?
	The time of the second hypotensive reading that is within a time frame for *Initial Hypotension* would be used. The time frame is six hours prior through six hours after the *Severe Sepsis Presentation Time*. The second hypotensive reading within that time frame is abstracted.

Question 67:	Slide 32. Does initial hypotension require two readings again? I thought that changed to one reading in the current manual.
	Initial Hypotension does require two readings within the time frame. The second hypotensive reading within that time frame needs to be documented to consider *Initial Hypotension* to be present.

Question 68:	Slide 32. If the physician does not order fluids to equal 30 mL/kg, but the patient is hypotensive (systolic blood pressure [SBP] less than 90), do we still select "No" to *Initial Hypotension* since the fluids did not equal 30 mL/kg?
	If two hypotensive readings are documented within the time frame for determining *Initial Hypotension*, then Value "1" (Yes) would be selected for *Initial Hypotension*. This is independent of the amount of fluids ordered by the physician/APN/PA.

Question 69: **Slide 32. Do the hypotensive readings need to be one right after the other or can they be anytime in the acceptable time frame?**

The hypotensive readings need to be within the time frame of six hours prior to or within six hours following *Severe Sepsis Presentation Time*. The hypotensive readings do not need to be consecutive.

Question 70: **Slide 32. Can you please re-explain the example on the bottom of the slide?**

In the second example, the *Initial Hypotension Time* is 1600 and the target ordered volume of crystalloid fluids completed is 1530. Since the target ordered volume of crystalloid fluids completed prior to *Initial Hypotension*, Value "2" (No) would be selected for *Initial Hypotension*.

Question 71: **Slide 32. In discussing *Initial Hypotension*, you have written "hypotension that is present prior to the target ordered volume of crystalloid fluids being completely infused." I am assuming these fluids were started due to the patient having septic shock or a lactic acid (LA) greater than 4. That is not clear from the way this slide is presented. Would there be another reason for fluids to be given for severe sepsis?**

Since *Crystalloid Fluid Administration* can be initiated prior to *Initial Hypotension* or septic shock, there is an opportunity for the target ordered volume to be completed prior to *Initial Hypotension*. If the target ordered volume is completed prior to *Initial Hypotension*, regardless of the trigger for fluid resuscitation, Value "2" (No) would be selected for *Initial Hypotension*.

Question 72: **Slide 32. For *Initial Hypotension*, why do we also look at the six hours after severe sepsis? That is no longer "initial." In the second example, where you answer "No" for *Initial Hypotension*, does that mean that the 30mL/kg fluids were not required then if lactate was 2.5?**

The *Initial Hypotension* data element is referring to hypotension that presents prior to the target ordered volume of crystalloid fluids being completed. Therefore, if the target ordered volume of crystalloid fluids completes prior to the second hypotensive reading that identifies *Initial Hypotension,* then Value "2" (No) would be selected for *Initial Hypotension.*

Question 73:   **Slide 32. If the patient is sent to us from an extended care facility (ECF), do we use documentation of blood pressure (BP) readings at the ECF for this question?**

If the BPs from the ECF is part of the medical record and within the specified time frame of six hours prior through six hours after the *Severe Sepsis Presentation Time*, then yes, the BP readings would be used.

Question 74:   **Slide 33. If hypotension is the only organ dysfunction present, does there need to be two hypotensive readings or just one?**

For documentation of organ dysfunction, only one hypotensive reading is required.

Question 75:   **Slide 35. Why would you select Value "3" when there are two SBPs less than 90 within the hour?**

Based on the guidance in the *Persistent Hypotension* data element, when multiple BPs are documented in the hour to assess for *Persistent Hypotension*, refer to the last two BPs in the hour. If the last two BPs include a normal reading followed by a hypotensive reading, then Value "3" (No) would be selected.

In this scenario, Value "3" (No) is selected for *Persistent Hypotension* because there must be follow up for the hypotensive BP. If another BP is not obtained following a hypotensive reading, then *Persistent Hypotension* cannot be determined.

Question 76:   **Slide 35. The example has a case where multiple BPs were obtained, but the case will fall out since the last two were normal and then low. This is discouraging.**

Based on the guidance in the *Persistent Hypotension* data element, when multiple BPs are documented in the hour to assess for *Persistent Hypotension*, refer to the last two BPs in the hour. If the last two BPs include a normal reading followed by a hypotensive reading, then Value "3" (No) would be selected.

In this scenario, Value "3" (No) is selected for *Persistent Hypotension* because there must be follow up for the hypotensive BP. If another BP is not obtained following a hypotensive reading, then *Persistent Hypotension* cannot be determined.

Question 77:   **Slide 35. What is Value "3"?**

Based on the guidance in the *Persistent Hypotension* data element, when multiple BPs are documented in the hour to assess for *Persistent Hypotension*, refer to the last two BPs in the hour. If the last two BPs include a normal reading followed by a hypotensive reading, then Value "3" (No) would be selected.

In this scenario, Value "3" (No) is selected for *Persistent Hypotension* because there must be follow up for the hypotensive BP. If another BP is not obtained following a hypotensive reading, then *Persistent Hypotension* cannot be determined.

Question 78:   **Slide 35. If you have a hypotensive BP as your last BP, after a within normal limits BP, then you have to answer Value "3." Will this cause the case to fail? That does not seem fair.**

In this scenario, a hypotensive value followed by a normotensive value, response Value "3" (No) is selected for *Persistent Hypotension* because the hypotensive BP must be followed up on. If another BP is not obtained following a hypotensive reading, then *Persistent Hypotension* cannot be determined. The case will not fail unless there is not a follow up BP to the hypotensive BP.

Question 79:   **Slide 35. If the second low BP assessed is after the "hour" timeline following the bolus, this would be contradictory to the stated guidelines. Please clarify.**

Based on the guidance in the *Persistent Hypotension* data element, when multiple BPs are documented in the hour to assess for *Persistent Hypotension*, refer to the last two BPs in the hour. If the last two BPs include a normal reading followed by a hypotensive reading, then Value "3" (No) would be selected.

In this scenario, Value "3" (No) is selected for *Persistent Hypotension* because there must be follow up for the hypotensive BP. If another BP is not obtained

following a hypotensive reading, then *Persistent Hypotension* cannot
be determined.

Question 80:   **Slide 35. If there are one or more normal BPs in the hour after crystalloid fluids closer to the end time of one hour, but there are two consecutive low BPs earlier in the hour post-IVF, what do you do?**

If multiple BPs are documented in the hour, the last two BPs in the hour would be used. If two consecutive hypotensive BPs were documented earlier in the hour and then the BP normalized, a vasopressor might not be appropriate. Therefore, referring to the last two BPs in the hour provides a better determination of whether or not hypotension persists and *Vasopressor Administration* is indicated.

Question 81:   **Slide 35. In reference to the *Persistent Hypotension* caused by the last two BPs being a hypotension followed by a normal BP, will this make all patients fail the metric due to their own response to fluid? If there was another BP taken after the two, but it is after the one-hour time frame and is normal, why is that not taken into consideration?**

Only BPs within the hour are used to determine *Persistent Hypotension* and whether *Vasopressor Administration* is required. Based on the guidance in the *Persistent Hypotension* data element, when multiple BPs are documented in the hour to assess for *Persistent Hypotension*, refer to the last two BPs in the hour. If the last two BPs include a normal reading followed by a hypotensive reading, then Value "3" (No) would be selected.

In this scenario, Value "3" (No) is selected for *Persistent Hypotension* because there must be follow up to the hypotensive BP. If another BP is not obtained following a hypotensive reading, then *Persistent Hypotension* cannot be determined.

Question 82: **Slide 35. The example giving six BP values in the hour states "Select Value '3' for *Persistent Hypotension*," which is "The patient was not assessed for persistent hypotension or new onset of hypotension within one hour after the conclusion of CFA at the target ordered volume, or unable to determine." Shouldn't this example state Value "2," which is "Persistent hypotension or new onset hypotension was not present within one hour of the conclusion of CFA at the target ordered volume"?**

Based on the guidance in the *Persistent Hypotension* data element, when multiple BPs are documented in the hour to assess for *Persistent Hypotension*, refer to the last two BPs in the hour. If the last two BPs include a normal reading followed by a hypotensive reading, then Value "3" (No) would be selected.

In this scenario, Value "3" (No) is selected for *Persistent Hypotension* because there must be follow up for the hypotensive BP. If another BP is not obtained following a hypotensive reading, then *Persistent Hypotension* cannot be determined.

Question 83: **Slide 35. The example appears to have two consecutive hypotensive episodes (87/55 and 89/60); please explain again why this is not a Value "1" instead of Value "3."**

Based on the guidance in the *Persistent Hypotension* data element, when multiple BPs are documented in the hour to assess for *Persistent Hypotension*, refer to the last two BPs in the hour. If the last two BPs include a normal reading followed by a hypotensive reading, then Value "3" (No) would be selected.

In this scenario, Value "3" (No) is selected for *Persistent Hypotension* because there must be follow up for the hypotensive BP. If another BP is not obtained following a hypotensive reading, then *Persistent Hypotension* cannot be determined.

Question 84: **Slide 35. The example does show that the patient's BP is not stable; the patient cannot maintain an SBP greater than 90 within an hour. It is unreasonable to think providers are going to take an additional BP when they already know it is low.**

Thank you for the comment and concerns.

Based on the guidance in the *Persistent Hypotension* data element, when multiple BPs are documented in the hour to assess for *Persistent Hypotension*, refer to the last two BPs in the hour. If the last two BPs include a normal reading followed by a hypotensive reading, then Value "3" (No) would be selected.

In this scenario, Value "3" (No) is selected for *Persistent Hypotension* because there must be follow up for the hypotensive BP. If another BP is not obtained following a hypotensive reading, then *Persistent Hypotension* cannot be determined.

Question 85: **Slide 35. If within the hour after crystalloid fluids administration date and time, there are 50 separate BP readings and with the last reading taken at 59 minutes after and it is hypotensive, it appears that the case would unfairly fail the measure just due to the last minute reading. I hope CMS will relook at this data element.**

Based on the guidance in the *Persistent Hypotension* data element, when multiple BPs are documented in the hour to assess for *Persistent Hypotension*, refer to the last two BPs in the hour. If the last two BPs include a normal reading followed by a hypotensive reading, then Value "3" (No) would be selected.

In this scenario, Value "3" (No) is selected for *Persistent Hypotension* because there must be follow up for the hypotensive BP. If another BP is not obtained following a hypotensive reading, then *Persistent Hypotension* cannot be determined.

CMS, the measure stewards, and the measure writers routinely monitor the situation in order to make appropriate updates in future versions of the manual.

