ADULT DATA DICTIONARY FOR SEVERE SEPSIS OR SEPTIC SHOCK

Version 7.1

January 16, 2020

1 Version 7.1 The most recent version of this document, the *Frequently Asked Questions* document, and the *Table of Elements* data template and instructions may always be found at: <u>https://ny.sepsis.ipro.org</u>

Questions regarding this document should be sent to: <u>sepsis-ny@support.ipro.us</u>

Prepared by: Office of Quality and Patient Safety New York State Department of Health Released for use January 1, 2020 Revised January 16, 2020

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Points to remember during data collection

NYSDOH has aligned with select CMS SEP-1 data elements and measures. The denominator for the NYSDOH data submission still requires reporting ALL cases that meet criteria for severe sepsis or septic shock INCLUDING cases identified through coding AND/OR other avenues (e.g., concurrent case identification; retrospective review; and so forth).

- It is expected that cases with clinical signs and symptoms of septic shock (severe sepsis with either lactate >=4 (with elevated lactate reason=2) and/or persistent hypotension despite fluid resuscitation) are reported with *Septic Shock Present=1*.
- CMS Version 5.7 will be used for guidance for CMS aligned variables effective <u>January 1,</u> <u>2020</u> for the NYSDOH data collection.

(https://www.qualitynet.org/inpatient/specifications-manuals#tab2). Note that the NYSDOH has aligned with the CMS data dictionary release(s) which typically results in two dictionaries in a year. Therefore a second dictionary for 7/1/2020 discharges will also be released by the NYSDOH. While these data elements are described in this document, the latest version of CMS guidance documents should be referenced for detailed information for the correct abstraction and submission of all data for those data elements. The only exception is with respect to failed/contaminated laboratory specimen collection (e.g. blood culture and lactates.). Currently the NYSDOH is not allowing any failed attempts or contaminated specimens to be reported as collected.

- The hospital is responsible for reporting all diagnosed cases of severe sepsis or septic shock, regardless of billing code designation. Cases diagnosed as sepsis but that do not meet criteria for severe sepsis or septic shock are not to be submitted.
- Patients who arrive through your Emergency Department (ED) and are admitted to your inpatient unit are not considered transfers for *Source of Admission*. The location prior to the ED should be reported as the admission source for patients admitted through ED.
- All hospitals should report patients in inpatient settings. This includes psychiatric inpatient hospitals and units within hospitals but excludes ambulatory clinics.
- If an ED patient was not admitted, but the patient had severe sepsis or septic shock then the data is to be reported for this patient.
- For multiple sepsis events during a single admission, report the first event of severe sepsis or septic shock. Hospitals should report a single case for patients who are internal transfers from other units within the hospital, thereby reporting the full episode of patient care as a single record. If a patient is admitted and discharged from one unit/department (e.g. psychiatric unit) and admitted to another unit/department within the same facility (e.g. ICU), the full care for that entire period should be reported as one case. Also, in these cases of admission/discharge to different units within the same facility, the FIRST unit "admission" should be used for the admission data element, and the LAST "unit discharge" from the facility itself is to be used for the discharge data element. Even though the

patient is "admitted/discharged" from individual units/departments for billing purposes, those do not apply to the actual initial admission or actual terminal discharge.

- The full care for the severe sepsis or septic shock episode, regardless of the hospital unit for which the patient may have presented during the stay, should be reported. For example, if the severe sepsis was identified and treatment begun in the psychiatric unit of your hospital, then you also should report the care provided in that unit in addition to the continued care in a different unit of the same hospital. The case should not be reported again. Transfer status will be reported as 1=Not a Transfer-Patient was neither admitted as a transfer nor discharged as a transfer to/from a different acute care hospital.
- Unless a case is excluded from the protocol using an acceptable exclusion reason in the data dictionary, hospitals must report all data for adherence variables. This enables accurate data capture of treatment provided to the patient. If the ED patient had severe sepsis or septic shock but was never admitted, the data would still need to be reported. Admissions to observation alone would also need to be reported.
- The term "sepsis" may be used in this data dictionary, but it always refers to "severe sepsis or septic shock."
- Unless specified differently in the variable description (e.g., blood cultures) the reporting period relates to treatment events in the 3 and 6 hour bundle periods. All reported adherence measures are to be reported for the severe sepsis or septic shock episode.
- For the receiving hospital reporting on patients transferred with sepsis 'present on admission', from either another ED or as a direct inpatient hospital transfer, both the transferring and receiving hospitals are responsible for collecting and reporting the variables, including demographics, adherence, severity adjustment and co-morbidity variables. Data from both institutions will eventually be linked for outcomes and adherence measures reporting. It is understood that the hospital may not have data on all elements, but is expected to report on the data that is available for each hospital.

Links to CMS specifications are included for convenience. Hospitals are responsible for ensuring they are using the most current CMS specifications and direction in place for the discharge timeframe.

CMS Specifications Manual for National Hospital Inpatient Quality Measures Discharges 01-01-20 (1Q20) through 06-30-20 (2Q20) Version 5.7. Excerpts from these documents are included in this document in addition to providing the links. Again, note that the NYSDOH data dictionary is using Version 5.7 and aligning with CMS regarding two dictionary releases in a year. Hospitals can expect to receive a revised data dictionary to align with the CMS 5.8 release effecting for 07-01-20 discharges.

You may download the CMS Version 5.7 dictionary by clicking the below link: <u>https://www.qualitynet.org/files/5d55ace2c84b4540884322e4?filename=1b-AlphaDD,0.pdf</u> Demographic Variables

Dataset Segment:	Demographic Variables
Data Element Name:	Admission Datetime
Format – Length:	Datetime-16
SPARCS variable:	Yes
CMS SEP-1 variable:	No
Mandatory:	Yes

The date and time that the patient was admitted to inpatient status at the hospital.

This is the administrative admission datetime which aligns with your SPARCS data set. If a patient is admitted to observation only, then the datetime of admission to observation is to be reported.

Codes and Values:

Notes for Abstraction:

- Formatting:
 - 1. Format must be YYYY-MM-DD hh:mm
 - a. YYYY-MM-DDThh:mm is also valid
 - 2. YYYY = four-digit year

MM = two-digit month (01=January, etc.)

- DD = two-digit day of month (01 through 31)
- hh = two digits of hour (00 through 23) (am/pm NOT allowed)
- mm = two digits of minute (00 through 59)
- 3. Example: 11:42 pm November 3, 1959=1959-11-03 23:42
 - a. 1959-11-03T23:42 is also valid
- 4. Midnight = 00:00, not 24:00
- Cannot have been after *Discharge Datetime*.

For a patient who is admitted to one unit/department from another unit/department within the same facility, the <u>initial administrative admission to the facility</u> is what should be reported for *Admission Datetime*. Do not use admissions from internal transfers, since these are not actually separate hospital admissions – the entire period should be submitted as one record. This is regardless of whether the internal transfers are billed separately. Observation only cases which do not progress to an admission may use the arrival time as admission time.

Dataset Segment:

Demographic Variables

Data Element Name:	Arrival Datetime
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Yes

Description:

The earliest documented date and time the patient arrived at the hospital.

Format:

- Formatting:
 - 1. Format must be YYYY-MM-DD hh:mm
 - a. YYYY-MM-DDThh:mm is also valid
 - 2. YYYY = four-digit year

MM = two-digit month (01=January, etc.)

DD = two-digit day of month (01 through 31)

hh = two digits of hour (00 through 23) (am/pm NOT allowed)

- mm = two digits of minute (00 through 59)
- 3. Example: 11:42 pm November 3, 1959=1959-11-03 23:42
 a. 1959-11-03T23:42 is also valid
- 4. Midnight = 00:00, not 24:00

- Review the Only Acceptable Sources to determine the earliest datetime the patient arrived at the ED, nursing floor, or observation, or as a direct admit to the cath lab. The intent is to utilize any documentation which reflects processes that occurred after arrival at the ED or after arrival to the nursing floor/observation/cath lab for a direct admit.
- Documentation outside of the Only Acceptable Sources list should NOT be referenced (e.g., ambulance record, physician office record, H&P).
- The arrival datetime may differ from the admission date.
- Cannot have been after *Discharge Datetime*.
- If the patient is in either an outpatient setting of the hospital other than observation status (e.g., dialysis, chemotherapy, cardiac cath) or a SNF unit of the hospital, and is subsequently admitted to acute inpatient, use the datetime the patient arrived at the ED or on the floor for acute inpatient care as the arrival date.
- Observation Status:
 - If the patient was admitted to the observation from an outpatient setting of the hospital, use the datetime the patient arrives at the ED or on the floor of observation care as the arrival datetime.

- If the patient was admitted to observation from the ED of the hospital, use the datetime the patient arrived at the ED as the arrival datetime
- Direct Admits:
 - If the patient is a "Direct Admit to the cath lab, use the earliest datetime the patient arrived at the cath lab (or cath lab staging/holding area) as the arrival date.
 - If the patient is a "Direct Admit" to acute inpatient or observation, use the earliest datetime the patient arrived at the nursing floor or in observation (as documented in the Only Acceptable Sources) as the arrival datetime
- If the patient was transferred from your hospital's satellite/free-standing ED or from another hospital within your hospital's system (as an inpatient or ED patient), and there is one medical record for the care provided at both facilities, use the arrival datetime at the first facility.
- The source "Emergency Department record" includes any documentation from the time period that the patient was an ED patient (e.g., ED face sheet, ED consent/Authorization for treatment forms, ED/Outpatient Registration/sign-in forms, ED vital sign record, ED triage record, ED physician orders, ED ECG reports, ED telemetry/rhythm strips, ED laboratory reports, ED x-ray reports, ED head CT scan, CTA, MRI, MRA reports).
- The source "Procedure notes" refers to procedures such as cardiac caths, endoscopies, and surgical procedures. Procedure notes do not include ECG and x-ray reports.

Suggested Data Sources:

ONLY ACCEPTABLE SOURCES: Emergency Department record Nursing admission assessment/admitting note Observation record Procedure notes Vital signs graphic record

Dataset Segment:	Demographic Variables
Data Element Name:	Date of Birth
Format – Length:	Date-10
SPARCS variable:	Yes
CMS SEP-1 variable:	No
Mandatory:	Yes

The date of birth of the patient.

Codes and Values:

- Formatting:
 - 1. Format must be YYYY-MM-DD
 - YYYY = four-digit year
 MM = two-digit month (01=January, etc.)
 DD = two-digit day of month (01 through 31)
 - 3. Example: November 3, 1959=1959-11-03
- Date of Birth cannot have been after Admission Datetime.
- Patients 18 years and older are considered adult. Patients under 18 as of arrival date will be rejected and required for submission to the pediatric sepsis data file.

Dataset Segment:	Demographic Variables
Data Element Name:	Discharge Datetime
Format – Length:	Datetime-16
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

The date and time the patient was discharged from the hospital, left against medical advice, or expired.

Codes and Values:

- Formatting:
 - 4. Format must be YYYY-MM-DD hh:mm
 - a. YYYY-MM-DDThh:mm is also valid
 - 5. YYYY = four-digit year
 MM = two-digit month (01=January, etc.)
 DD = two-digit day of month (01 through 31)
 hh = two digits of hour (00 through 23) (am/pm NOT allowed)
 mm = two digits of minute (00 through 59)
 - 6. Example: 11:42 pm November 3, 1959=1959-11-03 23:42
 - a. 1959-11-03T23:42 is also valid
 - 7. Midnight = 00:00, not 24:00
- Cannot precede 2014-04-01 00:00
- Cannot precede Admission Datetime
- If the time of death and administrative discharge datetimes are not the same, use the time of death for *Discharge Datetime*.
- For a patient who is discharged from one unit/department to another unit/department within the same facility, the <u>final discharge from the facility</u> is what should be reported for *Discharge Datetime*. Do not use discharges from internal transfers, since these are not actually separate hospital admissions the entire period should be submitted as one record. This is regardless of whether the internal transfers are billed separately.
- Hospitals are directed to report the date/time of death if this is earlier than the administrative discharge date.
- Discharge data sources to include; discharge summary, face sheet, nursing discharge notes, progress note or physician orders as per CMS guidelines.

- If there are multiple times documented when the patient was discharged from acute inpatient care or left AMA, use the earliest datetime.
- If the patient was discharged from acute inpatient care, left AMA, or transferred out to another facility, use the datetime the patient actually left, not the datetime the order was written

Dataset Segment:	Demographic Variables
Data Element Name:	Discharge Status
Format – Length:	Enumerated-2
SPARCS variable:	Yes
CMS SEP-1 variable:	No
Mandatory:	Yes

The code that best represents the patient's destination after discharge from the hospital.

Codes and Values:

- 01 = Discharge to Home or Self Care (Routine Discharge). Includes discharge to home; home on oxygen if DME only; any other DME only; group home, foster care, independent living and other residential care arrangements; outpatient programs, such as partial hospitalization or outpatient chemical dependency programs.
- 02 = Discharged/transferred to a Short-Term General Hospital for Inpatient Care
- 03 = Discharged/transferred to Skilled Nursing Facility (SNF) with Medicare Certification in anticipation of Skilled Care. Medicare indicates that the patient is discharged/transferred to a Medicare certified nursing facility. For hospitals with an approved swing bed arrangement, use Code 61 Swing Bed. For reporting other discharges/transfers to nursing facilities see 04 and 64.
- 04 = Discharged/transferred to a Facility that Provides Custodial or Supportive Care. This is used to designate patients that are discharged/transferred to a nursing facility with neither Medicare nor Medicaid certification and for discharges/transfers to Assisted Living Facilities.
- 05 = Discharged/transferred to a Designated Cancer Center or Children's Hospital.
- 06 = Discharged/transferred to Home under Care of Organized Home Health Service Organization in Anticipation of Covered Skilled Care. Report this code when the patient is discharged/transferred to home with a written plan of care (tailored to the patient's medical needs) for home care services. Not used for home health services provided by a DME supplier or from a Home IV provider for home IV services.
- 07 = Left against Medical Advice or Discontinued Care
- 09 = Admitted as an Inpatient to this Hospital-Patient admitted to the same short-term medical or specialty hospital where the hospital-based ambulatory surgery service was performed (excluding chronic disease hospitals).
- 20 = Expired
- 21 = Discharged/transferred to Court/Law Enforcement.
- 50 = Hospice Home
- 51 = Hospice Medical Facility (Certified) Providing Hospice Level of Care
- 61 = Discharged/transferred to Hospital-Based Medicare Approved Swing Bed

- 62 = Discharged/transferred to an Inpatient Rehabilitation Facility (IRF) including Rehabilitation Distinct Part Unit of a Hospital
- 63 = Discharged/transferred to a Medicare Certified Long Term Care Hospital (LTCH)
- 64 = Discharged/transferred to a Nursing Facility Certified under Medicaid but not certified under Medicare
- 65 = Discharged/transferred to a Psychiatric Hospital or Psychiatric Distinct Part Unit of a Hospital
- 66 = Discharged/transferred to a Critical Access Hospital (CAH)
- 69 = Discharged/transferred to a Designated Disaster Alternative Care Site
- 70 = Discharged/transferred to another Type of Health Care Institution not defined Elsewhere in this Code List
- 81 = Discharged to Home or Self Care with a Planned Acute Care Hospital Inpatient Readmission
- 82 = Discharged/transferred to a Short-Term General Hospital for Inpatient Care with a Planned Acute Care Hospital Inpatient Readmission
- 83 = Discharged/transferred to Skilled Nursing Facility (SNF) with Medicare Certification with a Planned Acute Care Hospital Inpatient Readmission
- 84 = Discharged/transferred to a Facility that Provides Custodial or Supportive Care with a Planned Acute Care Hospital Inpatient Readmission
- 85 = Discharged/transferred to a Designated Cancer Center or Children's Hospital with a Planned Acute Care Hospital Inpatient Readmission
- 86 = Discharged/transferred to Home under Care of Organized Home Health Service Organization with a Planned Acute Care Hospital Inpatient Readmission
- 87 = Discharged/transferred to Court/Law Enforcement with a Planned Acute Care Hospital Inpatient Readmission
- 88 = Discharged/transferred to a Federal Health Care Facility with a Planned Acute Care Hospital Inpatient Readmission
- 89 = Discharged/transferred to Hospital-Based Medicare Approved Swing Bed with a Planned Acute Care Hospital Inpatient Readmission
- 90 = Discharged/transferred to an Inpatient Rehabilitation Facility (IRF) including Rehabilitation Distinct Part Units of a Hospital with a Planned Acute Care Hospital Inpatient Readmission
- 91 = Discharged/transferred to a Medicare Certified Long Term Care Hospital (LTCH) with a Planned Acute Care Hospital Inpatient Readmission
- 92 = Discharged/transferred to a Nursing Facility Certified under Medicaid but not Certified under Medicare with a Planned Acute Care Hospital Inpatient Readmission
- 93 = Discharged/transferred to a Psychiatric Hospital or Psychiatric Distinct Part Unit of a Hospital with a Planned Acute Care Hospital Inpatient Readmission
- 94 = Discharged/transferred to a Critical Access Hospital (CAH) with a Planned Acute Care Hospital Inpatient Readmission

95 = Discharged/transferred to another Type of Health Care Institution not Defined Elsewhere in this Code List with a Planned Acute Care Hospital Inpatient Readmission

Dataset Segment:	Demographic Variables
Data Element Name:	Ethnicity
Format – Length:	Enumerated-1
SPARCS variable:	Yes
CMS SEP-1 variable:	No
Mandatory:	Yes

The code that best describes the ethnicity of the patient based on documentation.

Codes and Values:

- 1 = Spanish/Hispanic Origin
- 2 = Not of Spanish/Hispanic Origin
- 9 = Unknown

Dataset Segment:	Demographic Variables
Data Element Name:	Excluded Datetime
Format – Length:	Datetime-16
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Situational

The date and time that the person met the exclusion criteria (see excluded reason for acceptable reasons).

Codes and Values:

- Formatting:
 - 1. Format must be YYYY-MM-DD hh:mm
 - a. YYYY-MM-DDThh:mm is also valid
 - YYYY = four-digit year
 MM = two-digit month (01=January, etc.)
 DD = two-digit day of month (01 through 31)
 hh = two digits of hour (00 through 23) (am/pm NOT allowed)
 mm = two digits of minute (00 through 59)
 - 3. Example: 11:42 pm November 3, 1959=1959-11-03 23:42
 - a. 1959-11-03T23:42 is also valid
 - 4. Midnight = 00:00, not 24:00
- *Excluded Datetime* cannot have been after *Discharge Datetime*.
- If *Excluded from Protocol* = 1, then must be completed.
- If *Excluded from Protocol* = 0, then must be blank.

Dataset Segment:	Demographic Variables
Data Element Name:	Excluded Explain
Format – Length:	Set-7
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Situational

If the patient was excluded from the protocol/treatment due to a clinical contraindication to one or more of the bundle interventions, submit all interventions that were contraindicated.

Codes and Values:

- 1 = IV or IO fluids (acute, decompensated congestive heart failure, pulmonary edema and LVAD)
- 2 = IV or IO fluids (end stage renal disease with signs of fluid overload)
- 5 = Vasopressors or inotropes for refractory hypotension (significant, uncorrectable coagulation abnormalities)
- 6 = Vasopressors or inotropes for refractory hypotension (anatomic obstacles or limitations)

- Submit a number for each applicable intervention, separated by a colon.
- Example:
 - o 1:2:4 represent options 1, 2, and 4
 - <u>Each</u> number represents an intervention that was contraindicated.
- If *Excluded Reason* = 1, then a valid value must be reported, else must be blank.
- The above four intervention clinical contraindications are the only options that are currently being accepted by the Department for explaining exclusion. If none of the above is applicable, then exclusion due to clinical contraindication may not be reported.
 - For example, if a Physician/APN/PA medical note documents a physical exam at the time of the assessment that shows acute CHF with clinical signs of fluid overload and this Physician/APN/PA documents on the same medical note that they "will not fluid overload further" or "fluid resuscitation is contraindicated", this documentation qualifies for Value "1".
- Codes and Values 3 & 4 are intentional not present. They existed as options in a previous version of the dictionary.

Dataset Segment:	Demographic Variables
Data Element Name:	Excluded from Protocol
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Indicate if the patient was excluded from the sepsis protocol. Note that the exclusion must be in place before or during the treatment window to constitute an eligible exclusion.

Codes and Values:

0 = Patient was not excluded from the protocol

1 = Patient was excluded from the protocol

Notes for Abstraction:

- All data elements outside of adherence (i.e. Demographic, Severity Adjustment, and Comorbidity Variables) will have valid values.
- The four interventions for *Excluded Explain* are the only options that are being accepted by the Department for explaining exclusion due to clinical contraindication. If none are applicable, then exclusion from the protocol may not be reported.
- Exclusion criteria must be in place before or during the treatment window. **Example:**

If a sepsis protocol was started in the ED

- o And on the following day, the patient was made comfort care
- <u>Do not</u> report that the patient was excluded since the patient was not excluded during the six hour treatment window.

Dataset Segment:	Demographic Variables
Data Element Name:	Excluded Reason
Format – Length:	Set-7
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Situational

The code(s) that represents the reason the patient was excluded from the protocol. If interventions were clinically contraindicated, check the specific intervention(s) that were clinically contraindicated in the *Excluded Explain* variable. You may select more than one reason for excluding the patient from the protocol. The exclusion must be in place at the time in which the protocol would be initiated (i.e., before or during the treatment window).

Codes and Values:

- 1 = Interventions were clinically contraindicated
- 2 = Patient had advanced directives in place that precluded one or more elements of the protocol
- 3 = Patient, or surrogate decision maker, declined interventions
- 4 = Patient was enrolled in an IRB approved trial that was inconsistent with the protocol interventions

- If *Excluded from Protocol* = 1, *Excluded Reason* must be completed.
- If *Excluded from Protocol* = 0, *Excluded Reason* must be blank.
- If *Excluded Reason* = 1, then a valid value must be reported for *Excluded Explain*, else *Excluded Explain* will be blank.
- If Excluded from Protocol = 0, Excluded Reason must be blank.
- If reporting multiple exclude reason codes, use one field and separate using a colon, e.g. "1:3". Remember that when *Excluded Reason* = 1 (even if it is one of multiple reasons selected), then data element *Excluded Explain* must be completed.
- If the patient met the clinical contraindication criteria and there was clear documentation in the record at the time of treatment for severe sepsis/septic shock that they were excluded from your institution's protocol as a result of this contraindication, that contraindication would be submitted.
 - The four interventions for *Excluded Explain* are the only options that are being accepted by the Department for explaining exclusion due to clinical contraindication. If none are applicable, then exclusion due to clinical contraindication may not be reported.

- If the patient had advanced directives or a DNR in place prior to (or at) the development of severe sepsis or septic shock that precluded one or more elements of the protocol, then the protocol is not reported/patient is excluded from the protocol but the case must be submitted to the portal.
 - <u>Note: Palliative Care Order</u> by itself does NOT exclude patient from sepsis protocol. Medical record needs to have explicit documentation that patient has advanced directives in place that precluded one or more elements of the protocol (Value "2") OR patient, or surrogate decision maker, declined interventions (Value "3").
- All other data elements (i.e. Demographic, Severity Adjustment, and Comorbidity Variables) will have valid values.
- If a patient met acceptable exclusion criteria, then documentation of that reason by a physician, advanced practice nurse, or physician assistant will need to be present in the medical records. Be sure to report all case(s), including excluded cases to the portal. These cases may be used in annual risk-adjusted modeling.

Dataset Segment:	Demographic Variables
Data Element Name:	Facility Identifier
Format – Length:	Varchar -6
SPARCS variable:	Yes
CMS SEP-1 variable:	No
Mandatory:	Yes

This number is the facility's four to six digit Permanent Facility Identifier (PFI) assigned by the Department of Health.

Department regulations state that services must be reported under the physical location where they are provided. Common ownership of different facilities does not change this requirement.

Codes and Values:

- Must be a valid number as maintained by the NYSDOH Division of Health Facility Planning.
- Must contain numbers 0-9.

Dataset Segment:	Demographic Variables
Data Element Name:	Gender
Format – Length:	Enumerated-1
SPARCS variable:	Yes
CMS SEP-1 variable:	No
Mandatory:	Yes

The gender of the patient.

Codes and Values:

M = Male F = Female U = Unknown

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Dataset Segment:	Demographic Variables
Data Element Name:	Insurance Number
Format – Length:	Varchar-19
SPARCS variable:	Yes
CMS SEP-1 variable:	No
Mandatory:	Yes

The insurance policy identification number for the patient.

Codes and Values:

Notes for Abstraction:

- Allow blanks only if Element Payer is not Medicare ("C"), Medicaid ("D"), Insurance Company ("F"), or Blue Cross ("G").
- Must be numeric (0-9) and/or alphabetic (a-z, A-Z).
- Special characters are invalid entries.

Facilities are directed to enter the following values:

Payer	Type of Number
Blue Cross	Enter the information depending on specific Blue Cross Plan needs and contract requirement.
CHAMPUS	Enter the information depending on CHAMPUS regulations.
Medicaid	Enter Medicaid Client Identification Number (CIN) of the insured or case head Medicaid number shown on the Medicaid Identification Card.
Medicare	Enter the patient's Medicare HIC number as shown on the Health Insurance Card, Certificate of Award, Utilization Notice, Temporary Eligibility Notice, and Hospital Transfer Form or as reported by the Social Security Office.

For all other payer types, commercial Insurers, etc., enter the insured's unique number assigned by the payer.

Dataset Segment:	Demographic Variables
Data Element Name:	Medical Record Number
Format – Length:	Varchar-17
SPARCS variable:	Yes
CMS SEP-1 variable:	No
Mandatory:	Yes

The number used by the hospital's Medical Records Department to identify the patient's permanent medical record file. This number is not the same as the Patient Control Number.

Codes and Values:

- Must not equal zero or blanks.
- Must be numeric (0-9) and/or alphabetic (a-z, A-Z).
- Special characters are invalid entries.

Dataset Segment:	Demographic Variables
Data Element Name:	Patient Control Number
Format – Length:	Varchar-20
SPARCS variable:	Yes
CMS SEP-1 variable:	No
Mandatory:	Yes

A patient's unique number assigned by the provider to facilitate retrieval of individual financial and clinical records and posting of payment.

Codes and Values:

- Must not equal zero or blanks.
- Must be numeric (0-9) and/or alphabetic (a-z, A-Z).
- Special characters are invalid entries.

Dataset Segment:	Demographic Variables
Data Element Name:	Payer
Format – Length:	Enumerated -1
SPARCS variable:	Yes
CMS SEP-1 variable:	No
Mandatory:	Yes

The code that indicates the primary payer for this hospitalization.

Codes and Values:

- A = Self-Pay
- B = Workers' Compensation
- C = Medicare
- D = Medicaid
- E = Other Federal Program
- F = Insurance Company
- G = Blue Cross
- H = CHAMPUS
- I = Other Non-Federal Program
- J = Disability
- K = Title V
- L = Unknown

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Dataset Segment:

Demographic Variables

Data Element Name:	Pregnancy Status
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Description:

The patient's documented pregnancy/postpartum status during the sepsis episode.

Codes and Values:

- 1 = Patient was pregnant at severe sepsis/septic shock presentation.
- 2 = Patient was 0-42 days postpartum at severe sepsis/septic shock presentation.
- 3 = Patient was 0-42 days post spontaneous abortion or induced abortion at severe sepsis/septic shock presentation.
- 4 = Patient was not pregnant, postpartum or post spontaneous abortion/induced abortion at severe sepsis/septic shock presentation.
- 5 = Unable to determine

- Select "1" if there is documentation that patient is pregnant or there is a positive pregnancy test at severe sepsis/septic shock presentation in the medical record.
- Select "2" if there is documentation in the medical record that the patient presents with severe sepsis/septic shock after delivery on same day as delivery up to 42 days post-delivery. Include deliveries of live births and stillbirths (gestational age ≥ 20 weeks).
- Select "3" if there is documentation in the medical record that the patient presents with severe sepsis/septic shock after spontaneous abortion (gestational age < 20 weeks) or induced abortion. Include ectopic pregnancies and spontaneous fetal loss of uncertain gestational age in this selection.
- Select "4" if there is no documentation in the medical record that the patient is pregnant, 0-42 days post spontaneous abortion, induced abortion or delivery at severe sepsis/septic shock presentation. Select "4" for males.
- Select "5" if patient is postpartum, post-spontaneous abortion or post-induced abortion but number of days post procedure or post-delivery is not documented.

Dataset Segment:	Demographic Variables
Data Element Name:	Race
Format – Length:	Set-47
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

The code that best describes the race of the patient based on documentation.

Codes and Values:

- 01 = White
- 02 = African American (Black)
- 03 = Native American (American Indian/Eskimo/Aleut)
- 41 = Asian Indian
- 42 = Chinese
- 43 = Filipino
- 44 = Japanese
- 45 = Korean
- 46 = Vietnamese
- 49 = Other Asian
- 51 = Native Hawaiian
- 52 = Samoan
- 53 = Guamanian or Chamorro
- 59 = Other Pacific Islander
- 88 = Other Race
- MR = Multi-racial

Notes for Abstraction:

• If reporting multiple race codes, use one field and separate using a colon, e.g. "01:41"

Dataset Segment:	Demographic Variables
Data Element Name:	Sepsis Identification Place
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

The code that best represents where the severe sepsis or septic shock was first identified.

Codes and Values:

- 1 = Severe sepsis or Septic Shock was identified in the Emergency Department
- 2 = Severe sepsis or Septic Shock was identified on an inpatient floor (not ICU)
- 3 = Severe sepsis or Septic Shock was identified in the ICU
- 4 = Severe sepsis or Septic Shock was identified in the observation unit
- 5 = Severe sepsis or Septic Shock was identified in an outpatient setting prior to hospital arrival, e.g., clinic or dialysis facility

- Must be completed.
- If the patient has severe sepsis and septic shock then the place of identification will align with severe sepsis.
 - Regardless of where the sepsis diagnosis is made in the acute care setting (e.g., ED, ICU, floor, procedure unit, etc.), all variables are to be reported, unless the patient was excluded from the protocol.

Dataset Segment:	Demographic Variables
Data Element Name:	Source of Admission
Format – Length:	Enumerated-1
SPARCS variable:	Yes
CMS SEP-1 variable:	No
Mandatory:	Yes

The code that best describes the patient's origin before coming to the hospital.

Codes and Values:

- 1 = Non-Health Facility Point of Origin-The patient was admitted to this facility from home or from an assisted living facility.
- 2 = Clinic-The patient was referred to this facility as a transfer from a freestanding or nonfreestanding clinic.
- 4 = Transfer from a Hospital (Different Facility)-The patient was admitted to this facility as a hospital transfer from an acute care facility where he or she was an inpatient or outpatient.
- 5 = Transfer From a Skilled Nursing Facility (SNF) or Intermediate Care Facility (ICF)-The patient was admitted to this facility as a transfer from a SNF or ICF where he or she was a resident.
- 6 = Transfer From Another Health Care Facility-The patient was admitted to this facility as a transfer from another type of health care facility not defined elsewhere in this code list.
- 8 = Court/Law Enforcement- The patient was admitted to this facility upon the direction of a court of law, or upon the request of a law enforcement agency representative.
- 9 = Information Not Available-The means by which the patient was admitted to this hospital was not known.
- E = Transfer from Ambulatory Surgery Center-The patient was admitted to this facility as a transfer from an ambulatory surgery center.
- F = Transfer from Hospice and is Under a Hospice Plan of Care or Enrolled in a Hospice Program- The patient was admitted to this facility as a transfer from a hospice.

- If a patient is moved from one area of the hospital to another i.e., from the Emergency Department to the ICU the patient is not considered a transfer. Only if the patient is moved between different hospitals, with discharge and admission at each location, and separate billing from each location, is the case considered a transfer.
- Assisted Living is reported as Non-Health Facility Point of Origin.

Data Element Name:	Transfer Facility Identifier
Format – Length:	Varchar -6
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Situational

Demographic Variables

Description:

Dataset Segment:

This number is the transfer sending or transfer receiving facility's four to six digit Permanent Facility Identifier (PFI) assigned by the Department of Health. If you received the patient in severe sepsis or septic shock, report the sending hospital's PFI. If you are transferring the patient in severe sepsis or septic shock, report the receiving hospital's PFI.

Department regulations state that services must be reported under the physical location where they are provided. Common ownership of different facilities does not change this requirement.

Codes and Values:

Notes for Abstraction:

- Must be a valid number as maintained by the NYSDOH Division of Health Facility Planning.
- Must contain numbers 0-9.
- Must be completed if *Transfer Status* is reported as a value of 3, 4, or 5.
- Must be blank if *Transfer Status* is reported as a value of 1 or 2.
- When transferring a patient to or from an out of state facility, please submit the two digit state identifier (<u>http://www.census.gov/geo/reference/ansi_statetables.html</u>) to represent the transfer facility state. This is ONLY to be used when patients are transferred in/out of state therefore the code for New York will not be accepted for data submission. For example, a patient transferred to a Connecticut hospital is submitted with the Transfer Facility Identifier of 09.

To find a hospital PFI, please visit:

http://www.health.ny.gov/statistics/sparcs/reports/compliance/alpha_facilities.htm

Dataset Segment:Demographic VariablesData Element Name:Transfer StatusFormat – Length:Enumerated-1SPARCS variable:NoCMS SEP-1 variable:NoMandatory:Yes

Description:

The code that best represents the patient's acute care transfer status.

Codes and Values:

- 1 = Not a Transfer Patient was <u>neither</u> admitted as a transfer nor discharged as a transfer to/from a different acute care hospital.
- 2 = Transfer without Severe Sepsis or Septic Shock (SS) Patient was admitted as a transfer or discharged as a transfer to/from a different acute care hospital but **did not have** Severe Sepsis or Septic Shock (SS) as primary diagnosis or reason for transfer.
- 3 = Admission Transfer with SS Patient was admitted (admitted = sent to ED or directly admitted as inpatient to floor or ICU) as a transfer from a different acute care hospital with SS. Note: You will need to enter the PFI of the sending hospital.
- 4 = Discharged Transfer with SS No Protocol Patient was **transferred** from this hospital to a different acute care hospital with SS, <u>and</u> the hospital's sepsis protocol was <u>not initiated</u> prior to transfer to the receiving acute care hospital. *Note: You will need to enter the PFI of the receiving hospital.*
- 5 = Discharged Transfer with SS Initiated Protocol Patient was **transferred** from this hospital to a different acute care hospital with SS, <u>and</u> the hospital's sepsis protocol was <u>initiated or</u> <u>completed</u> prior to transfer to the receiving acute care hospital. *Note: You will need to enter the PFI of the receiving hospital.*

- Internal consistency requirement: source of admission and/or discharge status must align with a transfer status designation.
- Hospitals are expected to report all cases of severe sepsis or septic shock regardless of transfer status.
- Both the transferring and receiving hospitals are responsible for collecting and reporting all of the data elements, including demographics, adherence, severity adjustment, and comorbidity variables.

- Data from both institutions may be linked (by NYSDOH/IPRO) for outcomes and adherence measures reporting. It is understood that the hospital may not have data on all elements, but it is expected to report on the data that's available for each hospital.
- Be sure that you are submitting the full care for the severe sepsis or septic shock episode, regardless of the hospital unit to which the patient may have presented during the stay. For example, if the severe sepsis was identified and treatment initiated in the psychiatric unit of your hospital, then you also want to report the care provided in that unit in addition to the continued care in a different unit of the same hospital. The entire period should be submitted as one record regardless of whether the treatments in the separate units are billed separately.
- Out of state transfers are to be reported, and instructions for doing so are found under *Transfer Facility Identifier.*
- If a patient is moved from one area of the hospital to another i.e., from the Emergency Department to the ICU the patient is not considered a transfer. Only if the patient is moved between different hospitals, with discharge and admission at each location, and separate billing from each location, is the case considered a transfer.