Question 86: **Slide 35. Why was this changed from the previous version 5.2? Hour to assess 0100-0200; BP 0157 92/60, BP 0159 89/60, BP 0201 92/60. We have to select Value "3" just because time runs out before the next BP is done. In version 5.2, we used to be able to select Value "2" because there were not two consecutive low readings. Our physicians are having difficulty understanding this.**

If multiple BPs are documented in the hour, the last two BPs in the hour would be abstracted. If two consecutive hypotensive BPs were documented earlier in the hour and then the BP normalized, a vasopressor would not be administered. Therefore, referring to the last two BPs in the hour provides a better determination of whether or not hypotension persists and *Vasopressor Administration* is indicated.

Question 87: **Slide 35. This example is discouraging because the registered nurses (RNs) were doing their best to assess the patient by getting multiple BPs. RNs at my facility have repeated that they feel like this is a trap since they were providing the best care by getting five to six BPs in an hour and the case still falls out. Can these be excluded rather than counting as a failure in the future?**

CMS, the measure stewards, and the measure writers routinely monitor the situation in order to make appropriate updates in future versions of the manual.

If multiple BPs are documented in the hour, the last two BPs in the hour would be abstracted. If two consecutive hypotensive BPs were documented earlier in the hour and then the BP normalized, a vasopressor would not be administered. Therefore, referring to the last two BPs in the hour provides a better determination of whether or not hypotension persists and *Vasopressor Administration* is indicated.

Question 88: **Slide 35. Would it be reasonable to increase the time after bolus for *Persistent Hypotension*? Some vital signs are taken just before the "official" end time.**

Thank you for the suggestion. CMS, the measure stewards, and the measure writers routinely monitor the situation in order to make appropriate updates in future versions of the manual.

Question 89: Slide 35. With *Persistent Hypotension* that results in the selection of Value "3," this results in a failure even if there is a BP taken every minute during the time frame and one minute after the *Persistent Hypotension* time frame completes. Unable to determine (UTD) is understandable, but why should we be penalized if we are constantly assessing closely monitoring a patient's BP?

CMS, the measure stewards, and the measure writers routinely monitor the situation in order to make appropriate updates in future versions of the manual.

If multiple BPs are documented in the hour, the last two BPs in the hour would be abstracted. If two consecutive hypotensive BPs were documented earlier in the hour and then the BP normalized, a vasopressor would not be administered. Therefore, referring to the last two BPs in the hour provides a better determination of whether or not hypotension persists and *Vasopressor Administration* is indicated.

Question 90: Slide 35. What is the rationale for changing the 2018 guidelines so that a normal BP followed by a low BP (as the last two BPs of the hour) results in Value "3"? This makes it very challenging to pass the measure. Previous requirements were that two consecutive low BPs needed to be present in the medical record to abstract Value "1"; otherwise, if at least two BP checks were completed, Value "2" would be chosen.

CMS, the measure stewards, and the measure writers routinely monitor the situation in order to make appropriate updates in future versions of the manual.

If multiple BPs are documented in the hour, the last two BPs in the hour would be abstracted. If two consecutive hypotensive BPs were documented earlier in the hour and then the BP normalized, a vasopressor would not be administered. Therefore, referring to the last two BPs in the hour provides a better determination of whether or not hypotension persists and *Vasopressor Administration* is indicated.

Question 91: **Organ dysfunction of only one hypotensive event counts for severe sepsis, but both *Initial Hypotension* and *Persistent Hypotension* are a two-event count?**

This is correct. Only one hypotension reading is required for organ dysfunction. *Initial Hypotension* and *Persistent Hypotension* require two low BP readings from different measurements.

Question 92: **For *Initial Hypotension* requiring two different measurements, do they have to be mean arterial pressure (MAP) versus SBPs or can it be two MAPs less than 65?**

Initial Hypotension requires two low BP readings from different measurements either six hours prior to or within six hours following *Severe Sepsis Presentation Time*. The abstraction may be two separate MAPs or a MAP and an SBP as long as the two measurements are from separate BPs.

Example:

0900 – MAP 61/S BP 79
0930 – MAP 59

The MAP and SBP at 0900 would count as one measurement and not two because they were documented from the same measurement. The MAP at 0930 would count as one measurement, as well. The SBP at 0900 and the MAP at 0930 may be used as two separate measurements.

Question 93: **For *Persistent Hypotension*, we are to measure one BP within the hour following fluids. Does that mean we are to wait one hour after fluids start to measure the BP or can it be anytime within that one hour?**

Persistent Hypotension is assessed during the hour following the administration of the target ordered volume of crystalloid fluids. During this time frame, BPs would be monitored frequently. Two consecutive documented hypotensive BP readings are required to select Value "1" (Yes). Do not wait an hour to start measuring the BP. The BPs abstracted is anytime within the hour following the conclusion of the target ordered volume of crystalloid fluids.

Question 94: **I am totally confused about *Initial Hypotension* and *Persistent Hypotension*. Are you saying that we would use the time of the last hypotensive reading documented prior to either the total 30 mL crystalloid fluids infused for *Initial Hypotension* and within the hour after 30mL/kg crystalloid fluids? If I have four BPs documented within each of the required time frames and they were all SBP less than 90, would I use the time of the fourth SBP? This has not been my understanding as of this point.**

Initial Hypotension requires two low BP readings from different measurements within the time frame. If multiple BP readings are documented, abstract the time of the second hypotensive reading for *Initial Hypotension.*

Persistent Hypotension requires two **consecutive** documented hypotensive readings within the time frame to select Value "1" (Yes). If there are more than two BPs documented, refer to the last two consecutive BPs within the hour.

In this example, use the first two SBPs that are less than 90 for *Initial Hypotension* and use the last two SBPs for *Persistent Hypotension.*

Question 95: **I think there are some of us who are mixing up *Initial Hypotension* requirements (two BPs required) with SBP or MAP readings as criteria for organ dysfunction (one required). Is that correct?**

Organ dysfunction requires only one hypotensive reading. *Initial Hypotension* requires two hypotensive readings from different measurements within the time frame.

Question 96: **If the MAP is not in the flow sheet, are we able to measure it in order to meet initial or persistent hypotension?**

The MAP must be documented in the medical record in order to use it. MAPs may not be calculated by the abstractor.

Question 97: **If there are no IVFs ordered, do you still abstract *Initial Hypotension*?**

Yes, even if there is not an order for IVFs, abstraction for *Initial Hypotension* would still occur.

Question 98: **If there is a MAP, as well as a BP documented, should you abstract only the BP readings, or can you take the MAP and BP reading and use the second one that qualifies?**

In order to abstract both the MAP and the SBP, the readings must be from different measurements.

Example:
0900 – MAP 61/SBP 79
0930 – MAP 59

The MAP and SBP at 0900 would count as one measurement and not two because they were documented from the same measurement. The MAP at 0900 and the MAP at 0930 may count as two measurements or the SBP at 0900 and the MAP at 0930 may count as two measurements.

Question 99: **In regard to *Persistent Hypotension* assessment. If there are several BP values performed in the one hour following crystalloid fluids and the last one is abnormal, could CMS consider adding another value after "3" to determine if patient was on vasopressor? If there were repeat values in the hour it appears the hospital was assessing appropriately.**

Thank you for your suggestion. CMS continues to work with the measure stewards to reassess the measure and the specifications on a routine basis to ensure the most appropriate care is provided.

Question 100: **Is the time frame for *Initial Hypotension* still "and prior to CFA completion"?**

The time frame for *Initial Hypotension* is six hours prior through six hours after the *Severe Sepsis Presentation Date* and *Time*. *Initial Hypotension* must also be present prior to the completion of the target ordered volume of crystalloid fluids.

Question 101: *Initial Hypotension* **is six hours prior to six hours after presentation, but** *Initial Hypotension* **fluid timing is six hours prior to three hours after. Is this three hours after** *Initial Hypotension***? Please review the two situations one more time if possible.**

The time frame for *Initial Hypotension* is six hours prior through six hours after the *Severe Sepsis Presentation Date* and *Time*.

For *Crystalloid Fluid Administration,* crystalloid fluids started within six hours prior through three hours after *Initial Hypotension* is acceptable.

Question 102: **What if** *Initial Hypotension* **does not line up with time zero? A patient may have** *Initial Hypotension* **on arrival and then not meet all time zero elements for hours or days. Is** *Initial Hypotension* **timing from the first hypotension episode or from time zero for** *Severe Sepsis Presentation***?**

The time frame for *Initial Hypotension* is six hours prior through six hours after "time zero," which is the *Severe Sepsis Presentation Date* and *Time*.

Question 103: **With the MAP being a more accurate BP reading, why must we use an SBP and a MAP to determine** *Persistent Hypotension***? Many facilities have protocol for MAP less than 65 to begin vasopressors. Please explain as this causes fallouts.**

Persistent Hypotension allows the use of either hypotensive SBPs **or** hypotensive MAPs. While some facilities only use MAP readings in the critical care setting, other facilities use SBPs or a combination of SBP and MAP readings.

Question 104: **Please clarify the algorithm for** *Persistent Hypotension,* **if the answer is 2, 3, or 4; the algorithm is followed by** *Initial Lactate Level Result***. If** *Initial Lactate Level Result* **equals 1 or 2, it asks for** *Persistent Hypotension* **again. How is the second** *Persistent Hypotension* **abstracted?**

The recheck in the SEP-1 algorithm for *Persistent Hypotension* is due to algorithm design in order to guide cases through the correct sequence. The allowable value selected for *Persistent Hypotension* would be the same each time the data element is checked in the algorithm.

Question 105: **If the patient has two low BPs less than 90 systolic documented by paramedics (i.e., 0856 and 0900) and severe sepsis time is 1030 and IV fluids completed at 1130, would we use 0900 as the *Initial Hypotension* time?**

Yes, the time of the second hypotensive BP reading (0900) is the *Initial Hypotension Time.*

Question 106: **If a one liter (L) normal saline (NS) fluid bolus is administered and two hours later a 30 mL/kg order is ordered and administered, would we look for *Persistent Hypotension* when the target is completed, which would be earlier than the completion of the 30 mL/kg order due to the one L bolus administered prior to the order? All fluids were administered within the specified time frame of the required fluid.**

In this case, both the one L of NS and 30 mL/kg order would be used to determine the target ordered volume completion time. *Persistent Hypotension* would then be assessed within the one hour after the completion of the target ordered volume.

Question 107: **Is there any consideration needing two readings of hypotension for organ dysfunction instead of one so that the guidelines line up with *Initial Hypotension* and *Persistent Hypotension*?**

Thank you for the question. At this time, there are no plans for updating the organ dysfunction criteria.

Question 108: **Is hypotension considered an acute condition?**

Although hypotension can be an acute or chronic condition, for this measure, hypotension is a sign of organ dysfunction unless there is appropriate physician/APN/PA documentation stating otherwise.

Question 109: **Crystalloid fluids must be initiated within three hours of *Initial Hypotension*. If both low BPs are four to six hours before *Severe Sepsis Presentation Time*, we must begin a 30ml/kg fluid bolus before it has even been determined that severe sepsis is present. For example: 1200 low BP #1; 1215 low BP #2; 1600 crystalloid fluids administered; 1700 severe sepsis present (last criterion met). In this scenario, the crystalloid fluids**

are required to be started no later than 1515, which is more than an hour before criteria for severe sepsis are met. Please comment.