To find a hospital PFI, please visit:

http://www.health.ny.gov/statistics/sparcs/reports/compliance/alpha_facilities.htm

Dataset Segment:	Demographic Variables
Data Element Name:	Triage Datetime
Format – Length:	Datetime-16
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Situational

The date and time that the triage assessment of the patient was <u>started</u>. This is to be reported even if the patient developed sepsis on the floor. This will only be blank if a patient was a direct admission and did not come through the ED at any point.

Codes and Values:

- Formatting:
 - 1. Format must be YYYY-MM-DD hh:mm
 - a. YYYY-MM-DDThh:mm is also valid
 - YYYY = four-digit year
 MM = two-digit month (01=January, etc.)
 DD = two-digit day of month (01 through 31)
 hh = two digits of hour (00 through 23) (am/pm NOT allowed)
 mm = two digits of minute (00 through 59)
 - 3. Example: 11:42 pm November 3, 1959=1959-11-03 23:42
 - a. 1959-11-03T23:42 is also valid
 - 4. Midnight = 00:00, not 24:00
- Cannot have been after *Discharge Datetime*.
- NOTE: This is asking for the **start** of the triage assessment, not the datetime of its completion.
- If a patient was a direct admission, this data element will not be reported. If the patient developed sepsis on the floor but at some previous point arrived through the ED, *Triage Datetime* is to be reported.
- The Triage Datetime is referring to the start or initiation of the triage assessment process in the ED.

Dataset Segment:	Demographic Variables
Data Element Name: Format – Length:	Unique Personal Identifier Varchar-10
SPARCS variable:	Yes
CMS SEP-1 variable:	No
Mandatory:	Yes

A composite field comprised of portions of the patient last name, first name, and social security number.

Included below are the individual components of this data element.

- "First 2" and "Last 2" characters of the Patient's Last Name. The birth name of the patient is preferable if it is available on the facility's information system.
- "First 2" characters of the Patient's First Name.
- "Last 4" digits of the Patient's Social Security Number.

Joe Tan with Social Security Number 123-456-7890 would be reported as TAANJO7890

NOTE: This data element is not to be confused with *Patient Control Number*, which provides linkage of all record types containing patient-related data for a specific discharge.

First and Last Name Components: Must be <u>UPPERCASE</u> alphabetic characters. If the last name is less than 4 characters, the first two and last two characters are used even if some characters are repeated.

Included below are examples of how to report some unusual scenarios. A three character last name, a two character last name, a name with junior, a one character first name, a last name with an apostrophe, and a hyphenated last name.

- Joe Tan would be reported as TAANJO
- Bill Su Jr. would be reported as SUSUBI
- E John Smith would be reported as SMTHEE
- Bob O'Brien would be reported as OBENBO
- Sue Jones-Davis would be reported as JOISSU

Social Security Number Component: Must be numeric. If no Social Security Number is available, this sub-field must be zeroes e.g. TAANJO0000

Adherence Variables

Dataset Segment:	Adherence Variables
Data Element Name:	Adult Crystalloid Fluid Administration
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Situational

This variable has been aligned with the CMS SEP-1 data element Crystalloid Fluid Administration. Please use the information from CMS's data element for submission of *Adult Crystalloid Fluid Administration*. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable.

Definition: Documentation of initiation of crystalloid fluids within the specified time frame AND complete infusion of the target ordered volume.

Crystalloid fluid volumes ordered that are equivalent to 30 mL/kg or within 10% less than 30 mL/kg are considered the target ordered volume.

Codes and Values:

- 1= (Yes) Target volume of crystalloid fluids were ordered AND initiated within the specified time frame. Additionally, the target ordered volume was completely infused.
- 2 = (No) Less than the target volume of crystalloid fluids were ordered OR initiated within the specified time frame. The target ordered volume was not completely infused.
- 3= (No) The target volume of crystalloid fluids was NOT initiated within the specified time frame, or Unable to Determine.
- 4= (No) There is documentation the patient has an implanted Ventricular Assist Device (VAD) OR documentation of the patient or authorized patient advocate refusal of IV fluids.

- The specified time frame for abstraction of crystalloid fluids is within 6 hours prior through 3 hours after either of the following trigger events. If both are present the specified time frame is determined by the earliest trigger.
 - Initial Hypotension Date and Time
 - Septic Shock Presentation Date and Time
- The target ordered volume must be ordered and initiated within the specified time frame if Initial Hypotension or Septic Shock is present. Additionally, in order to choose Value "1," the target ordered volume must be documented as completely infused. The target ordered

volume is NOT required to be completely infused within the specified time frame. If the target ordered volume is not completely infused, choose Value "2."

- Must be completed if Septic Shock Present = 1 or Initial Hypotension = 1 and patient >=18 years old.
- If Adult Crystalloid Fluid Administration = 1 AND Septic Shock Present = 1 AND Persistent Hypotension = 1 or 2, then Repeat Volume Status and Tissue Perfusion Assessment Performed must be completed.
- Crystalloid fluid volumes ordered that are equivalent to 30 mL/kg or within 10% less than 30 mL/kg are considered the target ordered volume.

Example:

2000 mL of normal saline was ordered and initiated in the ED. The patient's weight is not available or documented at the time of the order. After admission to critical care a weight is obtained of 74 kg. Based on this weight 30 mL/kg is 2220 mL. The 2000 mL ordered is within 10% lower of 2220 mL (2220 mL – 222 mL = 1998 mL) and is an acceptable volume.

- To determine the target ordered volume: o Use the patient weight in kilograms (kg) if documented.
 - If not documented, divide the weight in pounds by 2.2; that yields the weight in kg. Round the weight to the nearest whole number.
 - Multiply the weight in kg by 30; the result is the number of mL of IV fluid that should be specified in the physician/APN/PA order(s).
 - Round the volume of IV fluid (mL) to the nearest whole number. **Examples**:
 - Patient weight is 160 pounds. 160/2.2 = 72.72 kg. Round to 73 kg. 73 x 30 = 2190 (mL). Physician order is "Infuse 2400 mL 0.9% Normal Saline over the next two hours." This is acceptable because 2400 mL is greater than 2190.
 - Patient weight is 160 pounds. 160/2.2 = 72.72 kg. Round to 73 kg. 73 x 30 = 2190 (mL). Physician order is "Give 1000 mL Lactated Ringers over the next 4 hours." This is not acceptable because 1000 mL is less than 2190.
- To calculate the appropriate target ordered volume use the actual or estimated weight in the following priority order.
 - 1. Weight documented in the crystalloid fluid order
 - 2. Weight documented closest and prior to the order for crystalloid fluids
 - 3. Weight documented closest and after the order for crystalloid fluids
- Physician/APN/PA can use Ideal Body Weight (IBW) to determine the target ordered volume if all of the following conditions are met:
 - Physician/APN/PA documents the patient is obese (defined BMI >30).
 - Physician/APN/PA documents IBW is used to determine target ordered volume.
 - IBW must be present in the medical record, abstractors should not calculate the IBW.
- Other acceptable weight terms include predicted weight, dosing weight, and adjusted body weight.
- If the total volume of crystalloid fluids ordered is less than the target ordered volume, select Value "2."

- If there is documentation the infusion was stopped prior to reaching the target ordered volume, select Value "2."
- Documentation of fluid initiation:
 - Medical record documentation must be clear that crystalloid fluids were actually initiated (i.e., date and time of administration is noted).
 - Do not use physician/APN/PA orders as equivalent to actual initiation of fluids as they are not specific to initiation.
- Crystalloid fluid orders:
 - Physician/APN/PA orders are required for the fluids.
 - The order must include the type of fluid, the volume of fluid, and a rate or time over which the fluids are to be given.
 - The terms bolus, wide-open, or open are acceptable for a rate or infusion duration.
 - If the type of fluid, volume of fluid, rate or infusion duration is missing, do not use the order toward the target ordered volume.
 - The target ordered volume may be in a single order or a series of multiple orders. o
 - If crystalloid fluids are initiated via multiple physician/APN/PA orders, only abstract crystalloid fluids initiated within the specified time frame.
- Exception for Prior to Arrival: Documentation of crystalloid fluids administered prior to arrival to the hospital (e.g., ambulance, nursing home) that are part of the medical record are acceptable if the documentation of fluid administration contains the type, volume, start time, and either a rate, duration, or end time of the fluid infusion. A physician/APN/PA order for fluids administered prior to arrival is not required.
- Exception for Operating Room (OR): Crystalloid fluids administered in the OR by a physician/APN/PA are acceptable without an order if a fluid type, an infusion start time, and an infusion rate or infusion end time is documented.
- To determine if the target ordered volume was completely infused, one of the following must be documented along with the infusion start time. If one of the following is not documented, do not use the fluids toward the target ordered volume:
 - o An infusion rate
 - o Infusion duration or time over which to infuse
 - Infusion end or completion time

Examples:

- Order for 1500 mL (30 mL/kg) of normal saline over 1 hour started at 08:00. There is no infusion end time documented, and no documentation indicating the 1500 mL was not infused. The infusion end time can be determined based on the duration in the order. Select Value "1."
- Order for 1000 mL (30 mL/kg) normal saline bolus started at 09:30. The nurse documented an infusion rate of 1000 mL/hour. There is no fluid bolus end time documented, and no documentation indicating the 1000 mL was not infused. The infusion end time can be determined based on the rate. Select Value "1."
- Order for 2000 mL (30 mL/kg) normal saline bolus started at 08:30. There is no infusion rate documented and no fluid bolus end time documented. An infusion end time cannot be determined. Choose Value "2."

• If a rate or duration to infuse fluids contained within the order is different from the rate or duration the fluids were actually administered, use the rate or duration the fluids were actually administered over.

Example:

- Fluid Order: 0.9% NS 1000 mL bolus at 150 mL/hrNurse documents a start time of 1500 and end time of 1800 for the 1000 mL bolusUse the start and stop time documented by nursing that reflects the duration over which the fluids were actually administered.
- Only those crystalloid fluids given at a rate greater than 125 mL/hour should be used towards the target ordered volume. Do not use crystalloid fluids given at 125 mL/hr or less toward the target ordered volume.
- Acceptable fluids are crystalloid or balanced crystalloid solutions.
 - Crystalloid fluids or balanced crystalloid fluids that are given to dilute medications may be used toward the target ordered volume. If the volume infused without dilution fluids is the same as the target ordered volume, fluids used for diluting medications do not need to be counted.
 - Crystalloid fluid volumes to which the following electrolytes have been added may be counted toward the target ordered volume requirement: potassium, magnesium, calcium, lactate, acetate, or gluconate.
- Only abstract fluids administered through the intravenous or intraosseous route.
- If there is documentation that the patient has an implanted ventricular assist device (VAD) prior to or at the time of identifying need for crystalloid fluids, choose Value "4" regardless of the volume and rate of crystalloid fluids ordered.
- Physician/APN/PA or nursing documentation indicating patient or authorized patient advocate has refused IV fluid administration prior to or within 6 hours following presentation of septic shock can be used to select Value "4."

Suggested Data Sources:

- o Ambulance or transport vehicle records
- o Entire ED record
- Input and Output (I&O) flowsheet
- o IV therapy record
- o Medication Administration Record
- Patient weight record
- Physician/APN/PA orders

Inclusion Guidelines for Abstraction:

- o 0.9% saline solution
- o 0.9% Sodium Chloride Solution
- o Isolyte
- Lactated Ringers Solution
- o normal saline
- o Normosol
- o PlasmaLyte

Exclusion Guidelines for Abstraction:

o Crystalloid solutions that are given to flush other medications or IV lines

Dataset Segment:	Adherence Variables
Data Element Name:	Antibiotic Administration
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Situational

This variable has been aligned with the CMS SEP-1 data element Broad Spectrum or Other Antibiotic Administration. Please use the information from that data element for submission of *Antibiotic Administration*. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable.

Definition: Documentation of administration of a broad spectrum or other antibiotic in the time window 24 hours prior to or 3 hours after *Severe Sepsis Presentation Date and Time*. **Codes and Values:**

- 1 = (Yes) A broad spectrum or other antibiotic was administered intravenously in the time window 24 hours prior to or 3 hours following the presentation of severe sepsis.
- 2 = (No) No antibiotic was administered intravenously in the time window 24 hours prior to or3 hours following the presentation of severe sepsis, or unable to determine.

- If *Antibiotic Administration* = 1, then *Antibiotic Administration Selection* must be completed.
- If *Excluded from Protocol* = 1, may be blank, else must be completed.
- Only IV antibiotic administered in the 24 hours prior to or 3 hours after severe sepsis presentation is acceptable.
 - **EXCEPTION:** If there is documentation indicating IV access could not be established, antibiotics administered via intramuscular (IM) or intraosseous (IO) started in the 24 hours prior to or 3 hours after the severe sepsis presentation is acceptable to select Value "1."
- If no antibiotic was started within the 24 hours preceding or 3 hours following the Severe Sepsis Presentation Date and Time, choose Value "2."
- Antibiotic administration information should only be abstracted from documentation that demonstrates actual administration of the antibiotic (i.e., antibiotic name, route, date and time).
- A physician/APN/PA order for antibiotics is not sufficient unless the antibiotic ordered was marked as "started" with date/time noted.

• Do not collect antibiotics documented on an operative report unless the surgeon states that the surgeon actually administered the dose.

Suggested Data Sources:

Anesthesia record Entire Emergency Department record ICU flow sheet IV flow sheet Medication administration record Nurses notes Operating room record PACU/recovery room record Perfusion record Physician/APN/PA notes Pre-arrival documentation that is part of the medical record

Inclusion Guidelines for Abstraction:

Antibiotic administered via intravenous route Intramuscular or IM Intraosseous or IO Intravenous IV Bolus IV infusion

Exclusion Guidelines for Abstraction:

Give antibiotic stat Hang antibiotic Order for xx antibiotic

Dataset Segment:	Adherence Variables
Data Element Name:	Antibiotic Administration Datetime
Format – Length:	Datetime-16
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Situational

This variable has been aligned with the CMS SEP-1 data elements Broad Spectrum or Other Antibiotic Administration Date and Broad Spectrum or Other Antibiotic Administration Time. Please use the combination of those data elements for submission of *Antibiotic Administration Datetime*. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable.

Definition: The earliest datetime on which an antibiotic was started in the time window of 24 hours preceding or 3 hours after *Severe Sepsis Presentation Date and Time*.

Codes and Values:

- Formatting:
 - 1. Format must be YYYY-MM-DD hh:mm
 - a. YYYY-MM-DDThh:mm is also valid
 - 2. YYYY = four-digit year
 - MM = two-digit month (01=January, etc.)
 - DD = two-digit day of month (01 through 31)
 - hh = two digits of hour (00 through 23) (am/pm NOT allowed)
 - mm = two digits of minute (00 through 59)
 - 3. Example: 11:42 pm November 3, 1959=1959-11-03 23:42
 - a. 1959-11-03T23:42 is also valid
 - 4. Midnight = 00:00, not 24:00
- If Antibiotic Administration = 1, then must be completed.
- If Antibiotic Administration is blank or contains a value of 2, then must be blank.
- If *Blood Culture Collection Acceptable Delay* = 1, then must be completed.
- Cannot have been after *Discharge Datetime*.
- If one or more antibiotic was started within 24 hours prior to severe sepsis presentation, and none of those same antibiotics were started more than 24 hours prior to presentation; and/or If antibiotic(s) was administered both 24 hours prior to and within 3 hours after severe sepsis presentation, THEN abstract the earliest date and time that the antibiotic was started.

- This may be the same date as the date of presentation or may be a date any time before presentation.
- Do not review for antibiotic doses started more than 72 hours prior to severe sepsis presentation.
- If one or more antibiotic was started within the 3 hours after severe sepsis presentation, and the patient did not receive an antibiotic in the 24 hours before severe sepsis presentation, abstract the dose started closest to severe sepsis presentation.
- Do not cross reference between different sources to infer that an antibiotic was started if it was documented only with name/date/time given but no route indicated. The route on the MAR for an antibiotic cannot be used as the route for a dose of the same antibiotic on another form.
- If the antibiotic name, route, date or time is missing, disregard that dose.
- Antibiotic administration information should only be abstracted from documentation that demonstrates actual administration of the specific antibiotic within the time window of 24 hours prior to or 3 hours following the presentation of severe sepsis.

Examples:

- A physician order for IV antibiotics is not sufficient unless the antibiotic ordered was marked as "started" with date/time noted.
- Do not collect antibiotics documented on an operative report unless the surgeon states that the surgeon actually administered the dose.
- Specific documentation by one person that another person administered the antibiotic is acceptable for determining the date and time of administration.

Example:

- OR nurse, S. Smith RN, documents, "Cefazolin 1 gm IV given on 1/7/20xx at 0500 per J Doe RN." This dose can be abstracted as given if not documented by the person that gave the dose.
- The method of designation of administration on hand-written or pre-printed forms such as MARs or eMARs, with pre-printed scheduled times for administration, must be clearly designated as started. The methods may vary. Whatever method is used, it must be clear that the dose was administered.
- Do not abstract test doses of antibiotics.
- Do not abstract antibiotics from sources that do not represent actual administration. **Examples** that *do not* represent actual administration:
 - Pre-Op Checklist states:
 - X IV Started at 1730
 - X Preop Antibiotic Given at 1800
 - X Lab on Chart
 - Operative report states: IV antibiotics were given prior to procedure.
- Do not abstract antibiotics from narrative charting unless there is no other documentation that reflects that the same antibiotic was started during the specified time frame.
 - Example:

Narrative states: "Ancef 1 gram given IV prior to incision." No other doses of Ancef are documented. The dose in the narrative should be abstracted using UTD for missing data (no date and time).

Pre-hospital records (e.g., ambulance records, nursing home records) that are considered part of the medical record should be used for abstracting antibiotics.

Suggested Data Sources:

- Anesthesia record
- Entire Emergency Department record
- ICU flow sheet
- IV flow sheet
- Medication administration record
- Nurses notes
- Operating room record
- PACU/recovery room record
- Perfusion record
- Physician/APN/PA notes
- Pre-arrival documentation that is part of the medical record

Inclusion Guidelines for Abstraction:

- Antibiotic administered via intravenous route
- Intramuscular or IM
- Intraosseous or IO
- Intravenous
- •IV Bolus
- •IV infusion

Exclusion Guidelines for Abstraction:

- Give antibiotic stat
- Hang antibiotic
- Order for xx antibiotic

Examples:

Examples.						
More than 24 hours Before Presentation (Max. lookback 72 hrs.)		ours B esenta		Severe Sepsis	3 Hours After Presentation	
	<u>A</u>	Α	Α			First dose of A
	<u></u>	С	С			Antibiotic B
G	<u>A</u>	Α	Α			First dose of A
<u>B</u>	В	}	В			First dose of B
<u></u>	D	С	С			First dose of C

 If one or more antibiotic was started within the 3 hours after presentation of severe sepsis, and the patient did not receive an antibiotic in the 24 hours before severe sepsis presentation, abstract the dose started closest to severe sepsis presentation.

Examples:

More than 24 hours Before Presentation (Max. lookback 72 hrs. from presentation)	24 hours Before Presentation	Severe Sepsis	3 Hours After Presentation	Antibiotic Dose to Abstract
E			<u>L</u>	Antibiotic L
V			KA	Dose of K in 3

If antibiotics were administered both 24 hours prior to and within 3 hours after the time of presentation of severe sepsis, abstract the earliest date and time that an antibiotic in the 24 hours prior was started. This may be the same date as the date of presentation or may be a date any time before presentation. Do not review for antibiotic doses started more than 72 hours prior to severe sepsis presentation.

More than 24 hours Before Presentation (Max. lookback 72 hrs. from presentation)	24 hours Before Presentation		Severe Sepsis	3 Hours After Presentation	Antibiotic Dose to Abstract
	<u>D</u>	D		D	First dose of D
		<u>E</u>		F	Antibiotic E
<u>E</u>	E	E		L	First dose of E
м	<u>A</u> B	А		м	First dose of A
<u>M</u>	A B M	Α		М	First dose of M

Stop abstracting 3 hours after the presentation of severe sepsis.

 If no antibiotic was started in the 24 hours before or 3 hours after the severe sepsis presentation, enter "UTD."

Dataset Segment:	Adherence Variables
Data Element Name:	Antibiotic Administration Selection
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Situational

This variable has been aligned with the CMS SEP-1 data element Broad Spectrum or Other Antibiotic Administration Selection. Please use the information from that data element for submission of *Antibiotic Administration Selection*. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable.

Definition: The selection of the antibiotic administered within 3 hours following *Severe Sepsis Presentation Date and Time*.

Codes and Values:

- 1 = (Yes) The IV antibiotic that was given within 3 hours following the presentation of severe sepsis is consistent with antibiotic selection guidelines.
- 2 = (No) The IV antibiotic that was given within 3 hours following the presentation of severe sepsis is **not** consistent with antibiotic selection guidelines, or Unable to Determine

Notes for Abstraction:

- If *Antibiotic Administration* = 1, then this must be completed. If *Antibiotic Administration* = 2 or is blank, then this must be blank or contain a value of 2.
- Only IV antibiotic(s) administered within 3 hours after the Severe Sepsis Presentation Time is acceptable.

EXCEPTION:

If there is documentation indicating IV access could not be established, antibiotics administered via intramuscular (IM) or intraosseous (IO) started within 3 hours after the *Severe Sepsis Presentation Time* are acceptable to select Value "1."

- Antibiotic administration information should only be abstracted from documentation that demonstrates actual administration within the appropriate timeframe.
- If there is one antibiotic started within 3 hours after presentation of severe sepsis that is on the monotherapy table in Appendix C, Table 5.0, choose Value "1."
- If the administered antibiotics were NOT on Table 5.0, determine if the antibiotics are on Table 5.1 in Appendix C (see table attached).
 - Determine the class the administered antibiotics belong to, based on the class name in the shaded row above the antibiotic names.

- Next, refer to the following Combination Antibiotic Therapy Table to determine if an antibiotic from a class in both Column A and Column B were given.
- There must be at least one from a class in column A and at least one from a class in column B administered to select Value "1."
- Review the chart to see that both drugs were started within 3 hours of severe sepsis presentation and if so, choose Value "1." If both drugs were not started within 3 hours, choose Value "2."

Example:

Severe Sepsis Presentation Time 1200

Ciprofloxacin initiated at 1230

Vancomycin initiated at 1330

Combination Antibiotic Therapy Table:

Ciprofloxacin is in column A

Vancomycin is in column B

Both antibiotics were initiated within 3 hours of the Severe Sepsis Presentation Time, therefore value "1" should be selected

Combination Antibiotic Therapy Table

Column A		Column B
Aminoglycosides	+	Cephalosporins (1st and 2nd Generation)
OR		OR
Aztreonam OR		Clindamycin IV OR
Ciprofloxacin		Daptomycin OR
		Glycopeptides OR
		Linezolid OR
		Macrolides OR
		Penicillins

- If IV antibiotic(s) from Table 5.0 or an appropriate combination of IV antibiotics from Table 5.1 are not started within the 3 hours following presentation of severe sepsis, and the following conditions are met, choose value "1."
 - There is Physician/APN/PA documentation referencing the results of a culture from within 5 days prior to the antibiotic start time. The documentation must:
 - 1. Identify the date of the culture results (must be within 5 days prior to the antibiotic start time).
 - 2. Identify the suspected causative organism from the culture result and its antibiotic susceptibility.
 - The IV antibiotic(s) identified as appropriate per the physician/APN/PA documentation is started within 3 hours following the presentation of severe sepsis.
 Example:

Acceptable physician/APN/PA documentation: "Urine culture results from 9/10/17 show enterococcus, sensitive to vancomycin."

The patient has severe sepsis with criteria met on 9/15/17 at 15:00 and the only antibiotic started is IV vancomycin at 15:30.

• If the patient has C. difficile, and IV antibiotic(s) from Table 5.0 or an appropriate combination of IV antibiotics from Table 5.1 are not started within the 3 hours following presentation of severe sepsis, and the following conditions are met, choose value "1."

- There is physician/APN/PA documentation within 24 hours prior to the antibiotic start time identifying the presence of C. difficile. Documentation that C. difficile is suspected or likely is acceptable.
- Any one of the treatments below is initiated within 3 hours following severe sepsis presentation:
 - 1. Oral vancomycin with or without oral or IV metronidazole (Flagyl)
 - 2. Rectal vancomycin with or without IV metronidazole (Flagyl)
 - 3. IV metronidazole (Flagyl) monotherapy

Suggested Data Sources:

- Anesthesia record
- Entire Emergency Department record
- ICU flow sheet
- IV flow sheet
- Medication administration record
- Nurses notes
- Operating room record
- PACU/recovery room record
- Perfusion record
- Physician/APN/PA progress notes

Inclusion Guidelines for Abstraction:

- Antibiotic administered via intravenous route
- Intramuscular or IM
- Intraosseous or IO
- Intravenous
- IV Bolus
- •IV infusion

Exclusion Guidelines for Abstraction:

- Give antibiotic stat
- Hang antibiotic
- Order for xx antibiotic

Table 5.0: Antibiotic Monotherapy, Sepsis

Antibiotic Selection Options (includes trade name or generic name)	Generic Name Crosswalk
Avelox	Moxifloxacin
Avycaz	Ceftazidime/avibactam
Ceftriaxone	Ceftriaxone
Claforan	Cefotaxime
Doribax	Doripenem
Fortaz	Ceftazidime
Invanz	Ertapenem
Levaquin	Levofloxacin
Maxipime	Cefepime
Merrem	Meropenem
Primaxin	Imipenem/Cilastatin
Teflaro	Ceftaroline fosamil
Unasyn	Ampicillin/sulbactam
Zerbaxa	Ceftolozane/tazobactam
Zosyn	Piperacillin/tazobactam

Table 5.1: Antibiotic Generic/Trade Name Crosswalk, Sepsis

Antibiotic Selection Options (includes trade name or generic name)	Generic Name Crosswalk
Aminoglycosides	
Amikacin	Amikacin
Gentamicin	Gentamicin
Kanamycin	Kanamycin
Tobramycin	Tobramycin
Aztreonam	
Azactam	Aztreonam
Cephalosporins	
(1st and 2nd Generation)	
Ancef	Cefazolin
Cefotan	Cefotetan
Cefuroxime	Cefuroxime
Mefoxin	Cefoxitin
Ciprofloxacin	
Ciprofloxacin	Ciprofloxacin
Clindamycin IV	
Cleocin	Clindamycin
Daptomycin	
Cubicin	Daptomycin

Table 5.1: Antibiotic Generic/Trade Name Crosswalk, Sepsis

Antibiotic Selection Options (includes trade name or generic name)	Generic Name Crosswalk
Glycopeptides	
Targocid	Teicoplanin
Vancocin	Vancomycin
Vibativ	Telavancin
Linezolid	
Zyvox	Linezolid
Macrolides	
Erythocin	Erythromycin
Sumamed	Azithromycin
Xithrone	Azithromycin
Zithromax	Azithromycin
Penicillins	
Ampicillin	Ampicillin
Nafcillin	Nafcillin
Oxacillin	Oxacillin
Penicillin G	Penicillin G

Dataset Segment:	Adherence Variables
Data Element Name:	Blood Culture Collection
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Situational

This variable has been aligned with the CMS SEP-1 data element Blood Culture Collection. Please use the information from that data element for submission of *Blood Culture Collection*. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable. <u>The only exceptions</u> are with respect to failed/contaminated laboratory specimen collection. Currently the NYSDOH is not allowing any failed attempts or contaminated specimens to be reported as collected. Additionally, the NYSDOH does not exclude cases of sepsis that are determined to be due to viral, parasitic, or fungal infections after the identification window. Exclude only those cases identified at presentation as solely due to viral, parasitic, or fungal infection. Please report ALL cases that meet criteria for severe sepsis/septic shock as per specifications.

Definition: Documentation of the collection of a blood culture.

Codes and Values:

- 1 = (Yes) A blood culture was collected in the appropriate time window.
- 2 = (No) A blood culture was not collected in the appropriate time window or unable to determine.

- If *Blood Culture Collection* = 1, then *Blood Culture Collection Datetime* must be completed.
- If *Blood Culture Collection* = 2 or is blank, then *Blood Culture Collection Datetime* must be blank.
- If *Excluded from Protocol* = 1, may be blank, else must be completed.
- Failed attempts or contaminated specimens may not be reported as "collected" for cases reported to the NYSDOH. This is not meant to affect clinician care this only applies to the reporting of the quarterly data for the NYSDOH.
- If a patient **does not** receive an IV or IO antibiotic within the 24 hours before the presentation of severe sepsis, the appropriate time window is:

- 24 hours prior to Severe Sepsis Present Date and Time through 3 hours following Severe Sepsis Present Date and Time.
- If a patient **does** receive an IV or IO antibiotic within the 24 hours before the presentation of severe sepsis, the appropriate time window is:
 - 24 hours prior to the administration of the antibiotic through 3 hours following *Severe Sepsis Present Date and Time.*
- Use documentation specifying a blood culture was actually drawn or collected.
 - Do not use "Labs Drawn" or similar documentation, as it is not specific to blood culture.
 - Do not use physician orders to determine a blood culture was collected, as they do not demonstrate collection of the blood culture.
- If there is supportive documentation that a blood culture was collected in the appropriate time window and is the earliest mention of a blood culture, this date and time can be used, e.g. "BC sent to lab", "blood culture received time." Select Value "1".

Suggested Data Sources:

Emergency Department record History and physical Laboratory report Microbiology report Nursing notes Physician/APN/PA Progress notes

Dataset Segment:	Adherence Variables
Data Element Name:	Blood Culture Collection Acceptable Delay
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Situational

This variable has been aligned with the CMS SEP-1 data element Blood Culture Collection Acceptable Delay. Please use the information from that data element for submission of *Blood Culture Collection Acceptable Delay*. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable. <u>The only exceptions</u> are with respect to failed/contaminated laboratory specimen collection. Currently the NYSDOH is not allowing any failed attempts or contaminated specimens to be reported as collected.

Definition: Documentation supporting there was an acceptable delay in the collection of a blood culture.

Codes and Values:

- 1 = (Yes) There is documentation supporting an acceptable delay in the collection of a blood culture.
- 2 = (No) There is no documentation supporting an acceptable delay in the collection of a blood culture, or Unable to Determine.

- If *Blood Culture Collection* = 1, then *Blood Culture Collection Acceptable Delay* must be completed.
- If there was no delay in the collection of a blood culture, than an "acceptable delay" did not occur. Choose Value "2" (No-there is no documentation supporting an acceptable delay in the collection of a blood culture) would be the appropriate selection if a delay never occurred for a blood culture collection.
- Only the following situations demonstrate an acceptable delay where the blood culture was drawn after the *Broad Spectrum or Other Antibiotic Administration Date* and *Time*. If there is an acceptable delay, choose Value "1."
 - Surgical patients who receive a pre-op or post-op prophylactic antibiotic within 24 hours before severe sepsis was identified and had a blood culture drawn after the prophylactic antibiotic was started.

- Antibiotics were started in the hospital for an infection within 24 hours before severe sepsis was identified, and a blood culture was drawn sometime after the antibiotic dose was started.
- Antibiotics were started prior to hospital arrival within 24 hours before severe sepsis was identified, and a blood culture was drawn after the pre-hospital antibiotics were started.
- A physician/APN/PA documented reason for the delay, which makes it clear that waiting to start the antibiotic would be detrimental to the patient. Examples:

• ED Physician Note: Patient condition worsening, IV Vanco ordered stat, blood and urine cultures ordered, awaiting CXR.

- Hospitalist Progress Note: Patient's deteriorating condition concern for rapidly advancing infection, starting IV antibiotics now, lab on way to collect blood cultures.
- Obstetric patients given prophylactic antibiotics for ruptured membranes, group B strep, or prior to a caesarean section.
- If there is no documentation supporting an acceptable delay in the collection of a blood culture, choose Value "2."

Suggested Data Sources:

Emergency Department record History and physical Laboratory report Microbiology report Nursing notes Physician/APN/PA Progress notes

Exclusion Guidelines for Abstraction:

Oral (PO) Antibiotics

Dataset Segment:	Adherence Variables
Data Element Name:	Blood Culture Collection Datetime
Format – Length:	Datetime-16
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Situational

This variable has been aligned with the CMS SEP-1 data elements Blood Culture Collection Date and Blood Culture Collection Time. Please use the combination of those data elements for submission of *Blood Culture Collection Datetime*. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable.

Definition: The datetime on which a blood culture was collected.

Codes and Values:

Notes for Abstraction:

- Formatting:
 - 1. Format must be YYYY-MM-DD hh:mm
 - a. YYYY-MM-DDThh:mm is also valid
 - 2. YYYY = four-digit year

MM = two-digit month (01=January, etc.)

DD = two-digit day of month (01 through 31)

hh = two digits of hour (00 through 23) (am/pm NOT allowed)

- mm = two digits of minute (00 through 59)
- 3. Example: 11:42 pm November 3, 1959=1959-11-03 23:42
 a. 1959-11-03T23:42 is also valid
- 4. Midnight = 00:00, not 24:00
- If *Blood Culture Collection* = 1, then must be completed.
- If *Blood Culture Collection* is blank or contains a value of 2, then must be blank.
- Cannot have been after *Discharge Datetime*.
- Please refer to blood culture collection data element for appropriate time window to abstract this data element.
- Use documentation specifying a blood culture was actually drawn or collected. Do not use "Labs Drawn" or similar documentation, as it is not specific to blood culture.
- If there is supportive documentation that a blood culture was collected in the time window 48 hours prior to or 3 hours following the presentation of severe sepsis and it is the earliest mention of a blood culture, this date and time can be used, e.g., "BC sent to lab," "blood culture received time."

- Do not use physician orders to determine that a blood culture was collected, as they do not demonstrate collection of the blood culture.
- If the patient was started on antibiotics within 24 hours before presentation of severe sepsis, begin abstracting 24 hours prior to the time the first antibiotic dose was given.
- If the patient was not on antibiotics at the time of presentation of severe sepsis, begin abstracting 24 hours prior to the time of presentation of severe sepsis.
- If multiple blood cultures were drawn or attempted, abstract the earliest blood culture drawn or attempted in the time window 48 hours prior to or 3 hours following the presentation of severe sepsis.
- Stop abstracting 3 hours after the presentation of severe sepsis.

Dataset Segment:	Adherence Variables
Data Element Name:	Crystalloid Fluid Administration Datetime
Format – Length:	Datetime-16
SPARCS variable:	No
CMS SEP-1 variable:	Situational
Mandatory:	Situational

This variable has been aligned with the CMS SEP-1 data elements Crystalloid Fluid Administration Date and Crystalloid Fluid Administration Time. Please use the combination of those data elements for submission of *Crystalloid Fluid Administration Datetime*. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable.

Definition: The earliest datetime on which crystalloid fluids were initiated within the specified time frame.