Thank you for the clarification question. The scenario from the presentation is accurate. The timing of acceptable crystalloid fluids is not based on the *Severe Sepsis Presentation Date* and *Time*. Fluid resuscitation is based on the event that triggers the need for fluids; in this case, hypotension.

Question 110: **For cases with septic shock based on severe sepsis and initial LA greater than 4 (no initial hypotension and no documentation of septic shock), they get the target ordered volume of fluids, but they fail *Persistent Hypotension* as there are in BP in the hour, and all the BPs in this episode of care are normal. Cases like these should be made exceptions. Is this being looked at?**

In order to determine if hypotension is present after fluid resuscitation and determine if a vasopressor is needed, BPs must be obtained within the hour after fluid resuscitation. If only normal BPs were documented in the hour to assess for *Persistent Hypotension*, the case would continue.

The measure steward is not considering any updates that would include not assessing BPs in septic shock patients following the administration for fluids.

Repeat Volume Status and Tissue Perfusion Assessment Performed

Question 111: **Slide 12. Does this mean that we will not need to look for the individual components of tissue perfusion reassessment? Do we just need to look for documentation that a tissue perfusion reassessment was done?**

Adding this data element resulted in removing a number of other data elements to simplify abstraction and data entry. This change also provides more options to meet the requirements for this measure; physician/APN/PA documentation that they performed a physical exam, a profusion, a re-profusion, a tissue profusion assessment, a sepsis exam, a sepsis reassessment, a sepsis evaluation, and a systems review are just some of the ways to meet the requirements.

Question 112: **Slide 36. Fluid challenge stayed as one of the element selections for passing repeat volume status. Could you clarify how fluid challenge could be documented? There are no explanations in previous versions of the definition for fluid challenge. Is it by providers documenting "fluid challenge completed" (What would be my date and time for this?) or is it documentation present on the MAR as 500 cc/1000 cc crystalloids given in 15/30 per minute? Please clarify the guidelines.**

For version 5.4, documentation must explicitly indicate a "fluid challenge" was performed. The date and time of the documentation "fluid challenge" performed would be abstracted.

Question 113: **Slide 36. If there is a header of "Physical Exam" with bullets for general appearance, respiratory, cardiovascular, skin, extremities, and neurological, and there is physician/APN/PA documentation within those bullets, does this allow you to abstract Value "1" for *Repeat Volume Status and Tissue Perfusion Assessment*?**

A header stating "Physical Exam" with various bullets listed would not suffice unless at least five of seven parameters are appropriately documented.

Question 114: **Slide 37. Do you use the fluid start or completion time?**

The time abstracted for the *Crystalloid Fluid Administration Date/Time* would be the start time to look for a perfusion reassessment.

Question 115: **Slide 37. Does it have to be titled something about the perfusion reassessment, or is the documentation of the assessment in anything, such as a note, a history, or a consult, acceptable?**

Documentation sufficing the *Repeat Volume Status and Tissue Perfusion Assessment Performed* data element may be found in any source within the medical record as long as it is documented within the specified time frame.

Question 116: **Slide 37. When crystalloid fluid is administered for *Initial Hypotension* (second reading) and septic shock is not present, must *Repeat Volume Status and Tissue Perfusion Assessment* be documented? Slide 37 states, "Start abstracting at the crystalloid fluid administration date and time**

and stop abstracting six hours after the presentation of septic shock date and time." As stated in my question above, this is not a septic shock scenario, so I get confused as to whether I should look for tissue perfusion/volume status documentation in the hour after fluid completion for *Initial Hypotension*.

If the patient does not have *Persistent Hypotension* in the hour after completion of fluids, septic shock is not present based on *Persistent Hypotension*. If septic shock is not present, a *Repeat Volume Status and Tissue Perfusion Assessment Performed* data element would not have to be performed.

Question 117: **Slide 38. If the review of systems occurs within the time frame, but it is the initial review of systems, is that still acceptable?**

Yes, physician/APN/PA documentation of "review of systems" within the specified time frame is acceptable.

Question 118: **Slide 38. Can the physician document "Review of systems completed" and have that count toward the sepsis focus examination without any further documentation?**

Yes, physician/APN/PA documentation of "review of systems completed" within the specified time frame is acceptable.

Question 119: **Slide 38. Will there be any exclusion criteria for this data element (e.g., "Review of Systems unable to obtain at this time")?**

No, at this time there are no exclusions/exceptions provided in the data element for not obtaining the repeat volume status and tissue perfusion assessment.

Question 120: **Slide 39. In version 5.3a, vital signs must include heart rate, respiratory rate, BP, and temperature. Are all still required for version 5.4?**

Yes, documentation must minimally reference heart rate, respiratory rate, BP, and temperature. If there is physician/APN/PA documentation in the allowable time frame attesting to their performance of a re-examination, that is also acceptable and Value "1" (Yes) would be selected.

Question 121: **Slide 39. To use urine output as a component for the perfusion reassessment, what must be documented?**

The physician/APN/PA documentation must reference the urine output.

Question 122: **Slide 40. If the history and physical (H&P) is done by the physician greater than six hours after the severe sepsis time, but within 24 hours, and says that an echocardiogram was done, can we say "Yes" to repeat volume status? Can nursing documentation of the echocardiogram being done count for it being within the time frame?**

Documentation of an echocardiogram must occur within the allowable time frame, which is the *Crystalloid Fluid Administration Date/Time* to six hours after *Septic Shock Presentation Date/Time*. Nursing documentation of the echocardiogram may be used if it was documented in the allowable time frame.

Question 123: **Slide 40. What verbiage needs to be in place to qualify as a fluid challenge?**

Documentation must explicitly indicate a "fluid challenge" was performed.

Question 124: **Slide 40. Does #3 need to be documented by a physician/APN/PA or will it suffice to just be documented in the electronic medical record (EMR)?**

Any documentation of the performance of the test, result, or value is acceptable. The central venous pressure (CVP), central venous oxygen saturation, echocardiogram, and fluid challenge or passive leg raise do not need to be documented by a physician/APN/PA.

Question 125: **Slide 40. Does the CVP reading need to be documented by a physician or is it sufficient if the CVP reading is documented by a nurse on the vital signs flow sheet?**

Any documentation of the performance of the test, result, or value is acceptable. The CVP, central venous oxygen saturation, echocardiogram, and fluid challenge or passive leg raise do not need to be documented by a physician/APN/PA.

Question 126: **Slide 41. For multiple repeat volume status and tissue perfusion, why would you require the date and time of the latest assessment rather than the first assessment in the time frame? This requires the abstractor to look for additional assessments in the time frame to find the latest, when the intent of the data element is met with the first assessment?**

If multiple parameters are used to meet the *Repeat Volume Status and Tissue Perfusion Assessment Performed* data element, the latest time is used, as some parameters may not have been completed prior to the last parameter being documented. If there is physician/APN/PA documentation in the allowable time frame attesting to their performance of a re-examination, that is also acceptable and Value "1" (Yes) would be selected.

Question 127: **If septic shock is listed on the problem list within a physician note and within that note is also a "Physical Exam" heading, would this meet the tissue perfusion assessment element?**

Documentation within a note with a heading called "Physical Exam" may not be used as physician/APN/PA documentation that a physical exam was performed unless at least five of seven parameters are appropriately documented.

Question 128: **Can the repeat volume status and tissue perfusion assessment components be taken from the H&P?**

The H&P is an acceptable data source for documentation sufficing the *Repeat Volume Status and Tissue Perfusion Assessment Performed* data element.

Question 129: **For the repeat volume status and tissue perfusion assessment, would a blood gas oxygen saturation (sO2) or venous point of care (POC) meet this requirement?**

The arterial oxygen saturation must be from an arterial source. If the blood gas oxygen saturation is from an arterial source, the sO2 meets the requirement. Other acceptable references include arterial oxygen saturation, oxygen saturation, pulse oximetry, and Pox (pulse oximetry). Oxygen saturation identified as from a venous source is not sufficient.

Question 130: **If the reassessment examination box is checked by the provider with a date and time present, is this still acceptable for the reassessment exam?**

Yes, physician/APN/PA documentation or selection of an option identifying their performance of a reassessment examination with a date and time within the specified time frame is acceptable.

Question 131: **If the re-examination statement is there, but there is no complete set of vital signs within the proper period, do we accept the statement?**

If there is physician/APN/PA documentation in the allowable time frame attesting to their performance of a re-examination, Value "1" (Yes) would be selected. In this case, further documentation sufficing the review of vital signs is not required.

Question 132: **Regarding *Repeat Volume Status and Tissue Perfusion Assessment Performed*, it states that at least five of the listed elements, including urine output, are required. For the urine output, must it be documented by a physician/APN/PA or can an intake and output sheet documented by a nurse be used?**

The physician/APN/PA documentation must reference the urine output to suffice this component of the *Repeat Volume Status and Tissue Perfusion Assessment Performed* data element. If there is physician/APN/PA documentation in the allowable time frame attesting to their performance of a re-examination, that is also acceptable and Value "1" (Yes) would be selected.

Question 133: **Is a CVP flow sheet enough to pass the *Repeat Volume Status and Tissue Perfusion Assessment Performed* data element?**

Documentation that the CVP was performed or measured on a CVP flow sheet would be sufficient for the *Repeat Volume Status and Tissue Perfusion Assessment Performed* data element.

Question 134: **Is "sepsis exam done" sufficient for repeat volume status and tissue assessment?**

Physician/APN/PA documentation "sepsis exam done" is sufficient for documentation attesting to their performance of an exam.

Question 135: **Is there a specific statement, like previously, that the physician can state that he has completed the assessment? We are currently using "completed sepsis focused exam." Are there examples you can tell us?**

Physician/APN/PA documentation of "completed sepsis focused exam" is acceptable. The *Repeat Volume Status and Tissue Perfusion Assessment Performed* data element has examples of acceptable physician/APN/PA documentation indicating or attesting to performing a physical exam.

Examples of acceptable physician/APN/PA documentation include:
- "I did the Sepsis reassessment"
- Flow sheet question: "Sepsis focused exam performed?" and selection of "Yes"
- "Review of systems completed"
- "I have reassessed tissue perfusion after bolus given"
- "Sepsis re-evaluation was performed"

Question 136: **What if the provider only documents the actual physical assessment per each body part but does not document "physical exam performed"; do we still have to search for each element having been assessed and if one is missing they would fail?**

Documentation of the findings of a physical exam/assessment are acceptable to meet the individual parameters (at least five of seven parameters) provided in the data element. Documentation of the findings of an exam would not suffice for physician/APN/PA documentation indicating or attesting to performing or completing a physical examination.