Codes and Values:

- Formatting:
 - 1. Format must be YYYY-MM-DD hh:mm
 - a. YYYY-MM-DDThh:mm is also valid
 - 2. YYYY = four-digit year
 - MM = two-digit month (01=January, etc.)
 - DD = two-digit day of month (01 through 31)
 - hh = two digits of hour (00 through 23) (am/pm NOT allowed)
 - mm = two digits of minute (00 through 59)
 - 3. Example: 11:42 pm November 3, 1959=1959-11-03 23:42
 - a. 1959-11-03T23:42 is also valid
 - 4. Midnight = 00:00, not 24:00
- If *Adult Crystalloid Fluid Administration* = 1, then *Crystalloid Fluid Administration Datetime* must be completed, else must be blank.
- Cannot have been after *Discharge Datetime*.
- Crystalloid fluid volumes ordered that are equivalent to 30 mL/kg or within 10% less than 30 mL/kg are considered the target ordered volume.
- The specified time frame for abstraction of crystalloid fluids is within 6 hours prior through 3 hours after either of the following trigger events. If both are present the specified time frame is determined by the earliest trigger.
 - o Initial Hypotension Date and Time
 - Septic Shock Presentation Date and Time

- If a single order is written for the target ordered volume, use the date the crystalloid solution was started as an IV infusion.
- If a single order is written for the target ordered volume and the infusion is given over multiple infusions, use the start date of the first crystalloid fluid infusion.
- 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.
- If a crystalloid infusion is running at a maintenance rate (125 mL/hour or less) and the rate is increased to administer the target ordered volume, use the date the infusion rate is increased.
- In some cases, the crystalloid fluid will be infusing prior to the time of presentation of *Initial Hypotension*, or physician/APN/PA *Documentation of Septic Shock*; if so, use the date the unit of fluid was started or hung.
- Do not abstract the date that fluids were ordered or the date that IV access was started. Abstract the date that the crystalloid fluid infusion began.
- Do not use physician orders as fluid administration start date and time; use the date and time that the fluid infusion was initiated.
- If there is physician/APN/PA documentation identifying the patient has obesity (defined as a Body Mass Index >30), the clinician may choose to use Ideal Body Weight (IBW) to determine the target ordered crystalloid fluid volume. If the clinician prefers to use IBW, it must be documented clearly and the clinician must indicate that IBW will be the weight used to determine the target ordered volume.
- Documentation of crystalloid fluids administered prior to arrival to the hospital (e.g., ambulance, nursing home) that are part of the medical record are acceptable if the documentation of fluid administration contains the type, volume, start time, and rate, duration, or end time of the fluid infusion. A physician/APN/PA order for fluids administered prior to arrival is not required.

Suggested Data Sources:

- Ambulance or transport vehicle records
- Entire ED record
- IV therapy records or flow sheet
- Medication Administration Record

Inclusion Guidelines for Abstraction:

None

Exclusion Guidelines for Abstraction:

None

Dataset Segment:	Adherence Variables
Data Element Name:	Elevated Lactate Reason
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Situational

This allows the identification of an elevated lactate (lactate >2/mmol) for a condition that is not an infection, or is due to a medication.

Codes and Values:

- 1 = (Yes) There is physician/APN/PA documentation prior to or within 24 hours after the initial lactate level result that indicates the initial lactate value is due to a condition that is not an infection, or is due to a medication, select Value "1.".
- 2 = (No) There is no physician/APN/PA documentation prior to or within 24 hours after the initial lactate level result that indicates the initial lactate value is due to a condition that is not an infection, or is due to a medication, or unable to determine.

Notes for Abstraction:

• If *Initial Lactate Level* >2, must answer.

Dataset Segment:	Adherence Variables
Data Element Name:	Initial Hypotension
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Situational

This variable has been aligned with the CMS SEP-1 data element Initial Hypotension. Please use the information from that data element for submission of *Initial Hypotension*. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable.

Definition: Documentation of the presence of initial hypotension within the specified time frame and prior to the completion of the target ordered volume (30 mL/kg or up to10% less than 30 mL/kg) of crystalloid fluids.

Codes and Values:

- 1 = (Yes) Initial Hypotension was present within the specified time frame.
- 2 = (No) Initial Hypotension was not present within the specified time frame or unable to determine from medical record documentation.

- The specified time frame for assessing Initial Hypotension is 6 hours prior to or within 6 hours following *Severe Sepsis Presentation Date* and *Time*.
- Must be completed unless *Excluded from Protocol* = 1.
- The criteria for determining that Initial Hypotension was present are as follows:
 - Two hypotensive blood pressure readings from measurements taken at different times within the specified time frame. The hypotensive blood pressure readings do not need to be consecutive but need to be within 3 hours of each other. Acceptable readings are:
 - 1. systolic blood pressures <90, or
 - 2. mean arterial pressures (MAP) <65 or
 - 3. a decrease in systolic blood pressure by >40 mm/Hg. Physician/APN/PA documentation must be present in the medical record indicating a >40 mmHg decrease in SBP has occurred and is related to infection or severe sepsis and not other causes.
- Use the time the hypotensive blood pressures were taken or obtained. If time taken or obtained is not available, use recorded or documented time. Do not abstract hypotensive

values from narrative charting unless there is no other documentation that reflects the time that the same hypotensive values were obtained.

- Of note, while hospital abstractors are not expected to calculate MAP, the reviewer may calculate a MAP (MAP= (SBP+2*DBP)/3) if the data submission reflective of hypotension cannot otherwise be validated, in order to validate an entry of severe sepsis/septic shock, initial hypotension and/or persistent hypotension.
- Hypotensive BPs obtained within the operating room (OR), interventional radiology, during active delivery, or procedural/conscious sedation **should not be used**.
- Hypotensive BPs documented from an orthostatic BP evaluation **should not be used**.
- For the following, physician/APN/PA documentation prior to or within 24 hours after Severe Sepsis Presentation Time **is required**.
 - If hypotension (SBP <90 mmHg or MAP <65 mmHg) is due to the following, it should not be used. Inferences should not be made. The abnormal value or reference to the abnormal value must be in the same documentation.
 - Normal for that patient
 - Is due to a chronic condition
 - Is due to a medication
 Example:

"Hypotensive after pain meds"

 If a hypotensive value is due to an acute condition that has a non-infectious source/process, it **should not be used** (Refer to Severe Sepsis Present criteria "a" to determine if the source of the acute condition is an infection).

Example:

"BP 85/50 r/t blood loss" "2 liters lost via GI bleed" (blood loss is the acute condition and GI bleed is the non-infectious source).

• If a hypotensive value should not be used based on the above guidance, all instances of less severe values **should not be used**.

Example:

"BP 80/50 secondary to Lasix" (systolic blood pressures \ge 80 would not be used).

- o If a hypotensive value is due to the following, the criteria value **should be used**.
 - Acute condition

Example:

Progress Note: "Hypotension r/t dehydration."

- Acute on chronic condition
 Example:
 - H&P: "Hypotension due to acute exacerbation of chronic heart failure."
- Infection
 Example:

Physician Note: "Sepsis, hypotensive."

• Documentation of a term that represents or is defined by an SBP <90 mmHg or MAP <65 mmHg is acceptable in place of an abnormal value when documented as normal for the patient, due to a chronic condition, due to a medication, or due to an acute condition that has a non-infectious source/process.

Example:

"Hypotension (Systolic blood pressure <90 mmHg)."

 If within the same physician/APN/PA documentation, there is conflicting documentation indicating hypotension is normal for the patient, or due to a chronic condition or medication AND due to or possibly due to an infection, Severe Sepsis, or Septic Shock, the criteria value should be used.

Example:

"Hypotensive post medications, possibly r/t sepsis."

• If within 24 hours after Severe Sepsis Presentation Time there is conflicting information within two or more separate pieces of physician/APN/PA documentation indicating hypotension is normal for the patient, or due to a chronic condition or medication AND due to or possibly due to an infection, Severe Sepsis, or Septic Shock, abstract based on the latest piece of documentation within the 24-hour period.

Example:

- Note 1200: "Antihypertensive discontinued due to hypotension."
- Note 1600: "Sepsis with hypotension and SIRS criteria.
 O Hypotensive readings should be used.
- Initial hypotension is hypotension that is present prior to the target ordered volume of crystalloid fluids being completely infused.
- If hypotension was present within 6 hours prior to or within 6 hours following Severe Sepsis Presentation Date and Time, select Value "1."
- If hypotension was not present within 6 hours prior to or within 6 hours following *Severe Sepsis Presentation Date and Time*, select Value "2."
- If within 24 hours of the severe sepsis presentation time there is physician/APN/PA or nursing documentation indicating a hypotensive reading is invalid, erroneous or questionable, disregard that reading when determining the presence of Initial Hypotension.
- If there is physician/APN/PA documentation indicating the patient does not have hypotension and it is referencing a specific time period in which there was one or more hypotensive values recorded, the hypotensive value(s) should not be used. The documentation must be within 24 hours following the low blood pressure value(s).

Example:

• Progress note: "Not hypotensive in ED."

• Hypotensive values in ED should not be used.

• Use of documentation in pre-hospital records (e.g., ambulance records, nursing home records) that is considered part of the medical record is acceptable for determining Initial Hypotension.

Suggested Data Sources:

- Entire ED record
- Nurses notes
- Physician/APN/PA notes
- Vital signs record or flow sheet

Dataset Segment:	Adherence Variables
Data Element Name:	Initial Hypotension Datetime
Format – Length:	Datetime-16
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Situational

This is the date and time that all criteria for Initial Hypotension Present are met.

Definition: The datetime of the documentation of initial hypotension in the 6 hours prior to or within 6 hours following *Severe Sepsis Presentation Date and Time* and prior to the completion of the target ordered volume (30 mL/kg or up to10% less than 30 mL/kg) of crystalloid fluids.

Codes and Values:

Notes for Abstraction:

- Formatting:
 - 1. Format must be YYYY-MM-DD hh:mm
 - a. YYYY-MM-DDThh:mm is also valid
 - 2. YYYY = four-digit year

MM = two-digit month (01=January, etc.)

- DD = two-digit day of month (01 through 31)
- hh = two digits of hour (00 through 23) (am/pm NOT allowed)
- mm = two digits of minute (00 through 59)
- 3. Example: 11:42 pm November 3, 1959=1959-11-03 23:42
 a. 1959-11-03T23:42 is also valid
- 4. Midnight = 00:00, not 24:00
- Cannot have been after *Discharge Datetime*.
- If *Initial Hypotension* = 1, then must be completed.
- If *Initial Hypotension* is blank or contains a value of 2, then must be blank.
- Use the earliest datetime of the second hypotensive blood pressure documented/ obtained within the time period of 6 hours prior to or within 6 hours following *Severe Sepsis Presentation Date and Time* (to determine the second hypotensive blood pressure, see the *Initial Hypotension* data element).
- For patients with more than two hypotensive blood pressures in the date time period of 6 hours prior to or within 6 hours following *Severe Sepsis Presentation Date and Time*, use the datetime of the second hypotensive blood pressure documented/ obtained within the time period.

• Use the datetime documented/obtained for when hypotensive blood pressure was taken or obtained. If datetime taken or obtained is not available, use recorded or documented datetime.

Suggested Data Sources:

- Entire ED record
- Nurses notes
- Physician/APN/PA notes
- Vital signs record or flow sheet

Dataset Segment:	Adherence Variables
Data Element Name:	Initial Lactate Level
Format – Length:	Decimal-4
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Situational

This is the actual lactate level that was reported by the lab for the initial lactate within the specified time frame.

Codes and Values:

- Enter the actual initial lactate level using the mmol value. Convert from mg/dL if needed.
 - Values might range from 0 to 9; numbers higher than nine may indicate the value has not been converted to mmol. Be sure to convert to mmol as subsequent data elements are required for values >2 mmol.

- If Initial Lactate Level Collection = 1, must answer.
- Must be numeric to one decimal place (example 19.8).
- If the lactate level was reported by the lab with more than one decimal place, use the rules of rounding to convert the number to one decimal place.
- Do not just truncate the number in order to convert it to one decimal place.
- Examples of rounding lactate level results:
 - o 7.81 is rounded to 7.8
 - o 7.85 is rounded to 7.9
 - o 7.97 is rounded to 8
 - **NOT CORRECT**: 7.85 is truncated to 7.8 (this should be rounded to 7.9)
- The specified time frame within which an initial lactate must be drawn is within 6 hours prior through 3 hours following severe sepsis presentation.
 - If multiple lactate levels are drawn within the specified time frame, use the lactate drawn PRIOR to the *Severe Sepsis Presentation Time* with the HIGHEST level.
 - If multiple lactate levels are drawn ONLY in the 3 hours after the *Severe Sepsis Presentation Time*, use the lactate drawn with the HIGHEST level within this time frame.
- If there is physician/APN/PA or nursing documentation that a lactate value is invalid, erroneous or questionable, disregard that value.
- If Initial Lactate Level > 2 mmol/L, then Repeat Lactate Level Collection MUST be completed.

- If Initial Lactate Level >= 4 mmol/L and Elevated Lactate Reason = 2 then Septic Shock Present must =1.
- If Initial Lactate Level >2, must answer Elevated Lactate Reason.

Dataset Segment:	Adherence Variables
Data Element Name:	Initial Lactate Level Collection
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Situational

This variable has been aligned with the CMS SEP-1 data element Initial Lactate Level Collection. Please use the information from that data element for submission of *Initial Lactate Level Collection*. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable. <u>The only exceptions</u> are with respect to failed **Iaboratory specimen collection.** Currently the NYSDOH is not allowing any failed attempts specimens to be reported as collected.

Definition: Documentation of collection of an initial lactate level between 6 hours prior to and 3 hours following the severe sepsis presentation.

Codes and Values:

- 1 = (Yes) An initial lactate level was drawn within the specified time frame.
- 2 = (No) An initial lactate level was not drawn within the specified time frame, or unable to determine.

- If *Initial Lactate Level Collection* = 1, answer additional lactate questions.
- If *Initial Lactate Level Collection* = 2 or is blank, then all of the below are blank:
 - o Initial Lactate Level Collection Datetime
 - o Initial Lactate Level
 - Repeat Lactate Level Collection
 - o Repeat Lactate Level Collection Datetime
- If *Excluded from Protocol* = 1, may be blank, else must be completed.
- If within 24 hours of the *Severe Sepsis Presentation Time* there is physician/APN/PA or nursing documentation that a lactate value is invalid, erroneous or questionable, disregard that value.
- The specified time frame within which an initial lactate must be drawn is within 6 hours prior through 3 hours following severe sepsis presentation.
 - If multiple lactate levels are drawn within the specified time frame, use the lactate drawn PRIOR to the *Severe Sepsis Presentation Time* with the HIGHEST level.

- If multiple lactate levels are drawn ONLY in the 3 hours after the *Severe Sepsis Presentation Time*, use the lactate drawn with the HIGHEST level within this time frame.
- If there is more than one time of documentation for the *Initial Lactate Level Collection*, use the following order to determine which time to abstract.
 - 1. Laboratory documentation indicating date and time lactate was drawn.
 - 2. Date and Time the lactate is documented as drawn in a non-narrative location (e.g., sepsis flowsheet, checklist, screening).
 - 3. Narrative note indicating lactate is drawn with an associated date and time.
- If there is no documentation indicating a lactate was drawn or collected, but there is supportive documentation that a lactate was drawn, use the earliest supportive documentation (e.g., lactate sent to lab, lactate received, lactate result).
- Use documentation specifying a lactate was actually drawn or collected. Do not use documentation such as "Labs Drawn" as it is not specific for lactate level.
- Do not use a physician order for lactate levels as it does not specify that lactate level was drawn; however, you may use a physician order that has a notation "drawn" or "collected" next to it.
- The NYSDOH data collection does not permit the submission of failed or contaminated specimens.

Suggested Data Sources:

- Laboratory Reports
- Nursing Notes
- Physician/APN/PA notes or orders

Inclusion Guidelines for Abstraction:

- •Lactate drawn
- Lactate level collected
- Lactic acid drawn

Exclusion Guidelines for Abstraction:

• Labs drawn

Dataset Segment:	Adherence Variables
Data Element Name:	Initial Lactate Level Collection Datetime
Format – Length:	Datetime-16
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Situational

This variable has been aligned with the CMS SEP-1 data elements Initial Lactate Level Collection Date and Initial Lactate Level Collection Time. Please use the combination of those data elements for submission of *Initial Lactate Level Collection Datetime*. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable.

Definition: The date on which the initial lactate level was drawn.

Codes and Values:

Notes for Abstraction:

- Formatting:
 - 1. Format must be YYYY-MM-DD hh:mm
 - a. YYYY-MM-DDThh:mm is also valid
 - 2. YYYY = four-digit year

MM = two-digit month (01=January, etc.)

DD = two-digit day of month (01 through 31)

hh = two digits of hour (00 through 23) (am/pm NOT allowed)

- mm = two digits of minute (00 through 59)
- 3. Example: 11:42 pm November 3, 1959=1959-11-03 23:42
 a. 1959-11-03T23:42 is also valid
- 4. Midnight = 00:00, not 24:00
- If *Initial Lactate Level Collection* = 1, then the following MUST be completed:
 - o Initial Lactate Level Collection Datetime
 - o Initial Lactate Level
- If *Initial Lactate Level Collection* is blank or contains a value of 2, then the following MUST be blank:
 - o Initial Lactate Level Collection Datetime
 - o Initial Lactate Level
- Cannot have been after *Discharge Datetime*.
- If there is more than one date of documentation for the *Initial Lactate Level Collection*, use the following order to determine which date to abstract.
 - 1. Laboratory documentation indicating date lactate was drawn.

- 2. Non-narrative location indicating lactate was drawn with an associated date (e.g., sepsis flowsheet, checklist, screening).
- 3. Narrative note indicating lactate is drawn with an associated date.
- If there is not a lactate draw or collected date documented, but there is supportive documentation that a lactate was drawn, use the date of the earliest supportive documentation (e.g., lactate sent to lab, lactate received date, lactate result date).
- Use documentation specifying a lactate was actually drawn or collected.
 - Do not use documentation such as "Labs Drawn" as it is not specific for lactate level.
- Do not use a physician order for lactate levels as it does not specify that lactate level was drawn; however, you may use a physician order that has a notation "drawn" or "collected" next to it.

Dataset Segment:	Adherence Variables
Data Element Name:	Persistent Hypotension
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Situational

This variable has been aligned with the CMS SEP-1 data element Persistent Hypotension. Please use the information from that data element for submission of *Persistent Hypotension*. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable.

Definition: Documentation of the presence of persistent hypotension or new onset of hypotension following the administration of the target ordered volume (30 mL/kg or up to 10% less than 30 mL/kg) of crystalloid fluids.

Codes and Values:

1 = (Yes)	Persistent hypotension or new onset of hypotension was present within one hour of conclusion of crystalloid fluid administration at the target ordered volume.
2 = (No)	Persistent hypotension or new onset of hypotension was not present within one hour of the conclusion of crystalloid fluid administration at the target ordered volume.
3 = (No) or UTD	The patient was not assessed for persistent hypotension or new onset of hypotension within one hour after the conclusion of crystalloid fluid administration at the target ordered volume, or Unable to Determine.
4 = (Not applicable)	Crystalloid fluids were administered but at a volume less than the target ordered volume.

Notes for Abstraction:

- Must be completed if *Initial Hypotension* = 1.
- Persistent hypotension means either the presence of persistent hypotension or new hypotension after the completion of fluid administration of the target volume (30ml/kg) (volume must be not less than 10% below the required amount).
- Criteria for determining persistent hypotension in the one hour following completion of the 30ml/kg fluid volume treatment are 2 consecutive measurements in <u>one</u> of the 3 types of measures below.
 - the systolic BP is <90, or
 - o mean arterial pressure <65mm, or

- decrease of systolic BP of >40mm/Hg. Physician/APN/PA documentation must be present in the medical record indicating a >40 mmHg decrease in SBP has occurred and is related to infection, severe sepsis or septic shock and not other causes.
- Use the time the hypotensive blood pressures were taken or obtained. If time taken or obtained is not available, use recorded or documented time. Do not abstract hypotensive values from narrative charting unless there is no other documentation that reflects the time that the same hypotensive values were obtained.
- Hypotensive BPs obtained within the operating room (OR), interventional radiology, during active delivery, or procedural/conscious sedation **should not be used**. If the patient is in one of these setting during the hour-long window to assess for *Persistent Hypotension*, select value "2".
- Hypotensive BPs documented from an orthostatic BP evaluation **should not be used**.
- Determining presence of persistent hypotension (low is SBP <90 or MAP <65):
 - If there were no blood pressures or only one blood pressure recorded within the hour:
 - If the only blood pressure within the hour is normal, select Value "2."
 - If there is no blood pressure or the only blood pressure within the hour is low, select Value "3."
 - If there are more than two blood pressures documented, refer to the last two consecutive blood pressures within the hour:
 - If there is a normal blood pressure followed by another normal blood pressure, select Value "2."
 - If there is a normal blood pressure followed by a low blood pressure, select Value "3."
 - If there is a low blood pressure followed by a normal blood pressure, select Value "2."
 - If there is a low blood pressure followed by another low blood pressure, select Value "1."
- If one or more blood pressures were documented within the time frame and persistent hypotension is unable to be determined but a vasopressor was administered, select Value "1."
- If persistent hypotension presentation is more than six hours after the *Septic Shock Presentation Time,* choose Value "2".
- For the following, physician/APN/PA documentation prior to or within 24 hours after *Severe Sepsis Presentation Time* **is required**.
 - If hypotension (SBP <90 mmHg or MAP <65 mmHg) is due to the following, it should not be used. Inferences should not be made. The abnormal value or reference to the abnormal value must be in the same documentation.
 - Normal for that patient
 - Is due to a chronic condition
 - Is due to a medication

"Hypotensive after pain meds."

 If a hypotensive value is due to an acute condition that has a non-infectious source/process, it should not be used (Refer to Severe Sepsis Present criteria "a" to determine if the source of the acute condition is an infection).

"BP 85/50 r/t blood loss" "2 liters lost via GI bleed" (blood loss is the acute condition and GI bleed is the non-infectious source.

• If a hypotensive value should not be used based on the above guidance, all instances of less severe values should not be used.

Example:

"BP 80/50 secondary to Lasix" (systolic blood pressures \ge 80 would not be used).

- If a hypotensive value is due to the following, the criteria value should be used.
 - Acute condition

Example:

Progress Note: "Hypotension r/t dehydration."

• Acute on chronic condition

Example:

H&P: "Hypotension due to acute exacerbation of chronic heart failure."

Infection

Example:

Physician Note: "Sepsis, hypotensive."

Documentation of a term that represents or is defined by an SBP <90 mmHg or MAP <65 mmHg is acceptable in place of an abnormal value when documented as normal for the patient, due to a chronic condition, due to a medication, or due to an acute condition that has a non-infectious source/process.

Example:

Hypotension (Systolic blood pressure <90 mmHg).

• If within the same physician/APN/PA documentation, there is conflicting documentation indicating hypotension is normal for the patient, or due to a chronic condition or medication AND due to or possibly due to an infection, Severe Sepsis, or Septic Shock, the criteria value **should be used**.

Example:

"Hypotensive post medications, possibly r/t sepsis."

• If within 24 hours after Severe Sepsis Presentation Time there is conflicting information within **two or more separate** pieces of physician/APN/PA documentation indicating hypotension is normal for the patient, or due to a chronic condition or medication AND due to or possibly due to an infection, Severe Sepsis, or Septic Shock, abstract based on the latest piece of documentation within the 24- hour period.

Example:

- Note 1200: "Antihypertensive discontinued due to hypotension."
- Note 1600: "Sepsis with hypotension and SIRS criteria."
- Hypotensive readings should be used.
- Begin abstracting at the time the target ordered volume concludes; abstract for the time period that follows for the next hour only. Choose Value "1" if persistent hypotension or new onset of hypotension was present, choose Value "2" if persistent hypotension or new onset of hypotension was not present.

- If the completion time of the target ordered volume is documented in the medical record use that time as the start for the one hour within which to determine presence of persistent hypotension or new onset of hypotension.
- If the completion time of the target ordered volume is not documented in the medical record use the following criteria to determine the conclusion time.
 - If the order includes a time frame over which to infuse the crystalloid fluid, identify the time the fluids are started and add to that the duration identified in the order. This will represent the conclusion of crystalloid fluids.

An order for 1500 mL over 1 hour and the infusion is started at 10:00. Add 1 hour to the start time to determine infusion conclusion time of 11:00.

• If the order includes a rate at which to infuse the crystalloid fluids, the end time can be calculated based on the volume, the rate and the start time.

Example:

An order for 1500 mL at 1000 mL/hour and the infusion is started at 10:00. The time over which 1500 mL is infused is the volume divided by the rate. 1500 mL divided by 1000 mL/hour is 1.5 hours. Add 1.5 hours to the start time to determine infusion conclusion time of 11:30.

• If the order is for more than 30 mL/kg, 30 mL/kg will have been infused before the entire volume ordered is infused.

Example:

An order for 3000 mL over 2 hours, infusion started at 10:00. Patient weighs 80 kg, 30 mL/kg target volume is 2400 mL (as determined for Crystalloid Fluid Administration). Divide the total volume ordered by the infusion duration in minutes to determine the infusion rate (3000 mL/120 minutes = 25 mL/minute). Divide the 30 mL/kg target volume by the infusion rate to determine the number of minutes it takes to infuse the target volume (2400 mL/25 mL/min = 96 minutes). Add the number of minutes to infuse the target the target volume to the infusion start time to determine the time 30 mL/kg was completed (10:00 + 96 minutes = 11:36).

- o If the order states "bolus" or "wide open" and does not include an infusion rate or time over which to infuse the fluids, an infusion rate recorded in the medical record by a nurse OR fluid bolus completed time or end time can be used to determine when the target ordered volume was completed.
- Use of documentation in pre-hospital records (e.g., ambulance records, nursing home records) that are considered part of the medical record is acceptable for determining the presence of Persistent Hypotension.
- If within 24 hours of the Severe Sepsis Presentation Time there is physician/APN/PA or nursing documentation indicating a hypotensive reading is erroneous or questioning the validity of a hypotensive reading, disregard that reading for determining the presence of persistent or new onset of hypotension.

Suggested Data Sources:

• Entire ED record

- Nurses notes
- Physician/APN/PA notes
- Vital signs record or flow sheet

Dataset Segment:	Adherence Variables
Data Element Name:	Repeat Lactate Level Collection
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Situational

This variable has been aligned with the CMS SEP-1 data element Repeat Lactate Level Collection. Please use the information from that data element for submission of *Repeat Lactate Level Collection*. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable. <u>The only exceptions</u> are with respect to failed/contaminated laboratory specimen collection. Currently the NYSDOH is not allowing any failed attempts or contaminated specimens to be reported as collected.

Definition: Documentation of obtaining a repeat lactate level in the time window beginning at severe sepsis presentation date and time and ending 6 hours thereafter. A repeat lactate level is the level drawn following the initial level.

Codes and Values:

- 1 = (Yes) A repeat lactate level was drawn in the time window beginning at severe sepsis presentation date and time and ending 6 hours thereafter.
- 2 = (No) A repeat lactate level was not drawn in the time window beginning at severe sepsis presentation date and time and ending 6 hours thereafter, or unable to determine.

Notes for Abstraction:

- If *Initial Lactate Level* > 2, then *Repeat Lactate Level Collection* MUST be completed.
- If Repeat Lactate Level Collection = 1, then Repeat Lactate Level Collection Datetime MUST be completed.
- If *Repeat Lactate Level Collection* = 2 or is blank, then *Repeat Lactate Level Collection Datetime* is blank.
- A repeat lactate level is the next lactate level drawn after the initial lactate level if the initial lactate is elevated (>2.0 mmol/L). This repeat level must be drawn in the time window beginning at severe sepsis presentation date and time and ending 6 hours thereafter to choose Value "1."
- If a repeat lactate level was drawn but not in the time window beginning at severe sepsis presentation date and time and ending 6 hours thereafter, choose Value "2."

Suggested Data Sources:

Laboratory Reports

- Nursing Notes
- Physician/APN/PA notes or orders

Inclusion Guidelines for Abstraction:

- Lactate level collected
- Lactate level drawn
- Lactic acid drawn

Exclusion Guidelines for Abstraction:

- •Labs drawn
- Labs reported

Dataset Segment:	Adherence Variables
Data Element Name:	Repeat Lactate Level Collection Datetime
Format – Length:	Datetime-16
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Situational

This variable has been aligned with the CMS SEP-1 data elements Repeat Lactate Level Collection Date and Repeat Lactate Level Collection Time. Please use the combination of those data elements for submission of *Repeat Lactate Level Collection Datetime*. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable.

Definition: The date on which the repeat lactate level was drawn in the time window beginning at severe sepsis presentation date and time and ending 6 hours thereafter.

Codes and Values:

Notes for Abstraction:

- Formatting:
 - 1. Format must be YYYY-MM-DD hh:mm
 - a. YYYY-MM-DDThh:mm is also valid
 - YYYY = four-digit year
 - MM = two-digit month (01=January, etc.)
 - DD = two-digit day of month (01 through 31)
 - hh = two digits of hour (00 through 23) (am/pm NOT allowed)
 - mm = two digits of minute (00 through 59)
 - 3. Example: 11:42 pm November 3, 1959=1959-11-03 23:42
 - a. 1959-11-03T23:42 is also valid
 - 4. Midnight = 00:00, not 24:00
- If *Repeat Lactate Level Collection* = 1, then must be completed.
- If Repeat Lactate Level Collection is blank or contains a value of 2, then must be blank.
- Cannot have been after *Discharge Datetime*.
- A repeat lactate level is the next lactate level drawn after the initial lactate level if the initial lactate is elevated (>2.0 mmol/L). This repeat level must be drawn in the time window beginning at severe sepsis presentation date and time and ending 6 hours thereafter.
- Do not use documentation such as "Labs Drawn" as it is not specific for lactate level. Similarly, do not use a physician order for lactate levels as it does not specify that lactate

level was drawn, unless there is a notation next to the order that it was drawn or collected and there is a date noted.

• If there is no documentation indicating a repeat lactate was drawn or collected, it is acceptable to use supporting documentation indicating that a repeat lactate was drawn (e.g., lactate sent to lab, lactate received, lactate result). If there are multiple instances of supporting documentation, use the earliest.

Dataset Segment:	Adherence Variables
Data Element Name:	Repeat Volume Status and Tissue Perfusion Assessment Performed
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Situational

This variable has been aligned with the CMS SEP-1 data element repeat volume status and tissue perfusion assessment. Please use the information from that data element for submission of Repeat Volume Status and Tissue Perfusion Assessment Performed. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable.

Definition: Documentation indicating that a repeat volume status and tissue perfusion assessment was performed to assess the patient's response to the administration of crystalloid fluids.

Codes and Values:

- 1 = (Yes) Repeat Volume Status and Tissue Perfusion Assessment was documented in the appropriate time window.
- 2 = (No) Repeat Volume Status and Tissue Perfusion Assessment was not documented in the appropriate time window, or unable to be determined.

Notes for Abstraction:

- Start abstracting at the crystalloid fluid administration date and time and stop abstracting six hours after the presentation of septic shock date and time. This is the appropriate time window
- A repeat volume status and tissue perfusion assessment may consist of any one of the following three:
 - Physician/APN/PA documentation indicating or attesting to performing or completing a physical examination, perfusion (re-perfusion) assessment, sepsis (severe sepsis or septic shock) focused exam, or systems review.
 - **Examples** of Physician/APN/PA documentation that is acceptable:
 - "I did the Sepsis reassessment"
 - Flowsheet 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"
- "I have reassessed the patient's hemodynamic status"
- Physician/APN/PA documentation indicating or attesting to performing or completing a review of at least five of the following eight parameters. Reference to the parameters must be made in physician/APN/PA documentation. Parameters do not need to all be contained within the same physician/APN/PA documentation.
 - Arterial Oxygen Saturation
 - Must be documented as from an arterial source, referenced as arterial oxygen saturation, oxygen saturation, pulse oximetry, POx, or using the abbreviation SaO2 (arterial oxygen saturation) or SpO2 (oxygen saturation measured by pulse oximetry).
 - Capillary Refill
 - Minimally includes documentation of a capillary refill test. (e.g., capillary refill 3 seconds, cap refill normal).
 - Cardiopulmonary Assessment
 - Minimally includes description of heart rate and rhythm, and results of auscultation of lungs. (e.g., heart normal rate & rhythm and lungs clear to auscultation, patient tachycardic and lungs decreased in bases)
 - Peripheral Pulses
 - Minimally includes documentation of presence or lack of presence of peripheral pulses (e.g., pulses present bilaterally, peripheral pulses faint, unable to palpate radial pulses).
 - Shock Index (SI)
 - A shock index value is documented in the medical record, or there is physician/APN/PA documentation that they have reviewed the shock index.
 - Skin Color or Condition
 - Minimally includes either a description of the skin color or condition (e.g., skin cool and clammy, peripheral cyanosis, skin pink and warm, patient appears pale, skin normal, skin normal for ethnicity).
 - Urine Output (UO)
 - Physician/APN/PA documentation must reference urine output. Documentation of the urine output volume is not required
 - Vital Signs
 - Minimally includes documentation referencing heart rate (HR) respiratory rate (RR), blood pressure (BP) and temperature (temp or t).
 - Values for these vital signs are not required.
- Documentation demonstrating one of the following was measured or performed. This documentation can be met by physician/APN/PA or non-physician/APN/PA

documentation of performance of the test, a result or value. Physician/APN/PA attestation to having reviewed the test is acceptable.

- Central Venous Pressure (CVP).
- Central Venous Oxygen Saturation (ScvO2 or SvO2).
 - If documentation indicates the oxygen saturation is not from a central line source such as a peripheral venous blood gas do not use it.
- Echocardiogram (Cardiac echo or cardiac ultrasound).
 - o An order for an echocardiogram is not sufficient.
- Fluid Challenge or Passive Leg Raise.
 - Documentation must explicitly indicate a "fluid challenge" or "passive leg raise" or "leg raise" was performed.
- If there are no repeat volume status and tissue perfusion assessment documented within the appropriate time window, choose Value "2."
- If Adult Crystalloid Fluid Administration = 1 AND Septic Shock Present = 1 AND Persistent Hypotension = 1 or 2, then Repeat Volume Status and Tissue Perfusion Assessment Performed must be completed.

Suggested Data Sources:

Cardiovascular ultrasound or echocardiogram report Consultation notes Critical Care flow sheet Emergency Department record History and physical Nurses notes Physician/APN/PA notes Procedure notes Respiratory Therapy notes or flow sheet Vital signs flow sheet

Dataset Segment:	Adherence Variables
Data Element Name:	Repeat Volume Status and Tissue Perfusion Assessment Performed Datetime
Format – Length:	Datetime-16
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Yes

This variable has been aligned with the CMS SEP-1 data element repeat volume status and tissue perfusion assessment date and time. Please use the information from that data element for submission of Repeat Volume Status and Tissue Perfusion Assessment Performed Date and Time. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable.

Definition: Documentation of the datetime indicating a repeat volume status and tissue perfusion assessment was performed.

- Formatting:
 - a) Format must be YYYY-MM-DD hh:mm
 - a. YYYY-MM-DDThh:mm is also valid
 - b) YYYY = four-digit year
 - MM = two-digit month (01=January, etc.)
 DD = two-digit day of month (01 through 31)
 hh = two digits of hour (00 through 23) (am/pm NOT allowed)
 mm = two digits of minute (00 through 59)
 - c) Example: 11:42 pm November 3, 1959=1959-11-03 23:42
 a. 1959-11-03T23:42 is also valid
 - d) Midnight = 00:00, not 24:00
- Cannot have been after *Discharge Datetime*.

Notes for Abstraction:

• Physician/APN/PA documentation must occur or reflect the assessment was performed between *Crystalloid Fluid Administration Date*, *Crystalloid Fluid Administration Time* and six hours after *Septic Shock Presentation Date*, *Septic Shock Presentation Time*.

- Documentation of what constitutes or is acceptable for a repeat volume status and tissue perfusion assessment is defined in the *Repeat Volume Status and Tissue Perfusion Assessment Performed* data element.
- If there are multiple repeat volume status and tissue perfusion assessments performed, abstract the date of the earliest assessment documented within the appropriate time window.
- If the repeat volume status and tissue perfusion assessment is in a physician/APN/PA note without a specific datetime documented within the note, use the datetime the note was started or opened.
- If *Repeat Volume Status and Tissue Perfusion Assessment Performed* = 1, then must be completed.
- If *Repeat Volume Status and Tissue Perfusion Assessment Performed* is blank or contains a value of 2, then must be blank.
- Cannot have been after *Discharge Datetime*.