Question 137: **If two physicians perform different components of the five required exams, do we enter the latest time the last one was documented for this data element? For example, the primary care physician documents cardiopulmonary, peripheral pulse, skin, and vital signs, and the nephrologist, 30 minutes later, but within six hours, documents the urinary output?**

The latest assessment (parameter) documented within the time frame specified would be abstracted for the *Repeat Volume Status and Tissue Perfusion Assessment Performed Date* and *Time*. If there is physician/APN/PA documentation in the allowable time frame attesting to their performance of a re-examination, that is also acceptable and Value "1" (Yes) would be selected.

Question 138: **Repeat tissue/perfusion examination admission H&P is still not able to be used, correct? Was it stated that the statement "clinical findings" can be used as the repeat tissue performance/reassessment?**

Documentation of the findings of a physical exam/assessment are acceptable to meet the individual parameters (at least five of seven parameters) provided in the data element. Documentation of the findings of an exam would not suffice for physician/APN/PA documentation indicating or attesting to performing or completing a physical examination. If there is physician/APN/PA documentation in the allowable time frame attesting to their performance of a re-examination, that is also acceptable and Value "1" (Yes) would be selected.

Question 139: **Does an H&P count for the sepsis exam, provided it has the right timing and something that says "All systems reviewed" or does it have to be called the reperfusion exam?**

Physician/APN/PA documentation of "all systems reviewed" within the specified time frame would suffice for physician/APN/PA documentation attesting to their performance of an exam.

Question 140: **How is a review of systems considered a physical exam?**

For the measure, physician/APN/PA documentation of "review of systems" is acceptable for physician/APN/PA documentation attesting to their performance of an exam/reassessment.

Question 141: **I do not understand why a physical examination documented under a "Physical Exam" heading does not meet the reassessment data element, when it obviously indicates that the patient was assessed/examined and contains much more detailed information than a statement of "reassessment performed," even if it does not include every specific element.**

Thank you for the comments and concerns. Documentation sufficing physician/APN/PA documentation indicating or attesting to performing or completing a physical examination should be narrative documentation identifying the physician/APN/PA's performance of a more general exam. Documentation of the findings of a physical exam is not the same as documentation attesting to the performance of an exam.

Question 142: **If a physician documents that a point of care ultrasound (POCUS) was completed, can we use this as a two-dimensional (2D) bedside echocardiogram?**

Documentation that a POCUS was completed alone would not suffice as an echocardiogram. The documentation must refer to cardiac echocardiogram, or ultrasound, or similar to suffice.

Question 143: **If the physician documents "peripheral pulse was completed" in an addendum to the H&P more than six hours after presentation, do you abstract the time the note was opened since the physician is adding it to the H&P?**

If the documentation is associated with a specified time, the specified time would be used. If the documentation of the peripheral pulse does not have a specified time, then the note opened time would be used.

Question 144: **Is the focused exam taken out and replaced with *Repeat Volume Status and Tissue Perfusion Assessment Performed*?**

The focused exam, as previously specified, has been modified and does not exist as a stand-alone element any longer. Many of the data elements, which were part of the original focused exam, are still present as options. It is important to note a facility may still have the focused exam programmed in the EHR or clinicians may continue to use the original terminology. This will still meet the requirements of the reperfusion assessment.

Severe Sepsis Present

Question 145: **Slide 42 and 43. Please clarify how specific the documentation has to be. Slide 42 says it must include abnormal values, but the example in slide 43 only mentions hypotension, not the specific value.**

The physician/APN/PA documentation must include the abnormal value or reference to the abnormal value in order to exclude the values. Since the term "hypotension" references the abnormal value, this documentation would be sufficient to exclude hypotensive BPs.

Question 146: **Slide 43. In the example, if there is documentation of hypotension being related to pain medications in one note and being related to septic shock in another note, would the hypotensive values be used or not?**

If the systemic inflammatory response syndrome (SIRS) criteria or sign of organ dysfunction are documented as due to a medication in one note and documented as due to an infection, severe sepsis, or septic shock in a separate note, use the latest documentation to determine if the criteria would be used. In this example, since the hypotension is documented as due to septic shock in the later note, the hypotensive readings would be used.

Question 147: **Slide 43. The example of "Hypotensive after pain meds" is given to exclude hypotensive episodes. How long would we not accept hypotensive readings after the pain medications?**

All hypotensive values recorded in the medical record that are not documented as due to an infection, severe sepsis, or septic shock would be disregarded.

Question 148: **Slide 43. It was mentioned that the platelet value of 65 would be the only platelet value excluded. Why? Can we also exclude platelet levels below 65, as well?**

In this example, the platelet value of 65 is excluded because it is documented that this specific value is due to a chronic condition, "Hep C." If additional values that are below 65 are recorded and noted as due to a chronic condition, they also would be excluded. Since the specific value of 65 is documented instead of thrombocytopenia, only this specific value of 65 may be excluded.

Question 149: **Slide 43. If the physician had noted "thrombocytopenia related to chronic hepatitis C," could we then exclude all platelet values for organ dysfunction?**

If the physician had documented "thrombocytopenia related to chronic hepatitis C," all abnormal platelet values would not be used.

Question 150: **Slide 43. Does SIRS criteria and organ dysfunction have to be in a note within six hours of presentation of severe sepsis or septic shock?**

The physician/APN/PA documentation considering SIRS criteria or a sign of organ dysfunction to be normal for the patient, due to a chronic condition or due to a medication, must be documented prior to or within 24 hours after the *Severe Sepsis Presentation Time*.

Question 151: **Slide 44. If the lactate level in the lab sheet is greater than two and there is documentation in the H&P that the elevated lactate level is due to a seizure, am I correct not to use the elevated lactate level result?**

No, unless the acute condition (seizure) is further documented as due to a non-infectious source, the elevated lactate would be used as evidence of organ dysfunction.

Question 152: **Slide 44. Please give an example of how to improve documentation so that an elevated lactate level due to seizure can be excluded.**

In order to not use SIRS criteria or sign of organ dysfunction that are documented as due to an acute condition (seizure), further physician/APN/PA documentation identifying the source of the acute condition is necessary. If the source is non-infectious, the SIRS criteria or sign of organ dysfunction may be excluded.

Question 153: **Slide 45. We were previously allowed to use that data in the same note, even if in separate sections. Why are we no longer allowed to do that? Physicians feel that Coumadin use and international normalized ratio (INR) is a given; that's just one example.**

The guidance was further clarified and designed to assist abstractors when to exclude abnormal values when explicit documentation is not present, and, as a result, inferences do not need to be made. The example on slide 45 is unacceptable because it does not provide physician/APN/PA documentation that the SIRS criteria or sign of organ dysfunction are due to a chronic condition or medication. Therefore, the abstractor would not infer that the SIRS criteria or sign of organ dysfunction are due to a chronic condition or medication in this example.

Question 154: **Slide 45. If a patient has an elevated creatinine and the physician has documented the patient's baseline creatinine, can we use that baseline documentation to determine whether or not the reading represents organ dysfunction?**

If the patient's baseline creatinine is documented, reported creatinine values within the documented baseline would not be used. If the creatinine value is greater than the baseline, it would be used for organ dysfunction.

Question 155: **Slide 45. If the physician states chronic kidney disease (CKD) with creatinine of 3.5 but doesn't give a baseline creatinine, do I use the creatinine value?**

In this scenario, the physician documents the chronic condition and specific creatinine value of 3.5, and the creatinine value of 3.5 would not be used. If a baseline creatinine is not documented, the bullet point in the *Severe Sepsis Present* data element referring to a documented baseline would not apply.

Question 156: **Slide 45 indicates INR is 2.2 and the home medication section lists Warfarin as unacceptable documentation for organ dysfunction. Slide 46 then says it is acceptable. Please clarify.**

If there is documentation of an anticoagulant on the home medication record, or if an anticoagulant is given in the hospital, the elevated INR is disregarded. This example is demonstrating physician documentation that it is unacceptable

to disregard certain organ dysfunctions when they're not specifically related or due to current condition or medication.

Question 157: **Slide 45 and 46. If warfarin or any anticoagulant is on the home medication list, can we disregard INR greater than 1.5 as a sign of organ dysfunction?**

If one of the anticoagulants from Appendix C Table 5.3 is documented on the home medication list, the INR or activated partial thromboplastin time (aPTT) level would not be used as organ dysfunction.

Question 158: **Slide 45 and 46. If the patient is on Coumadin and received it at the hospital or as a home medication, do we use the elevated INR?**

If one of the anticoagulants from Appendix C Table 5.3 is documented on the home medication list or is documented as received in the hospital, the INR or aPTT level would not be used as organ dysfunction.

Question 159: **Slide 46. If the patient only has the anticoagulant, is that enough to disregard the sign of organ dysfunction? Does the physician need to state anything specific?**

If there is documentation that an anticoagulant has been given to the patient, either on the home medication record or in the hospital on the MAR, the elevated INR or aPTT is disregarded. The physician/APN/PA does not need to document additional information to disregard the sign of organ dysfunction.

Question 160: **Slides 47 and 54. Slide 54 says to use six hours and slide 47 allows 24 hours. Can you please clarify why they are different?**

Slides 47 and 54 are referencing two different bullet points. Slide 47 is in reference to when there is SIRS or a sign of organ dysfunction and within 24 hours it is documented as due to an acute or acute on chronic condition. In this situation, the abnormal value for criteria would be used. Slide 54 is in reference to when criteria are met for *Severe Sepsis Present* and within six hours there is physician/APN/PA documentation that the patient does not have sepsis. In this situation Value "2" (No) would be selected and abstraction would stop.

Question 161: **Slide 48. Many times, we see "acute/chronic respiratory failure," do we use this?**

If a sign of organ dysfunction or SIRS is documented as due to an acute on chronic condition, the sign of organ dysfunction or SIRS for criteria would be used.

Question 162: **Slide 48. Please give an example of when we could or could not use heart rate due to atrial fibrillation (Afib), especially if it is a new onset of Afib.**

If the Afib was identified as acute or new onset, the heart rate would be used. If the Afib was identified as a chronic condition or due to a non-infectious source, the heart rate would be excluded.

Question 163: **Slide 48. The example states that the PA documents acute respiratory failure, bilevel positive airway pressure (BiPAP), and medication versus chronic obstructive pulmonary disease (COPD). I do not see why you would use this as organ dysfunction, as the PA indicates suspicion.**

The example considers acute respiratory failure evidenced by initiation of the BiPAP to be due to medication versus acute COPD exacerbation. With the documented consideration that the sign of organ dysfunction could possibly be due to acute COPD exacerbation, the BiPAP initiation would be used.

Question 164: **Slide 48. Why is lactic with seizure used? Is that not causative? What verbiage needs to be written for that scenario?**

In order to not use SIRS criteria or sign of organ dysfunction that were documented as due to an acute condition (seizure), further physician/APN/PA documentation identifying the source of the acute condition is necessary. Unless the acute condition (seizure) is further documented as due to a non-infectious source, the elevated lactate would be used as evidence of organ dysfunction.