Suggested Data Sources:

PHYSICIAN/APN/PA DOCUMENTATION ONLY

Consultation notes Emergency Department record History and physical Progress notes

Dataset Segment:	Adherence Variables
Data Element Name:	Septic Shock Present
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Yes

This variable has been aligned with the CMS SEP-1 data element Septic Shock Present. Please use the information from that data element for submission of *Septic Shock Present*. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable.

Definition: Documentation of the presence of septic shock.

Codes and Values:

1 = (Yes) Septic Shock is present.

2 = (No) Septic Shock is not present, or unable to determine.

Notes for Abstraction:

- Presence of Septic Shock may be identified based upon clinical criteria OR physician/APN/PA documentation of Septic Shock.
- If clinical criteria for Septic Shock are NOT met, but there is physician/APN/PA documentation of Septic Shock, choose Value "1."
- In order to establish the presence of Septic Shock by clinical criteria, one of following two criteria (a or b) must be met.
 - a) Severe Sepsis Present

AND

Persistent Hypotension evidenced by:

in the hour after the conclusion of the target ordered volume of *Crystalloid Fluid Administration*, two consecutive documented hypotensive blood pressure readings.

b) Severe Sepsis Present

AND

Tissue hypoperfusion evidenced by Initial Lactate Level Result is >=4 mmol/L

- For evaluation of blood pressure parameters to establish whether or not hypotension persists after crystalloid fluid administration, begin abstracting at the time that crystalloid fluid administration concludes (refer to the Persistent Hypotension data element); abstract for the time period that follows for the next hour only.
 - Choose Value "1" if hypotension (systolic blood pressure <90, or mean arterial pressure <65 or a decrease in systolic blood pressure by >40 mmHg) was present in the hour after crystalloid fluid administration for two or more consecutive readings.

- Hypotensive BPs obtained within the operating room (OR), interventional radiology, during active delivery, or procedural/conscious sedation **should not be used**.
- Hypotensive BPs documented from an orthostatic BP evaluation **should not be used**.
- Use the time the hypotensive blood pressures were taken or obtained. If time taken or obtained is not available, use recorded or documented time. Do not abstract hypotensive values from narrative charting unless there is no other documentation that reflects the time that the same hypotensive values were obtained.
- For the following, physician/APN/PA documentation prior to or within 24 hours after Severe Sepsis Presentation Time is **required**.
 - If hypotension (SBP <90 mmHg or MAP <65 mmHg) is due to the following, it should not be used. Inferences should not be made. The abnormal value or reference to the abnormal value must be in the same documentation.
 - Normal for that patient
 - Is due to a chronic condition
 - Is due to a medication

"Hypotensive after pain meds"

 If a hypotensive value is due to an acute condition that has a non-infectious source/process, it **should not be used** (Refer to *Severe Sepsis Present* criteria "a" to determine if the source of the acute condition is an infection).

Example:

"BP 85/50 r/t blood loss" "2 liters lost via GI bleed" (blood loss is the acute condition and GI bleed is the non-infectious source).

• If a hypotensive value should not be used based on the above guidance, all instances of less severe values **should not be used**.

Example:

"BP 80/50 secondary to Lasix" (systolic blood pressures \ge 80 would not be used).

- o If a hypotensive value is due to the following, the criteria value **should be used**.
 - Acute condition
 - Example:

Progress Note: "Hypotension r/t dehydration."

• Acute on chronic condition

Example:

H&P: "Hypotension due to acute exacerbation of chronic heart failure."

Infection
 Example:

Physician Note: "Sepsis, hypotensive."

• Documentation of a term that represents or is defined by a SBP <90 mmHg or MAP <65 mmHg is acceptable in place of an abnormal value when documented as normal for the patient, due to a chronic condition, due to a medication, or due to an acute condition that has a non-infectious source/process.

Example:

Hypotension (Systolic blood pressure <90 mmHg)

• If within the same physician/APN/PA documentation, there is conflicting documentation indicating hypotension is normal for the patient, or due to a chronic condition or medication AND due to or possibly due to an infection, Severe Sepsis, or Septic Shock, the criteria value **should be used**.

Example:

"Hypotensive post medications, possibly r/t sepsis."

• If within 24 hours after *Severe Sepsis Presentation Time* there is conflicting information within **two or more separate** pieces of physician/APN/PA documentation indicating hypotension is normal for the patient, or due to a chronic condition or medication AND due to or possibly due to an infection, Severe Sepsis, or Septic Shock, abstract based on the latest piece of documentation within the 24- hour period.

Example:

- Note 1200: "Antihypertensive discontinued due to hypotension." Note 1600: "Sepsis with hypotension and SIRS criteria."
 - Hypotensive readings should be used.
- If within 24 hours after the Severe Sepsis Presentation Time there is physician/APN/PA or nursing documentation that a hypotensive reading is invalid, erroneous or questionable, disregard that reading when determining the presence of Septic Shock.
- If Septic Shock presentation is more than six hours after Severe Sepsis Presentation Time, choose Value "2."
- Disregard documentation of Septic Shock in a discharge note, discharge summary, or documented after the time of discharge.
- The title or heading of an order set, protocol, checklist, alert, screening tool, etc. reflecting an infection, SIRS, Sepsis, Severe Sepsis, or Septic Shock should not be used to meet criteria.
- Documentation of a criterion or Septic Shock within an order set, protocol, checklist, alert, screening tool, etc., may be used if the following is true:
 - The documentation or value and recorded date and time is present and is the earliest date and time recorded for the criteria.
- Use of documentation in pre-hospital records (e.g., ambulance records, nursing home records) that is considered part of the medical record is acceptable for determining presence of Septic Shock.
- Choose Value "2" if within 6 hours after documentation meeting clinical criteria or physician/APN/PA documentation of Septic Shock there is additional physician/APN/PA documentation indicating:
 - Patient is not septic
 - o Patient does not have Sepsis, Severe Sepsis, Septic Shock
 - o Septic Shock is due to a viral, fungal or parasitic infection
- Sepsis cases that are determined after presentation of severe sepsis and later than 6 hours after presentation of septic shock to be due to viral, fungal or parasitic infections should continue to be reported. Cases of viral infection with bacterial suprainfection should be reported.
- All cases of unknown infectious etiology should be reported. For documentation of Septic Shock accompanied by a qualifier, the table below should be used. Documentation

containing a positive qualifier should be used to meet criteria, documentation containing a negative qualifier should not be used to meet criteria. Documentation containing both a positive and negative qualifier should not be used to meet criteria.

Positive Qualifiers	Negative Qualifiers
Possible	Impending
Rule out (r/o)	Unlikely
Suspected	Doubt
Likely	Risk for
Probable	Ruled out
Differential Diagnosis	Evolving
Suspicious for	Questionable
Concern for	

Suggested Data Sources:

- Any physician/APN/PA documentation
- •Entire ED record
- Hourly output record
- •Intake/Output record
- Laboratory results
- Nurses notes
- Vital signs record or flow sheet

Inclusion Guidelines for Abstraction:

- Septic Shock
- Severe Sepsis with Shock

Exclusion Guidelines for Abstraction:

- Bacteremia
- Septicemia
- Shock (not referenced as related to Severe Sepsis or Septic Shock)

Dataset Segment:	Adherence Variables
Data Element Name:	Septic Shock Presentation Datetime
Format – Length:	Datetime-16
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Situational

This variable has been aligned with the CMS SEP-1 data elements Septic Shock Presentation Date and Septic Shock Presentation Time. Please use the combination of those data elements for submission of *Septic Shock Presentation Datetime*. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable.

Definition: Clinical criteria must be met **within 6 hours of each other** at which point the earliest time of the final criterion is reported as the presentation datetime.

Codes and Values:

Notes for Abstraction:

- Formatting:
 - 1. Format must be YYYY-MM-DD hh:mm
 - a. YYYY-MM-DDThh:mm is also valid
 - 2. YYYY = four-digit year

MM = two-digit month (01=January, etc.)

DD = two-digit day of month (01 through 31)

hh = two digits of hour (00 through 23) (am/pm NOT allowed)

- mm = two digits of minute (00 through 59)
- 3. Example: 11:42 pm November 3, 1959=1959-11-03 23:42
 a. 1959-11-03T23:42 is also valid
- 4. Midnight = 00:00, not 24:00
- Cannot have been after *Discharge Datetime*.
- Cannot be before *Arrival Datetime*.
- If *Septic Shock Present* =2, then must be blank.
- If filled in and *Severe Sepsis Presentation Datetime* filled in, cannot be before *Severe Sepsis Presentation Datetime*.
- Use the earliest date/time on which the final (i.e. last) criterion met for determining septic shock presentation (See Septic Shock Present data elements for criteria list) or the earliest date/time the Physician/APN/PA documented septic shock.
- Septic Shock identified by severe sepsis present and persistent hypotension (*Septic Shock Present* criteria a):
 - Use the later date of either severe sepsis presentation or persistent hypotension.

- For persistent hypotension, use the date of the last consecutive blood pressure reading that identifies the presence of persistent hypotension.
- Septic Shock identified by severe sepsis present and initial lactate >=4 (Septic Shock Present criteria b):
 - Use the later date of either severe sepsis presentation or the initial lactate level result.
 - To determine the date of the *Initial Lactate Level Result* for *Septic Shock Present* criteria, use the following sources in priority order.
 - 1. Primary source: Lactate result date from lab
 - Supporting sources in priority order if primary source not available:
 - 1. Date within a narrative note that is directly associated with the lactate result
 - 2. Date the lactate result is documented in a non-narrative location (e.g., sepsis flowsheet)
 - 3. Initial Lactate Level Collection Date
 - 4. Physician/APN/PA or nursing narrative note open date
- In patients with multiple episodes of septic shock within the same stay, use the date/time from the first episode.
- Use the earliest documented arrival date for patients who enter the Emergency Department with the following:
 - o Septic shock clinical criteria met in pre-hospital records
 - Physician/APN/PA documentation of septic shock in pre-hospital records
 - Physician/APN/PA documentation that septic shock was present on arrival
- Use the earliest documented date patient arrives to floor or unit for admission for patients who are direct hospital admits and one of the following is present:
 - Septic shock clinical criteria met in pre-hospital records
 - o Physician/APN/PA documentation of septic shock in pre-hospital records
 - Earliest documentation is in a Physician/APN/PA note that states septic shock was present on admission
- If the only documentation of septic shock being present is in a Physician/APN/PA note that septic shock was present on admission, use the earliest date of the following:
 - o Physician/APN/PA note
 - o Admit order
 - o Disposition to inpatient
 - \circ $\,$ Arrival to floor or unit
- If septic shock is in a physician/APN/PA note without a specific date documented within the note or documented using the acronym POA, the following apply:
 - If it is the only documentation of Septic Shock in the note, use the date the note was started or opened.
 - If Septic Shock is documented multiple times within the same note, use the earliest specified date.

Suggested Data Sources:

- Any physician/APN/PA documentation
- Entire ED record

- Hourly output record
- Intake/Output record
- Laboratory results
- Nurses notes
- Vital signs record or flow sheet

Dataset Segment:	Adherence Variables
Data Element Name:	Severe Sepsis Present
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Yes

This variable has been aligned with the CMS SEP-1 data element Severe Sepsis Present. Please use the information from that data element for submission of *Severe Sepsis Present*. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable.

Definition: Documentation of the presence of severe sepsis. If met by clinical criteria, all three clinical criteria must be met **within 6 hours of each other.**

Codes and Values:

- 1 = (Yes) Severe Sepsis was present.
- 2 = (No) Severe Sepsis was not present, or Unable to Determine.

Notes for Abstraction:

- Presence of Severe Sepsis may be identified based upon clinical criteria or physician/APN/PA documentation of Severe Sepsis.
- In order to establish the presence of Severe Sepsis by clinical criteria, all three clinical criteria (a, b, and c) must **be met within 6 hours of each other.** The three clinical criteria do not need to be documented in any particular order.
- a. Documentation of an infection.
 - Physician/APN/PA or nursing documentation referencing the presence of an infection is acceptable.

• Physician/APN/PA, nursing, or pharmacist documentation indicating a patient is being treated with an antibiotic for an infection and that antibiotic is documented as administered within 6 hours of criteria b or c is acceptable (e.g., Levaquin is documented in MAR for pneumonia and nursing documentation within 6 hours of criteria b and c that indicates a dose was given).

• If documentation of an infection is in a physician/APN/PA, nursing, or pharmacist note without a specific date and time or documented using the acronym POA, use the date and time the note was started or opened.

• If the note states an infection was present on arrival, use the earliest documented arrival date and time.

• If the note states an infection was present on admission, use the earliest documented date and time that the patient arrives to the floor or unit for admission.

• If an infection is documented and within 6 hours following the initial documentation of the infection, there is additional physician/APN/PA documentation indicating the infection is not present, disregard the initial documentation of the infection.

• Documentation of an infection in an active problem list is acceptable if there is information in the medical record supporting the infection is current.

• If a condition documented in the medical record does not include the word "infection," or is not in the Inclusion Guidelines for Abstraction infection list, consulting other medical resources (such as a medical dictionary) to identify whether or not the condition is an infection or is caused by an infection is acceptable.

i. If the other medical resource indicates the condition is an infection or is caused by an infection, it may be used to meet the suspected infection criteria.

ii. If the other medical resource indicates the condition is NOT an infection and NOT caused by an infection, it may NOT be used to meet the suspected infection criteria.

iii. If the other medical resource indicates the condition may or may not be an infection, or may be caused by an infection or may be caused by something other than an infection, there must be additional documentation in the medical record supporting the condition is an infection (e.g., antibiotic ordered for the condition) to be used to meet the suspected infection criteria.

- If an antibiotic is ordered for a condition that may be inflammation or a sign or symptom of an infection this may be considered documentation of an infection (e.g., ceftriaxone ordered for colitis, Zosyn 3.375 g IV q6hr for cough).
- Exclude documentation of viral, fungal, or parasitic infections.

b. <u>Two or more</u> manifestations of systemic infection according to the Systemic Inflammatory Response Syndrome (SIRS) criteria, which are:

- Temperature >38.3 C or <36.0 C (>100.9 F or <96.8 F)
- Heart rate (pulse) >90
- Respiration >20 per minute
- White blood cell count >12,000 or <4,000 or >10% bands
- •

c. Organ dysfunction, evidenced by <u>any one of the following</u>:

- Systolic blood pressure (SBP) <90 mmHg or mean arterial pressure <65 mmHg.
 - **Do not use** hypotensive BPs documented from an orthostatic BP evaluation.
- Systolic blood pressure decrease of more than 40 mmHg.
 - Physician/APN/PA documentation must be present in the medical record indicating a >40 mmHg decrease in SBP has occurred and is related to infection, Severe Sepsis or Septic Shock and not other causes.
- Acute respiratory failure as evidenced by a new need for invasive or non-invasive mechanical ventilation.
 - o Documentation the patient is on mechanical ventilation.
 - Invasive mechanical ventilation requires an endotracheal or tracheostomy tube. Non-invasive mechanical ventilation maybe referred to as BiPAP or CPAP.

- New need for mechanical ventilation indicates the patient had a new need for mechanical ventilation that was not previously needed or the patient had an increased need from intermittent to continuous mechanical ventilation.
- Use the time mechanical ventilation was initiated or the time the mechanical ventilation changed from intermittent to continuous.
- Creatinine >2.0
 - If there is physician/APN/PA documentation prior to or within 24 hours following presentation of severe sepsis that the patient has end stage renal disease (ESRD) and is on hemodialysis or peritoneal dialysis all reported creatinine levels should be disregarded as signs of organ dysfunction. ESRD (on hemodialysis or peritoneal dialysis) and creatinine levels or reference to elevated creatinine levels do not need to be included in the same physician/APN/PA documentation.
 - If there is physician/APN/PA documentation prior to or within 24 hours following presentation of severe sepsis of chronic renal disease (e.g., CKD I, II, or III, or "chronic renal insufficiency") and the baseline creatinine is documented, creatinine values elevated >0.5 above baseline should be used as organ dysfunction (e.g., baseline 2.30, creatinine now2.81).
- Urine output <0.5 mL/kg/hour for 2 consecutive hours
 - Documentation must clearly indicate that urine output is being monitored hourly to be able to use this as organ dysfunction.
- Total Bilirubin >2 mg/dL (34.2 mmol/L)
- Platelet count <100,000
- INR >1.5 or aPTT >60 sec
 - If the suggested data source shows the patient was given an anticoagulant medication in Appendix C Table 5.3, an elevated INR or a PTT level should not be used as organ dysfunction. Physician/APN/PA documentation is not required. If only the following is given, the elevated INR or a PTT level should be used:
 - Heparin flushes
- Lactate >2 mmol/L (18.0 mg/dL)
- For the following, physician/APN/PA documentation prior to or within 24 hours after *Severe Sepsis Presentation Time* **is required**.
 - If the SIRS criteria or a sign of organ dysfunction is due to the following, it should not be used. Inferences should not be made. The abnormal value or reference to the abnormal value must be in the same documentation.
 - Normal for that patient
 - Is due to a chronic condition
 - Is due to a medication

- Do not use value since the creatinine and the chronic condition are in the same documentation and section of the H&P.
 - H&P: Assessment Section
 - **Renal Assessment**

History of CKD

Creatinine 3.0

HD daily

- Do not use the hypotensive readings since the medication is in the same sentence
 - "Hypotensive after pain meds"
- If SIRS criteria or a sign of organ dysfunction is due to an acute condition that has a noninfectious source/process, it **should not be used** (Refer to *Severe Sepsis Present* criteria "a" to determine if the source of the acute condition is an infection).