Question 165: **Slide 48. If a patient is placed on a new continuous positive airway pressure (CPAP) or BiPAP in the post-anesthesia care unit (PACU), does this automatically count as an organ dysfunction? We have certain surgical populations where CPAP is applied automatically per surgeon request.**

Yes, for version 5.4, a new need for mechanical ventilation initiated in the operating room (OR), PACU would be used unless there is physician/APN/PA documentation that the mechanical ventilation is due to a chronic condition, medication, is normal for the patient, or is due to an acute condition from a non-infectious process or source.

Question 166: **Slide 49. If the medical source used does not specify a possible infectious source, but the one used by validation does, how can this be validated? Is there a list of acceptable medical sources?**

Thank you for the question. Validation occurs using the information that is part of the submitted medical record and is validated at face value. For example, if the physician specifically documents "DKA likely due to non-infectious source," then this criterion would not be used to determine if severe sepsis is present. An outside source, such as a medical resource, would not be referenced to prove otherwise. For additional questions related to validation, please submit through the *QualityNet* Q&A tool available at https://cms-ocsq.custhelp.com/app/utils/login_form/redirect/ask.

Question 167: **Slide 49. The example talks about creatinine secondary to post diabetic ketoacidosis (DKA). Should we look at all DKA patients to see if the patient has an infectious source? Will physicians document that the DKA is due to non-infectious source?**

It is not necessary to look at all DKA patients to see if the patient has an infectious source. If SIRS criteria or sign of organ dysfunction is linked to DKA, further physician/APN/PA documentation considering DKA to be due to a non-infectious source is required in order to not use the SIRS criteria or sign of organ dysfunction.

Question 168: **Slide 49. How many times does an abstractor need to review SIRS and infection versus non-infection source? I had a case with 48 hours of SIRS and conflicting documentation if it was infectious or non-infectious. What is a reasonable time frame for an abstractor to continue reviewing the case?**

If there is documentation that the SIRS was due to both an infectious source and non-infectious source, the SIRS criteria would be used. The measure does not specify a general time frame for reviewing a case.

Question 169: **Slide 49. At our facilities, we have "code sepsis called" by any team member. Would this qualify as infection suspected criteria if documented by a nurse or provider?**

If "code sepsis called" is documented by a physician/APN/PA or nurse, it would be sufficient for the suspected infection criteria.

Question 170: **Slides 49, 50, and 51. Is CMS going to put out an all-inclusive list of acceptable medical resources?**

Currently, there are no plans to develop an all-inclusive list of acceptable medical resources.

Question 171: **Slides 50 and 51. Please describe what is meant by "medical resource."**

A medical resource is a resource (e.g., literature, medical encyclopedia) used to determine if a condition is infectious, non-infectious, or potentially one or the other.

Question 172: **Slide 50. How would "poor perfusion" be attributed to an infectious source?**

Slide 50 regarding "poor perfusion" is an example of an acute condition with a non-infectious source. The example was developed to provide a clear example of when there is an acute condition that is not caused by an infection.

Question 173: **Slide 52. Are we not to consider vital signs if the physician lists them in the H&P? In the past, we would consider these vitals and use the date and time the note was written.**

Per the manual, using the time the vitals were taken or obtained would be appropriate. If there is no time that the vitals were obtained, using the documented or recorded time would be sufficient. Using the date and time the H&P note was written that documents the vital signs is acceptable.

Question 174: **Slide 52. For narrative vitals, if the nurse documents vitals from the EMS in a note, do we not count these vitals? These are not normally added to flow sheets.**

If the nurse documents the vital signs from the EMS in a note and the time in which the viral signs were taken or obtained time is not documented for the vital signs, then the time of the nursing documentation of the vital signs in the narrative note would be acceptable.

Question 175: **Slide 53. In the example, what if the physician documents influenza and pneumonia? Would we be able to use that documentation?**

If the pneumonia was not documented as due to the influenza, the pneumonia could still be used for the suspected infection criteria.

Question 176: **Slide 53. For severe sepsis linked to influenza, if a superimposed bacterial infection exists, do we still select Value "2" for the *Severe Sepsis Present* data element?**

If there is physician/APN/PA documentation that severe sepsis is due to a viral infection, you would disregard this documentation and move on to consider the next piece of documentation. Selecting Value "2" (No) would be appropriate if severe sepsis was present initially and then within six hours after severe sepsis is documented as due to a viral infection.

Question 177: **Slide 53. I'm confused why fungal, viral, or parasitic infection can't be "severe sepsis."**

For purposes of the SEP-1 measure, only severe sepsis due to bacterial infections are abstracted. Severe sepsis can be caused by fungal, viral, and parasitic infections. The measure specifications are designed and intended to only address severe sepsis cases caused by a bacterial infection.

Question 178: **Slide 54. If the patient meets criteria in the emergency room and has an LA of 4, but the physician then documents severe sepsis without septic shock, can we say "No" to septic shock despite having an LA of 4 or greater?**

If the documentation of "severe sepsis without septic shock" was within six hours after the *Septic Shock Presentation Time*, selecting Value "2" (No) for *Septic Shock Present* would be appropriate.

Question 179: **Slide 54. If criteria are met and then the physician says no severe sepsis or septic shock within six hours, do we abstract "No"? Do we need to keep looking throughout the rest of stay for severe sepsis?**

If severe sepsis is met either by clinical criteria or physician/APN/PA documentation and within six hours after the presentation time there is physician/APN/PA documentation of "no severe sepsis," Value "2" (No) would be selected for *Severe Sepsis Present*.

Question 180: **Slide 54. The guidance indicates that additional provider documentation can make a case not meet severe sepsis criteria. Would it make any difference if the second provider (the attending physician) documents viral sepsis, but a third provider (a consult), who has seen the patient at the same time, provides unspecific documentation that does not clarify the condition is viral related? Would the third physician's note negate the second physician's note, even though the second physician's note is more specific?**

It would not make a difference whether the third physician's documentation occurred. If the second physician stated that severe sepsis was viral within six hours of criteria being met, this documentation would negate severe sepsis being present. Therefore, Value "2" (No) would be chosen and abstraction for this case would stop.

Question 181: **How should we abstract *Severe Sepsis Present* if the patient meets clinical criteria for severe sepsis, but, prior to meeting the criteria, the physician documents that the patient does not appear septic?**

Since the physician documented "the patient does not appear septic" **before** clinical criteria were met, Value "1" (Yes) would be selected for *Severe Sepsis Present* and abstraction would continue.

Question 182: **The physician documents that the patient has CKD or ESRD on hemodialysis in the past medical history; the creatinine is greater than two. Can we disregard all creatinine levels as the patient has a chronic condition, even if the physician does not document that the creatinine is elevated due to CKD or ESRD?**

If there is physician/APN/PA documentation that the patient has ESRD and is on dialysis, then the elevated creatinine values would not be used.

If there is only documentation of CKD without a documented baseline or reference to the creatinine, then the elevated creatinine values would be used.

Question 183: **If the physician documents that a patient is a dialysis patient and the creatinine is elevated, would we not exclude that as organ failure? Does it need to be explicit?**

The physician/APN/PA documentation of the creatinine and that the patient is on dialysis would need to be in the same section of the medical records in order to exclude the creatinine. Explicit documentation is not required.

Question 184: **Why are we still abstracting pre-hospital arrival vital signs? As triage time is not severe sepsis time, and the provider has not seen the patient yet, it would make sense not to use pre-arrival vital signs.**

Pre-arrival records that are part of the medical record are used in abstraction to better capture cases where criteria are met prior to arrival and represent presence of severe sepsis on arrival. Although SIRS criteria and organ dysfunction may be used in pre-arrival records, the *Severe Sepsis Presentation Date* and *Time* would not be earlier than the arrival time to the ED.

Question 185: **Can you explain why you would continue abstraction if severe sepsis is met by physician/APN/PA documentation only and is documented as due to a viral, fungal, or parasitic infection, but you would stop abstraction and choose Value "2," if within six hours after documentation meeting clinical criteria or physician/APN/PA documentation of severe sepsis, if there is additional documentation of severe sepsis due to a viral, fungal or parasitic infection? What is the difference between the two, to stop abstraction for one and disregard the documentation and continue abstraction for the other?**

The key to better understanding the difference is the chronology of events, which matters in this type of situation.

In the first scenario, the documentation of an infection or severe sepsis due to a viral, fungal, or parasitic infection is disregarded, and abstraction continues because the documentation of severe sepsis due to a viral, fungal, or parasitic infection comes **first**.

If, however, severe sepsis clinical criteria are met or there is physician/APN/PA documentation of severe sepsis **first** and within six hours after the severe sepsis is documented as due to a viral, fungal, or parasitic infection, then Value "2" (No) is selected.

Question 186: **For antibiotic orders used as source of organ dysfunction, can the reasons for the order include bacteremia or gastrointestinal?**

For *Severe Sepsis Present* criteria A (infection), documentation of a condition as an indication for the antibiotic is acceptable to use for criteria A (infection).

Question 187: **For the infection criteria, if the physician documents bacterial infection secondary to influenza pneumonia, can this be used for the infection criteria?**

Yes, documentation of a bacterial infection secondary to influenza pneumonia (a viral infection) would be used for *Severe Sepsis Present* criteria A (infection).

Question 188: **If the patient meets *Severe Sepsis Present* and the physician documents infection due to influenza, do we ignore influenza as a source of infection?**

For *Severe Sepsis Present* criteria A (infection), if the infection is documented as due to a viral, fungal, or parasitic infection, the condition would not be used for criteria A (infection). Influenza meets the criteria for viral infection.

Question 189: **In the admitting note, the physician documents "1) severe sepsis 2) influenza. Medication: Tamiflu." There were no antibiotics ordered. Would this case be excluded?**

Since there is no documentation indication that severe sepsis is due to the viral infection, selecting Value "1" (Yes) for *Severe Sepsis Present* would be appropriate.

Question 190: **Would you continue to abstract if the provider documents severe sepsis is related to a viral condition and mentions a bacterial infection in the same note, but does not mention severe sepsis?**

The documentation of severe sepsis related to a viral condition would be disregarded. The next documentation of severe sepsis that is not indicated as due to a viral condition would be used to abstract for *Severe Sepsis Present*.

Question 191: **If a physician does not document a suspected or confirmed source of infection, would the patient be considered an exclusion for severe sepsis?**

Since severe sepsis can be met either by meeting clinical criteria or physician/APN/PA documentation of severe sepsis, there would not need to be documentation of a suspected infection if there was physician/APN/PA documentation of severe sepsis. However, if there was no physician/APN/PA documentation of severe sepsis and the patient did not meet all three clinical criteria, including source of infection, Value "2" (No) would be selected for *Severe Sepsis Present*.

Question 192: **Lyme disease is a bacterial infection. Should we not use this because it is caused by a tic?**

Since Lyme disease is not included in the Inclusion Guidelines for Abstraction, if a medical resource determines Lyme disease to be a bacterial infection or caused by a bacterial infection it may be used for the suspected infection criteria.

Question 193: **If an antibiotic and an antiviral are ordered for severe sepsis, but documentation refers to viral causes for severe sepsis, will this patient be in SEP-1?**

This scenario is dependent upon the documentation and the timing of the documentation. If *Severe Sepsis Present* is met by the physician/APN/PA documentation of severe sepsis and, within six hours after the presentation time, severe sepsis is documented as viral, then Value "2" (No) would be selected for *Severe Sepsis Present*, and the case will be excluded.

Question 194: **If the physician documents Afib with rapid ventricular response (RVR) in a sepsis setting, do we automatically disregard the elevated heart rate, or does this link the Afib with RVR to infection, and can we use it? Why don't we need specific documentation for Afib with RVR stating the condition is not related to infection when this is a common occurrence in an infection setting?**

If the physician/APN/PA documentation of "Afib with RVR" includes "in a sepsis setting," the elevated heart rates would be used for SIRS criteria as the condition (Afib with RVR) is due to the infection (sepsis).

Question 195: **It was stated that heart rates could be discarded if there was Afib with a RVR. Does the patient have to have a history of or chronic Afib with RVR, or can they be excluded even if it is a new diagnosis?**

The documentation of "Afib with RVR" would allow the elevated heart rates to be disregarded as long as Afib is a chronic condition for the patient. If Afib is documented as an acute (new onset) condition, the elevated heart rates would be used.

Question 196: **On documentation of Afib, if the physician documents Afib with RVR, can we disregard all the heart rates or does the physician have to specifically list the heart rates?**

Only if Afib is documented as a chronic condition and the physician/APN/PA has also documented RVR, then all heart rates may be disregarded.

Question 197: **If the patient underwent chemotherapy within the week or month prior to being treated at the hospital and the white cell count and platelets are decreased, can severe sepsis be disregarded?**

There would need to be physician/APN/PA documentation linking the white blood cell (WBC) count and platelet count to chemotherapy in order to exclude these values. However, severe sepsis would not necessarily be disregarded in this case. Additional information is needed to fully answer this question. Questions related to the measure can be submitted through the *QualityNet* Q&A tool available at https://cms-ocsq.custhelp.com/app/utils/login_form/redirect/ask.

Question 198: **With cancer patients and low platelets, frequently it is not documented that the thrombocytopenia is a result of the chemotherapy. Will you consider chemotherapy documented in the H&P or in the MAR as a reason for thrombocytopenia?**

At this time, there must be physician/APN/PA documentation considering the low platelet count to be due to the medication. The low platelets must be directly linked to the chemotherapy. Currently, CMS has no plans to add guidance to disregard all platelet counts when a chemotherapy medication is documented in the medical record.

Question 199: **Is this considered a fallout for severe sepsis? Clinical criteria for severe sepsis (e.g., respiratory rate = 22, heart rate = 110, WBC count = 18.7, Bilirubin = 3.6, "sepsis") were all met within six hours of each other. The physician documentation of "severe sepsis" present on admission was written in the "hospital problem list." The physician, within six hours, documented: "The 'liver function' tests are elevated due to common duct stone." Is this an indicator of severe sepsis?**

The documentation of "liver function tests are elevated due to common duct stone" would not impact the abstraction of the severe sepsis clinical criteria.

The reference to "liver function" is not specific to any one SIRS criterion or sign of organ dysfunction. Therefore, abstraction of the **earliest** *Severe Sepsis Presentation Time* based on either the present on admission documentation or when all clinical criteria were met would continue.

Question 200: **When determining organ dysfunction, should only the current anticoagulant be used to disregard an elevated INR or aPTT?**

When determining organ dysfunction, the documentation must reflect that the patient was given the anticoagulant. Therefore, if the patient was not given the anticoagulant, this documentation would not be used in excluding the INR or aPTT.

Question 201: **Can we use reiteration of an elevated lactate in an H&P?**

If the documentation in the H&P is not the earliest time that the value was reported or resulted, this documentation would not be used.

Question 202: **How do we abstract if the provider states sepsis with septic shock, but you cannot find all of the supporting documentation in the medical record?**

Since septic shock can be met through physician/APN/PA documentation, this documentation would be used to select Value "1" (Yes) for *Septic Shock Present*. If the *Severe Sepsis Present* clinical criteria are not met prior to the documentation of septic shock, then the time of the documentation of septic shock would also be abstracted for the *Severe Sepsis Presentation Time*.

Question 203: **What if the physician documents severe sepsis due to viral, but there is also documentation of a bacterial infection, would this be used?**

Physician/APN/PA documentation for severe sepsis due to a viral condition or infection would be disregarded. The further documentation that there was a bacterial infection could be used to meet *Severe Sepsis Present* criteria A (infection).

Severe Sepsis Date and Time

Question 204: **Slide 55. What if the patient is held in the ED for greater than 12 hours? Then all the elements would fail because it is not within the time frame; however, the orders would be written upon admission to the intensive care unit (ICU).**

The earliest *Severe Sepsis Presentation Date* and *Time* would be abstracted. If the *Severe Sepsis Present* clinical criteria were not met prior to the physician/APN/PA documentation that severe sepsis or septic shock was present on admission, the earliest documented hospital observation or inpatient admission time would be abstracted. The earliest hospital observation or inpatient admission time, which is reflected as the earliest time documented for the patient's arrival to the floor or unit for admission, is used because the documentation "present on admission" is referencing a specific time.

Question 205: **Slide 55. The information on the slide conflicts with bullet number three under the "Notes for Abstraction" for the data element *Admission Date.* The bullet indicates that we are to abstract the date the order was written, not the date the patient was transferred.**

The *Admission Date* data element provides guidance specific to the abstraction of that data element. The abstraction of the *Severe Sepsis Presentation Date* and *Time* data elements provides guidance specific to the abstraction of the *Severe Sepsis Presentation Date* and *Time*. Guidance from the *Admission Date* data element is not applicable to the *Severe Sepsis Presentation Date* and *Time* data elements.

Question 206: **Slide 55. If the time that the patient got to the floor is not documented, what time would you abstract for severe sepsis presentation?**

If a hospital observation or inpatient admission time is not documented and severe sepsis or septic shock is documented as "present on admission," Value "3" (No) would be selected for the *Severe Sepsis Presentation Date* or *Time* data element.

Question 207: **Slide 55. Must "present on arrival" be documented or may an abbreviation, such as "POA," be utilized?**

The *Severe Sepsis Presentation Date* and *Time* data elements provide guidance specific to the documentation of "present on arrival," "present on admission," and "POA." Since the acronym "POA" is used to abbreviate multiple terms it is not an acceptable abbreviation for abstraction. The time of the documentation "severe sepsis POA" would be used rather than inferring "POA" reflects the arrival or admission time.

Question 208: **Slide 55. If the patient meets criteria for severe sepsis in the ED before the admission time, do we still use admission time and not the arrival time?**

The earliest *Severe Sepsis Presentation Time* would be abstracted. If all three *Severe Sepsis Present* criteria were met prior to the physician/APN/PA documentation of "severe sepsis present on admission," the time of the last criterion to meet severe sepsis would be abstracted.

Question 209: **Slide 55. Scenario: The ED physician admits a patient at 2230 on 4/29 for pneumonia, and then the physician that the patient was admitted to, comes in on 4/30 at 0730 and does the admission H&P. On that admission H&P the physician charts "severe sepsis on admission." Can we use the date and time of 4/29 at 2230 or do we use the time of 4/30 at 0730? Our ED physicians put in admission orders for our physicians most of the time unless the patient is admitted straight from the office. The physician then comes in later that day or the next day to put in an Admission H&P.**

With the physician documentation of "severe sepsis on admission," the earliest hospital observation or inpatient admission date and time would be used. In this example, as long as 4/29 at 2230 is the earliest admission date and time, this would be abstracted for the *Severe Sepsis Presentation Date* and *Time*.

Question 210: **Slide 55. Please clarify how 0945 is chosen for *Severe Sepsis Presentation Time*.**

With the documentation "severe sepsis present on admission," the earliest hospital observation or inpatient admission time, which is reflected as the earliest time documented for the patient's arrival to the floor or unit for

admission, would be used. In the example on slide 55, the documentation at 0945 reflects the arrival time to the inpatient floor or unit for admission.

Question 211: **Slide 55. In this example, if a patient meets criteria for severe sepsis or septic shock earlier than the time the provider writes septic shock present on admission, the abstractor would still use the time the criteria were met because it was the earlier of the two. Is that correct? Or would you disregard the time the criteria were met and use the admission time?**

Yes, that is correct. The earliest *Severe Sepsis* or *Septic Shock Presentation Date* and *Time* would be abstracted. If the clinical criteria for severe sepsis or septic shock was met prior to the documentation of severe sepsis or septic shock, the earlier date and time the clinical criteria were met would be abstracted.

Question 212: **Slide 55. If the patient met severe sepsis criteria prior to 0945, as per the example, do we use the time the patient met criteria?**

Yes, that is correct. The earliest *Severe Sepsis* or *Septic Shock Presentation Date* and *Time* would be abstracted. If the clinical criteria for severe sepsis or septic shock were met prior to the documentation of severe sepsis or septic shock, the earlier date and time the clinical criteria were met would be abstracted.

Question 213: **Slide 55: The nurse documents that she gave handoff to the ICU nurse and the patient was transferred at 1515. The patient was not changed into an ICU bed until 1520. Which is the admission time?**

If severe sepsis was documented as "present on admission," the earliest time reflecting the patient's arrival to the inpatient floor/unit would be used. If the documentation at 1515 does not reflect the time the patient actually arrived to the ICU, then the documentation at 1520 would be used.

Question 214: **Slide 55. If the medical record says present on admission (POA), do we use the time of arrival to the floor and not the admit time order?**

The earliest hospital observation or inpatient admission time is reflected as the earliest time documented for the patient's arrival to the inpatient floor or unit for admission. The time the order is written would not be acceptable.

Question 215: **Just to clarify, if the patient has met septic shock by both clinical criteria and physician documentation of septic shock, you would use the time of whichever is earlier?**

Yes, that is correct. The earliest *Severe Sepsis* or *Septic Shock Presentation Date* and *Time* would be abstracted. If the clinical criteria for severe sepsis or septic shock were met prior to the documentation of severe sepsis or septic shock, the earlier date and time the clinical criteria were met would be abstracted.

Question 216: **When using a lactate level for *Sever Sepsis Presentation Time*, do you use the collection time or the result time?**

For *Severe Sepsis Present* criteria B (SIRS criteria) and criteria C (evidence of organ dysfunction), use the time the lab(s) resulted. Do not use the lab collection time for abstraction.

Question 217: **For present on admission, what do you do if you do not have an arrival time to the floor? If you have the time that the nurse "collects" her admission nursing assessment, would you be able to use that time?**

Yes, that is correct. The earliest time documented for the patient arrival to the inpatient floor or unit for admission would be used. If the nurse is performing an admission nursing assessment on the unit, this time would count as admission time to the unit.

Question 218: **Present on admission is not when the patient presented to the ED?**

For the purposes of the measure, the documentation of "present on admission" reflects the earliest arrival time to the floor or unit for admission. The documentation of "present on arrival" reflects the arrival to the ED or hospital.

Question 219: **For present on admission, what about patients that are admitted but must be boarded in the ED due to lack of inpatient beds. Waiting until the patient is placed in a bed on a unit would not be representative of admit time. What time would be acceptable to use?**

Unless an earlier *Severe Sepsis Presentation Date* or *Time* is available, the earliest arrival time to the inpatient floor or unit for admission would be abstracted. There must be documentation stating the patient arrived on an inpatient floor or unit or comparable documentation stating the patient transferred to observation status and the appropriate assessment was performed at this time.

Question 220: **The ED doctor states severe sepsis or septic shock in their differential diagnosis. However, they do include it in their clinical impression/final diagnosis and does not state it has been ruled out, and the patient does not meet any other criteria. Would we use the differential diagnosis as time zero or exclude the severe sepsis/septic shock differential diagnosis?**

Yes, the physician/APN/PA documentation of severe sepsis and/or septic shock as a differential diagnosis would be used as documentation of severe sepsis and/or septic shock.

Question 221: **What if a provider documents that severe sepsis is present on admission several days after the admission. Should we still use the admission time given this documentation appeared several days later? This is, of course, is if criteria were either never met or were met after admission but prior to the note being written.**

If severe sepsis was not present prior to the admission date and time, then the earliest admission date and time to the inpatient floor or unit would be used.

Septic Shock Present

Question 222: **Slide 56.** *Persistent Hypotension* **requires two consecutive low BPs after fluid volume is administered. To my understanding, there is no acknowledgement of using vasopressors to maintain BP as evidence of septic shock. Am I correct? Is this an oversight? Example: one low BP, vasopressor started, next BP no longer meets criteria.**

For the purposes of the measure, *Persistent Hypotension* is addressed after the completion of the target ordered volume of crystalloid fluids and prior to the abstraction of *Vasopressor Administration*. *Persistent Hypotension* does require two consecutive hypotensive BPs within the hour after the completion of the target ordered volume of crystalloid fluids. If within the hour to assess for *Persistent Hypotension* there is one hypotensive BP followed by a normal BP, then Value "2" (No) would be selected for *Persistent Hypotension*. Furthermore, if *Persistent Hypotension* is not present, then *Persistent Hypotension* would not be used to meet *Septic Shock Present*.

Question 223: **Slide 56. What if the patient's physician/PA states admitted with severe sepsis or septic shock?**

The physician/APN/PA documentation of "admitted with" severe sepsis or septic shock would result in abstracting the earliest documented hospital observation/inpatient admission time for the *Severe Sepsis* or *Septic Shock Presentation Date* and *Time*. The earliest documented hospital observation/inpatient admission time is most accurately reflected as the earliest time documented for the patient's arrival to the inpatient floor or unit for admission.

Question 224: **Consulting physician states severe sepsis and septic shock. The criteria meet severe sepsis but do not meet septic shock. Do we select Value "1" or Value "2"?**

The physician/APN/PA documentation of severe sepsis and septic shock would allow Value "1" (Yes) to be selected for both *Severe Sepsis Present* and *Septic Shock Present*.

Question 225: **For *Septic Shock Present*, can a lactate of greater than or equal to 4 millimole (mmol)/liter (L) alone be used for *Septic Shock Presentation Time* or does the severe sepsis criteria also need to be met?**

An *Initial Lactate Level Result* greater than or equal to 4 alone, would not be sufficient to select Value "1" (Yes) for *Septic Shock Present*. Severe sepsis must be present in addition to an *Initial Lactate Level Result* greater than or equal to 4.

Question 226: **If the initial lactate is greater than 4, and is used as organ dysfunction to determine *Severe Sepsis Present*, and there is no other organ dysfunction does this meet septic shock?**

If the lactate greater than or equal to 4 used for evidence of organ dysfunction is the *Initial Lactate Level Result*, then yes, the same lactate used for evidence of organ dysfunction would be used to meet *Septic Shock Present* criteria.

Question 227: **In determining septic shock, if there is only one hypotensive value documented, but the doctor documents hypotension or septic shock, do we need a second hypotensive value documented?**

Value "1" (Yes) may be selected for *Septic Shock Present* if there is physician/APN/PA documentation of septic shock OR *Severe Sepsis Present* with *Persistent Hypotension*. If there is only one hypotensive BP documented in the hour after the completion of the target ordered volume of crystalloid fluids, *Persistent Hypotension* would not be present. In that case, *Persistent Hypotension* would not be used to meet *Septic Shock Present* criteria.

Lactic Level

Question 228: **Has there been any further consideration of excluding patients that are in the OR during the six-hour window? Just as an example, we had a patient with a ruptured diverticulum who had an LA drawn. He was in the OR when the repeat level was due so the case failed the measure.**

At this time, there are no plans to exclude patients in the OR that require a *Repeat Lactate Level Collection*.

Question 229: **I understand that initial LA is the LA drawn closest to severe sepsis time. However, these patients fail especially those who develop severe sepsis later in their stay. These patients have many LAs drawn that will not fit into the time frame for either initial LA or repeat LA. These patients have many LAs drawn as clinically appropriate. Cases like these should be made exceptions. Is this being looked at?**

Thank you for this feedback. Guidance for the abstraction of the *Initial Lactate Level Collection* is continually being reviewed for improvement by the measure stewards and CMS.

Question 230: *Initial Lactate Level Collection* **was not discussed, but I just want some clarifications. If there are multiple lactate levels, I was told by** *QualityNet* **to abstract the lactate closest to the** *Severe Sepsis Presentation Date and Time***. However, in the guidelines the initial lactate can be from between six hours prior to and three hours following** *Severe Sepsis Presentation***. Our clinicians are confused why we can't use the very first lactate between six hours prior to three hours following.**

For version 5.4 of the measure, if there are multiple lactate levels collected within the specified time frame, the lactate level collected/drawn closest to the *Severe Sepsis Presentation Time* would be used for the *Initial Lactate Level Collection*. The intent is that the lactate drawn closest to presentation time more accurately reflects the patient's condition at the time of presentation. We appreciate your comments and will share them with the measure stewards for future consideration.

Question 231: **The patient comes into the ED with severe sepsis. The first LA is drawn and elevated, however the patient is transferred within two hours to another facility and there is no time to collect the second LA. Why is this scenario an automatic fail to the measure instead of an exclusion to the measure?**

If the patient was discharged within six hours after the *Severe Sepsis Presentation Time*, the case will be excluded at the Sepsis Discharge Time calculation in the SEP-1 algorithm. Otherwise, if the patient was not discharged within six hours, the case would proceed in the algorithm and a *Repeat Lactate Level Collection* will be required if the *Initial Lactate Level Result* is elevated. Transfer from another facility is cause for exclusion of a case.

Question 232: *Repeat Lactate Level Collection*. **For the purpose of the measure, a lactate level collected within six hours prior to and within three hours after the presentation and is the closest, is considered an initial lactate level. From the site champions' feedback, there have been an increase in false positives due to multiple lactates present within the allowable time frame, but because of the guidelines to select the "closest lactate collected to presentation," the repeat lactate is failing the measure because of timings. For example:** *Severe Sepsis Presentation* **is 1530; lactate collected times are 1050, 1500 and 1535. By definition, the closest time to presentation is 1535, which becomes the initial lactate. There is no other lactate done until the morning of the next day.**

For version 5.4 of the measure, the initial lactate is the one that is drawn closest to *Severe Sepsis Presentation Time* when multiple lactate levels are obtained. A repeat lactate needs to be drawn after the *Initial Lactate Level Collection* if the *Initial Lactate Level Result* is elevated (>2.0 mmol/L). If the *Initial Lactate Level Result* was greater than 2.0 and collected at 1535 per the scenario in the question, then collecting another lactate is required. The *Repeat Lactate Level Collection* must occur within six hours after the *Severe Sepsis Presentation Time*. Therefore, a *Repeat Lactate Level Collection Time* greater than six hours after the *Severe Sepsis Presentation Time* would not be acceptable.

Administrative Contraindication to Care

Question 233: **Slide 15. Is it possible to review the impact on the measure when patient is pulling out IV lines implying significant delay for the three-hour bundle compliance (precisely IV antibiotics administration)? This can't be considered a refusal of care, but at the same time, patient is disengaging in the care by discontinuing IV sites due to physical state, altered mental status, or other.**

If the physician/APN/PA provides specific documentation of the patient's disruption of care, it would be acceptable.

Question 234: **Is there a timeline for refusing further treatment?**

For the *Administrative Contraindication to Care, Severe Sepsis* data element, the time frame is prior to or within six hours of *Severe Sepsis Presentation Time*. There needs to be documentation of the refusal. Similarly, for the

Administrative Contraindication to Care, Septic Shock data element, the documentation needs to be prior to or within six hours of the *Septic Shock Presentation Time*

Question 235: **Slide 15. What if the staff are unable to start a line on the patient, is this excluded?**

Documentation of failure to gain IV access will not suffice *Administrative Contraindication to Care, Severe Sepsis* or *Septic Shock* data elements, but other data elements, such as the *Blood Culture Collection* and *Initial Lactate Level Collection*, do provide guidance when there is documentation of a failed IV attempt.

Question 236: **Slide 16. Could you provide clarification regarding the patient's husband refusing a central line. If they refuse a central line and that is clearly documented, can we select "Yes" to refusal of care related to blood draw, antibiotics, and vasopressors?**

Yes, documentation of the patient's, or authorized patient advocate's, refusal of a central line within the time frame specified in the manual is acceptable to select Value "1" (Yes) for the *Administrative Contraindication to Care* data elements.

Question 237: **Would physician documentation "patient's husband does not want any further treatment" be sufficient for the *Administrative Contraindication to Care, Septic Shock* data element?**

If the husband is the patient's authorized advocate, then documentation of the patient's or authorized patient advocate's refusal of care (e.g., "patient's husband does not want any further treatment") within the time frame specified is acceptable to select Value "1" (Yes) for the *Administrative Contraindication to Care, Septic Shock* data element.

Public Reporting/Validation

Question 238: **Slide 9. I don't understand why this measure is being publicly reported when there have been so many measure changes during the reporting period.**

As stated in the fiscal year (FY) 2015 IPPS/LTCH PPS Final Rule in which the Sepsis (SEP)-1 measure was finalized for the Hospital IQR Program, Section

5001(a) of the Deficit Reduction Act (DRA) requires that the Secretary establish procedures for making information regarding measures available to the public after ensuring that a hospital can review its data before they are made public. In the FY 2014 Inpatient Prospective Payment System/Long-Term Care Hospital Prospective Payment System (IPPS/LTCH PPS) Final Rule, for the FY 2014 Hospital IQR Program and subsequent years, we finalized continuing our policy of publicly reporting data as soon as it is feasible on CMS websites, such as the website, http://www.medicare.gov/hospitalcompare, after a 30-day preview period (78 FR 50776 through 50778). As such, CMS is required to publicly report the measure. The changes to SEP-1, to date, have all been sub-regulatory changes, which have provided clarifications to both clinicians and abstractors but have not substantively changed the measure.

Question 239: **Public reporting of the SEP-1 measure will negatively affect our business operations as patients may not come through our doors if they notice a low compliance with the measure. I echo the comments from a previous question answered - there have been so many changes to the SEP-1 measure, I don't understand why this measure is considered to be ready for public reporting. The changes targeted at simplifying abstraction actually do affect the performance of the SEP-1 measure overall, so I would disagree with that comment.**

Thank you for your comments and question. As stated in the FY 2015 IPPS/LTCH PPS Final Rule in which the SEP-1 measure was finalized for the Hospital IQR Program, Section 5001(a) of the DRA requires that the Secretary establish procedures for making information regarding measures available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. In the FY 2014 IPPS/LTCH PPS Final Rule, for the FY 2014 Hospital IQR Program and subsequent years, we finalized continuing our policy of publicly reporting data as soon as it is feasible on CMS websites, such as the *Hospital Compare* website, http://www.medicare.gov/hospitalcompare, after a 30-day preview period (78 FR 50776 through 50778). As such, CMS is required to publicly report the measure. The changes to SEP-1, to date, have all been sub-regulatory changes, which have provided clarifications to both clinicians and abstractors but have not substantively changed the measure.

Question 240: **Once a measure is posted to *Hospital Compare*, how long does it have to be posted before it could potentially be considered to be added to the CMS pay for performance Hospital Value-Based Purchasing (VBP) Program? Is it 18 months?**

Hospital VBP Program measures may only be selected from the Hospital IQR Program measure set. Data must be publicly displayed on *Hospital Compare* for at least one year prior to inclusion in a Hospital VBP Program performance period. Implementation in the Hospital VBP Program would further require CMS to undergo notice and comment rulemaking, publicly proposing the measure for adoption for that specific program beginning with a specific program year and subsequent years.

Question 241: **When will reimbursement be affected in regard to the SEP-1 measure?**

SEP-1 has not been implemented in any other CMS value-based purchasing programs; the measure is only implemented in the Hospital IQR Program, a quality data reporting program in which measure performance is not tied to payment.

Question 242: **Fully agree with question on why publicly reporting with so many changes over time for this measure. It seems CMS is rushing to report publicly so they can use it in the pay for performance programs in the future.**

Thank you for your comment.

SEP-1 is not currently included in the Hospital VBP Program.

1. Hospital VBP Program measures may only be selected from the Hospital IQR Program measure set.

2. Data must be publicly displayed on *Hospital Compare* for at least one year prior to inclusion in a Hospital VBP Program performance period.

3. Implementation in the Hospital VBP Program would further require CMS to undergo notice and comment rulemaking, publicly proposing the measure for adoption for that specific program beginning with a specific program year and subsequent years.

Additionally, SEP-1 has not been implemented in any other CMS value-based purchasing program; it is only implemented in the Hospital IQR Program, a

quality data reporting program in which measure performance is not tied to payment.

Question 243: **Public reporting response from Bob does not reflect the fact that public reporting will reflect as poor outcomes for hospitals when SEP-1 is not in alignment with quick Sepsis Related Organ Failure Assessment (qSOFA). Public Reporting should indicate that for transparency to the public.**

Thank you for your input. The clinical criteria for the identification of severe sepsis and septic shock used by the SEP-1 measure are for the purpose of confirming that patients already assigned International Classification of Diseases (ICD)-10 codes for sepsis, severe sepsis, or septic shock meet criteria to be included in the measure. It is not for the purposes of defining how screening for sepsis should be performed at the bedside. The criteria used in SEP-1 represent a standardized method for purposes of confirming the denominator population for the measure. There are many variations to screening tools in use at the bedside. Facilities may use any screening criteria they feel most appropriate to identify sepsis in their clinical setting.

Question 244: **When answering the question about public reporting, it was mentioned that the measure rate is increasing. Has CMS set a goal yet? What is the national rate looking like?**

At this time, national averages are not available for public reporting.

Question 245: **Will a risk-adjusted mortality rate also be publicly reported or just SEP-1 overall performance?**

At this time, only the SEP-1 overall performance is planned for the July 2018 public release.

Question 246: **Will the SEP-1 measure also be reflected on our Hospital Star Rating Report beginning in July?**

Yes, individual facility performance along with state and national performance will be available in the *Hospital Compare* preview report.

Question 247: **I was curious how the data would be reported out in July 2018. Will it list all facilities by alphabetical order? Or will it just be by organization (i.e., Kaiser, Sutter, Stanford vs. Kaiser Oakland, Alta Bates Summit Medical Center [Oakland], Alta Bates Summit Medical Center [Berkeley], etc.)?**

Overall facility-level performance will be publicly reported.

Question 248: **I agree that public reporting of SEP-1 is not appropriate, since the algorithm with regards to those on antibiotics greater than 24 hours from severe sepsis time zero has definitely impacted compliance with the bundle measure compliance.**

Thank you for your comments and question. As stated in the FY 2015 IPPS/LTCH PPS Final Rule in which the SEP-1 measure was finalized for the Hospital IQR Program, Section 5001(a) of the DRA requires that the Secretary establish procedures for making information regarding measures available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. In the FY 2014 IPPS/LTCH PPS Final Rule, for the FY 2014 Hospital IQR Program and subsequent years, we finalized continuing our policy of publicly reporting data as soon as it is feasible on CMS websites, such as the *Hospital Compare* website, http://www.medicare.gov/hospitalcompare, after a 30-day preview period (78 FR 50776 through 50778). As such, CMS is required to publicly report the measure. The changes to SEP-1, to date, have all been sub-regulatory changes, which have provided clarifications to both clinicians and abstractors but have not substantively changed the measure.

Question 249: **We have not had any access to comparative data all along, so there has been no way to really know how we are doing compared to our peers. It would have been helpful to see that data and initiated additional performance improvement strategies as needed prior to public reporting.**

Thank you for your feedback. Hospitals have been able to see state and national averages for SEP-1 in the Facility, State, and National reports accessible via the facility's *QualityNet* account.

Question 250: **Are there any benchmarks yet? If so, are they posted? Additionally, is there benchmarking data available for overall rate, as well as bundle rates?**

Currently, we do not have any benchmarks published. CMS is working on developing a benchmark report that will have the overall performance for the measure. The tentative target release for the benchmarks is August of this year.

Question 251: **Do you know when a benchmark for bundle compliance will be available?**

Currently, we do not have any benchmarks published. CMS is working on developing a benchmark report that will have the overall performance for the measure. The tentative target release for the benchmark is August of this year. State and national rates have been and will continue to be available in the *Hospital Compare* preview report, which is available for your hospital to download from *QualityNet* at https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename= QnetPublic%2FPage%2FQnetTier2&cid=1228768205297.

Question 252: **What is the national accuracy rate for the sepsis measure on validation?**

This information is not available at this time.

Question 253: **When will sepsis abstracted measures be subject to validation? What data time frame would be requested?**

SEP-1 currently undergoes data validation under the Hospital IQR Program. More details about chart-abstracted measures for validation can be found on *QualityNet* at https://www.qualitynet.org/dcs/ContentServer?c=Page& pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228776288808.

Question 254: **When will an internal reliability rate be available for SEP-1?**

This information is not available at this time.

Question 255: **It was stated that the measure isn't included in the Hospital VBP Program, but it is being validated for Hospital Inpatient Quality Reporting (IQR). It seems unfair to be scored on validation with all of the measure abstraction specification changes.**

As stated in the FY 2015 IPPS/LTCH PPS Final Rule in which the SEP-1 measure was finalized for the Hospital IQR Program, Section 5001(a) of the DRA requires that the Secretary establish procedures for making information regarding measures available to the public after ensuring that a hospital can review its data before they are made public. In the FY 2014 IPPS/LTCH PPS Final Rule, for the FY 2014 Hospital IQR Program and subsequent years, we finalized continuing our policy of publicly reporting data as soon as it is feasible on CMS websites, such as the *Hospital Compare* website, http://www.medicare.gov/hospitalcompare, after a 30-day preview period (78 FR 50776 through 50778). As such, CMS is required to publicly report the measure. The changes to SEP-1, to date, have all been sub-regulatory changes, which have provided clarifications to both clinicians and abstractors but have not substantively changed the measure.

Other

Question 256: **Slide 30. If there is no documentation of when the patient left, is the time on the face sheet acceptable?**

If the documentation on a face sheet identifies the time of discharge, the documentation on the face sheet would be acceptable. Documentation that does not identify when the patient was discharged from acute inpatient care, left against medical advice (AMA), or expired would not be used for the *Discharge Time* data element.

Question 257: **Are check lists with physician/APN/PA signatures accepted?**

Thank you for the question. Further information is needed to provide an accurate response to this question. Questions can be submitted through the *QualityNet* Q&A tool available at https://cms-ocsq.custhelp.com/app/utils/login_form/redirect/ask.

Question 258: **If we have questions in the future where can we submit them?**

Questions related to the measure can be submitted through the *QualityNet* Q&A tool available at https://cms-ocsq.custhelp.com/app/utils/login_form/redirect/ask

Question 259: **Is it possible to consider presenting case studies webinars with actual provider documentation and actual cases? It would benefit the abstraction team, as we are looking for allowable documentation and having to make some justifications without implications but also could be misinterpreting the manual guidelines. Such webinar would be very helpful.**

Thank you for the input. This recommendation and all recommendations are always considered for future webinar presentations.

Question 260: **What are the key changes between version 5.3 that was released recently and version 5.4?**

The key changes between the two manual versions can be noted in the Release Notes for manual version 5.4, which is posted on *QualityNet* at https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228776364473.

Question 261: **Where can I find the new sepsis manual for the sepsis measures by CMS?**

The specifications manual is posted at https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228776364473.

Question 262: **I wanted to say thank you for these question and answer webinars. They are extremely helpful. I appreciate all of the examples provided. The CMS team does a great job with this measure.**

Thank you for the comments.

Question 263: **Suggestion, we need routine educational webinars such as this for SEP-1.**

Thank you for the input, CMS looks forward to providing additional opportunities to clarify guidance.

Question 264: **Thank you for allowing additional time on today's webinar for lots of questions to be answered; would love to see this happen more often for future CMS webinars. Very valuable use of time.**

Thank you for the comments.

Question 265: **These are always wonderful, but they always bring up more questions.**

Thank you for the comments. Please feel free to follow-up and submit all questions to https://cms-ip.custhelp.com/app/utils/login_form/redirect/ask.

Question 266: **This measure becomes so much more of a burden for everyone.**

Thank you for the input. CMS continues to strive to minimize burden for this measure. Please feel free to follow-up and submit all questions to https://cms-ip.custhelp.com/app/utils/login_form/redirect/ask.