Examples:

- "Lactate 4.3 r/t seizure" "Seizure post brain injury" (seizure is the acute condition and brain injury is the non-infectious source).
- "AKI, dehydrated due to nephrotoxic medication, creatinine 3.8." (AKI and dehydration are the acute conditions and medication is the non-infectious source).
- APN Note: "Elevated Cr secondary to dehydration post DKA." Physician Note: "DKA likely due to patient non-compliance with meds." (dehydration is the acute condition and DKA is the non-infectious source because it is due to medication non-compliance).
- If SIRS criteria or a sign of organ dysfunction should not be used based on the above guidance, all instances of less severe values **should not be used**.

Examples:

- "Platelet count 75 r/t chemo" (platelet counts ≥ 75 would not be used).
- "Cr 2.8, CKD" (creatinine values ≤ 2.8 would not be used).
- If SIRS criteria or a sign of organ dysfunction is due to the following, the criteria value **should be used.**
 - Acute condition

Examples:

- Progress Note: "Lactate 4.3 r/t seizure."
- H&P: "AKI, dehydration, creatinine 3.8."
- Acute on chronic condition

Examples:

- H&P: "Acute on chronic renal failure, creatinine 2.8."
- Progress Note: "Hypotension due to acute exacerbation of chronic heart failure."

o Infection

Example:

Physician Note: "Cholecystitis with Hyperbilirubinemia."

Antibiotic Order Indication: "Cholecystitis" (The antibiotic indication confirms cholecystitis is an infection).

Documentation of a term that represents or is defined by a SIRS criteria or sign of organ dysfunction is acceptable in place of an abnormal value when documented as normal for the patient, due to a chronic condition, due to a medication, or due to an acute condition that has a non-infectious source/process. **Examples** include but are not limited to:

- Tachypnea (Respiration >20 per minutes)
- Tachycardia, RVR (Heart rate >90)
- Leukopenia (White blood cell count <4,000)
- Leukocytosis (White blood cell count >12,000)
- Thrombocytopenia (Platelet count <100,000)
- Hypotension (Systolic blood pressure <90 mmHg)
- If <u>within the same physician/APN/PA documentation</u>, there is conflicting documentation indicating SIRS criteria or sign of organ dysfunction is normal for the patient, or due to a chronic condition or medication AND due to or possibly due to an infection, Severe Sepsis, or Septic Shock, the criteria value **should be used**.

- "Creatinine 4.3, CKD, potentially increasing due to worsening UTI," creatinine value should be used.
- "Thrombocytopenia possibly due to NSAID use, however complicated by sepsis," platelet value should be used.
- If <u>within 24 hours after Severe Sepsis Presentation Time</u> there is conflicting information within **two or more separate** pieces of physician/APN/PA documentation indicating SIRS criteria or sign of organ dysfunction is normal for the patient, or due to a chronic condition or medication AND due to or possibly due to an infection, Severe Sepsis, or Septic Shock, abstract based on the **latest** piece of documentation within the 24-hour period.

Examples:

- H&P 0900: "Tachypnea, on 2L NC, chronic emphysema." Consult 1500: "URI x 2 days with worsening tachypnea."
 - Elevated respiratory rate should be used.
- Note 1800: "Patient has been taking Lasix BID for 1 week, presenting with hypotension and dehydration."

Note 2230: "Dehydration and hypotension currently, Lasix discontinued, starting fluid resuscitation for possible sepsis."

- Hypotensive readings should be used.
- SIRS criteria or a sign of organ dysfunction obtained within the operating room (OR), interventional radiology, during active delivery, or procedural/conscious sedation **should not be used**.
- SIRS criteria or a sign of organ dysfunction due to artificial interventions **should not be used.**

Example:

Mechanical ventilator rate set at 24 and respiratory rate is 24, the respiratory rate would not be used for SIRS criteria.

• If an artificial intervention is unable to control a patient's physiological function, the SIRS criteria or a sign of organ dysfunction **should be used**.

Example:

Mechanical ventilator rate set at 24 and respiratory rate at 28, the respiratory rate should be used for SIRS criteria.

- The title or heading of an order set, protocol, checklist, alert, screening tool, etc. reflecting an infection, SIRS, Organ Dysfunction, Sepsis, Severe Sepsis, or Septic Shock should not be used to meet criteria.
- Documentation of an infection, SIRS, Organ Dysfunction, Sepsis, Severe Sepsis, or Septic Shock *within an* order set, protocol, checklist, alert, screening tool, etc., may be used if the following is true: The documentation or value and recorded date and time is present and is the earliest date and time recorded for the criteria.
- If within 24 hours after the *Severe Sepsis Presentation Time* there is physician/APN/PA or nursing documentation that SIRS criteria or sign of organ dysfunction is invalid, erroneous or questionable, disregard that value when determining the presence of Severe Sepsis.
- Use the time vital signs were taken or obtained. If time taken or obtained is not available, use recorded or documented time. Do not abstract vital signs from narrative charting unless there is no other documentation that reflects the time that the same vital sign was obtained.
- To determine the laboratory test value time for severe sepsis criteria, use the following sources in priority order.
 - Primary source: Laboratory test value result time from lab
 - Supporting sources in priority order if primary source not available:
 - 1. Time within a narrative note that is directly associated with the laboratory test value
 - 2. Time the laboratory test value is documented in a non-narrative location (e.g., sepsis flowsheet)
 - 3. Laboratory test sample draw or collected time
 - 4. Physician/APN/PA or nursing narrative note open time
- Use of documentation in pre-hospital records (e.g., ambulance records, nursing home records) that is considered part of the medical record is acceptable for determining presence of Severe Sepsis.
- If there is more than one presentation of Severe Sepsis in the record, abstract only the first presentation.
- If clinical criteria for Severe Sepsis are not met, but there is physician/APN/PA documentation of Severe Sepsis, choose Value "1."
- If Severe Sepsis is met by physician/APN/PA documentation only, and is documented as due to a viral, fungal, or parasitic infection, the documentation of Severe Sepsis should not be used.
- If clinical criteria for Severe Sepsis are not documented and there is not physician/APN/PA documentation of Severe Sepsis, but there is physician/APN/PA documentation of Septic Shock, choose Value "1."
- Disregard any documentation of SIRS criteria, organ dysfunction, an infection, Severe Sepsis, or Septic Shock in a discharge note, discharge summary, or documented after the time of discharge.
- Choose Value "2" if within 6 hours after documentation meeting clinical criteria or physician/APN/PA documentation of Severe Sepsis there is additional physician/APN/PA documentation indicating:
 - o Patient is not septic

- Patient does not have Sepsis or Severe Sepsis
- Patient does not have Septic Shock, and Severe Sepsis was met by Physician/APN/PA documentation that Septic Shock was present.
- Severe Sepsis or Septic Shock is due to a viral, fungal, or parasitic infection.
- For the infection criterion of severe sepsis present-exclude infections documented to be due to viral, fungal, or parasitic cause:
 - Exclude only those cases identified at presentation as solely due to viral, fungal, or parasitic infection.
- Sepsis cases that are determined after presentation of severe sepsis and later than 6 hours after presentation of septic shock to be due to viral, fungal or parasitic infections should continue to be reported.
- Cases of viral infection with bacterial suprainfection should be reported.
- All cases of unknown infectious etiology should be reported.
- For documentation of an infection, Severe Sepsis, or Septic Shock accompanied by a qualifier, the table below should be used. Documentation containing a positive qualifier should be used to meet criteria, documentation containing a negative qualifier should not be used to meet criteria. Documentation containing both a positive and negative qualifier should not be used to meet criteria.

Positive Qualifiers	Negative Qualifiers
Possible	Impending
Rule out (r/o)	Unlikely
Suspected	Doubt
Likely	Risk for
Probable	Ruled out
Differential Diagnosis	Evolving
Suspicious for	Questionable
Concern for	

Suggested Data Sources:

Any physician/APN/PA documentation Entire ED record Hourly output record Intake/Output record Laboratory results Nurses notes Vital signs record or flow sheet

Guidelines for Abstraction: Severe Sepsis

Inclusions

Documentation that is acceptable for Severe Sepsis. PHYSICIAN/APN/PA DOCUMENTATION ONLY Severe Sepsis

Exclusions

Documentation that is not acceptable for Severe Sepsis. Bacteremia Septicemia

Guidelines for Abstraction: Infections

Inclusions

Documentation that is acceptable for an infection.

The following is a list of conditions commonly associated with Severe Sepsis that are considered infections.

- o (This is not an all-inclusive list.)
- o Abscess
- o Acute abdomen
- Acute abdominal infection
- o Blood stream catheter infection
- o Bone/joint infection
- o C. difficile (C-diff)
- o Chronic Obstructive Pulmonary Disease (COPD) acute exacerbation
- o Endocarditis
- o Gangrene
- o Implantable device infection
- o Infection
- o Infectious
- o Meningitis
- o Necrosis
- Necrotic/ischemic/infarcted bowel
- o Pelvic Inflammatory Disease
- Perforated bowel
- o Pneumonia, empyema
- o Purulence/pus
- o Sepsis
- o Septic
- o Skin/soft tissue infection
- o Suspect infection, source unknown
- o Urosepsis, Urinary tract infection
- o Wound infection

Exclusions

Documentation that is not acceptable for an infection.

- Colonization, positive screens, or positive cultures (e.g., MRSA, VRE, or for other bacteria) without physician/APN/PA documentation referencing an infection.
- o Fungal infections

- History of infection, recent infection, or recurrent infection that is not documented as a current or active infection.
- o Orders for tests or screens without documentation of a suspected infection.
- o Parasitic infections
- Results of tests without documentation of a suspected infection (e.g., infiltrates on chest x-ray, positive cultures).
- Signs or symptoms of an infection without supportive documentation.
- $\circ \quad \text{Viral infections} \quad$

Dataset Segment:	Adherence Variables
Data Element Name:	Severe Sepsis Presentation Datetime
Format – Length:	Datetime-16
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Yes

This variable has been aligned with the CMS SEP-1 data elements Severe Sepsis Presentation Date and Severe Sepsis Presentation Time. Please use the combination of those data elements for submission of *Severe Sepsis Presentation Datetime*. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable.

Definition: The earliest date on which the final criterion was met to establish the presence of severe sepsis.

Codes and Values:

Notes for Abstraction:

- Formatting:
 - b) Format must be YYYY-MM-DD hh:mm
 - a. YYYY-MM-DDThh:mm is also valid
 - c) YYYY = four-digit year
 MM = two-digit month (01=January, etc.)
 DD = two-digit day of month (01 through 31)
 hh = two digits of hour (00 through 23) (am/pm NOT allowed)
 mm = two digits of minute (00 through 59)
 - d) Example: 11:42 pm November 3, 1959=1959-11-03 23:42
 a. 1959-11-03T23:42 is also valid
 - e) Midnight = 00:00, not 24:00
- Cannot have been after *Discharge Datetime*.
- Cannot be before Arrival Datetime.
- If *Severe Sepsis Present* = 2, then must be blank.
- If filled in and *Septic Shock Presentation Datetime* filled in, cannot be after *Septic Shock Presentation Datetime*.
- Use the earliest date/time the final clinical criterion for severe sepsis was noted (see *Severe Sepsis Present* data element for clinical criteria list) or the earliest date the Physician/APN/PA documented severe sepsis.
- In patients with multiple episodes of severe sepsis within the same stay, use the date/time from the first episode.
- If severe sepsis or septic shock is documented in a physician/APN/PA note without a specific date or documented using the acronym POA, the following apply:

- If it is the only documentation of Severe Sepsis or Septic Shock in the note, use the date the note was started or opened.
- If Severe Sepsis or Septic Shock is documented multiple times within the same note, use the earliest specified date.
- Use the earliest documented arrival date for patients who enter the Emergency Department with the following:
 - Severe sepsis clinical criteria met in pre-hospital records
 - Physician/APN/PA documentation of severe sepsis in pre-hospital records
 - Physician/APN/PA documentation that severe sepsis was present on arrival
- Use the earliest documented date patient arrives to floor or unit for patients who are direct hospital admits and one of the following is present:
 - Severe sepsis clinical criteria met in pre-hospital records
 - Physician/APN/PA documentation of severe sepsis in pre-hospital records
 - Earliest documentation is in a Physician/APN/PA note that states severe sepsis was present on admission
- If the only documentation of severe sepsis being present is in a Physician/APN/PA note that states severe sepsis was present on admission, use the earliest date of the following:
 - Physician/APN/PA note
 - o Admit order
 - o Disposition to inpatient
 - Arrival to floor or unit
- If clinical criteria for severe sepsis are met after physician/APN/PA documentation of septic shock, enter the date the physician/APN/PA documented septic shock.
- If clinical criteria for severe sepsis are not documented and there is not physician/APN/PA documentation of severe sepsis, but there is physician/APN/PA documentation of septic shock, enter the earliest date septic shock was documented for this data element.

Suggested Data Sources:

- Any physician/APN/PA documentation
- Entire ED record
- Hourly output record
- Intake/Output record
- Laboratory results
- Nurses notes
- Vital signs record or flow sheet

Dataset Segment:

Adherence Variables

Data Element Name:	Vasopressor Administration
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Situational

Description:

This variable has been aligned with the CMS SEP-1 data element Vasopressor Administration. Please use the information from that data element for submission of *Vasopressor Administration*. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable.

Definition: Documentation of administration of an intravenous or intraosseous vasopressor in the time window beginning at septic shock presentation and ending 6 hours after the presentation of septic shock, demonstrated by persistent hypotension after crystalloid fluid administration.

Codes and Values:

- 1 = (Yes) The patient was given an intravenous or intraosseous vasopressor in the time window beginning at septic shock presentation and ending 6 hours after the presentation of septic shock.
- 2 = (No) The patient was not given an intravenous or intraosseous vasopressor in the time window beginning at septic shock presentation and ending 6 hours after the time of presentation of septic shock, or Unable to Determine.

Notes for Abstraction:

- Must be completed if
 - Septic Shock Present = 1; AND,
 - Adult Crystalloid Fluids Administration = 1; AND,
 - Persistent Hypotension = 1.
- Only vasopressors on the CMS acceptable list can be abstracted and reported (Appendix C in CMS Specifications Manual v. 5.3).
- Only abstract a vasopressor given via the IV or intraosseous (IO) route.
- Vasopressor administration information should only be abstracted from documentation that demonstrates actual administration of the vasopressor. Do not abstract doses from a physician order unless they are clearly designated as given on the physician order form.

- The method of designation of administration on hand-written or pre-printed forms, such as MARs or eMARs, must be clearly designated as given. The methods may vary. Whatever method is used, it must be clear that the dose was administered.
- If a vasopressor was infusing at the time of presentation of septic shock, demonstrated by persistent hypotension after crystalloid fluid administration, choose Value "1." For example, septic shock patient was triaged in the ED at 08:00. The patient was receiving Levophed via an IV at the time of triage choose Value "1."
- Use of documentation in pre-hospital records (e.g., ambulance records, nursing home records) that are considered part of the medical record is acceptable.
- Do not abstract test doses of vasopressors.

Dataset Segment:	Adherence Variables
Data Element Name:	Vasopressor Administration Datetime
Format – Length:	Datetime-16
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Situational

This variable has been aligned with the CMS SEP-1 data elements Vasopressor Administration Date and Vasopressor Administration Time. Please use the combination of those data elements for submission of *Vasopressor Administration Datetime*. The most recent CMS definition, notes, and guidelines should be referenced for all questions and issues regarding this variable.

Definition: The date on which an intravenous or intraosseous vasopressor was administered within 6 hours following the presentation of septic shock, demonstrated by persistent hypotension after crystalloid fluid administration.

Notes for Abstraction:

- Formatting:
 - Format must be YYYY-MM-DD hh:mm
 - a. YYYY-MM-DDThh:mm is also valid
 - o YYYY = four-digit year

MM = two-digit month (01=January, etc.)

- DD = two-digit day of month (01 through 31)
- hh = two digits of hour (00 through 23) (am/pm NOT allowed)

mm = two digits of minute (00 through 59)

- o Example: 11:42 pm November 3, 1959=1959-11-03 23:42
 - a. 1959-11-03T23:42 is also valid
- Midnight = 00:00, not 24:00
- If *Vasopressor Administration* = 1, then must be completed.
- If Vasopressor Administration is blank or contains a value of 2, then must be blank.
- Cannot have been after *Discharge Datetime*.
- If a vasopressor was infusing at the time of presentation of septic shock, demonstrated by persistent hypotension after crystalloid fluid administration, or the vasopressor was infusing at the time of septic shock and multiple doses were subsequently given, abstract the date the vasopressor that was infusing at the time of presentation of septic shock was initiated.
- If the patient received multiple doses of a vasopressor and there was no vasopressor infusing at the time of presentation of septic shock, abstract the dose given closest to the time of presentation of septic shock.

• Only abstract from an undated MAR if it has a patient sticker on it and it is titled first day or initial MAR. If an undated MAR is designated as the initial or first day MAR and it does not have a patient sticker on it, use UTD for the date.

Severity Adjustment Variables

Dataset Segment:	Severity Adjustment Variables
Data Element Name:	Altered Mental Status
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Description: The clinical criteria timeframe for these data elements is within six hours before to six hours after the identification of severe sepsis and/or septic shock.

Was there any difference from the patient's baseline in any of the three spheres of orientation (sense of person/self, place and date/time) or in their level of alertness?

Codes and Values:

- 0 = No
- 1 = Yes
- 2 = Unknown

- Must be completed.
- Altered mental status refers to the difference in mental status at the time of the sepsis episode as compared to the patient's baseline.
- This is not automatically the first mental assessment of the patient for that admission.

Dataset Segment:	Severity Adjustment Variables
Data Element Name:	Bandemia
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Was the band count more than 5% of the total white blood cell count at the time of *Severe Sepsis Presentation Datetime*?

Codes and Values:

0 = No

1 = Yes

2 = Unknown

- Must be completed.
- Additional information for the bandemia critical limit value being set at 5%:
 - The bandemia element is one component of the Mortality in Emergency Department Sepsis (MEDS) score and has been used in various studies for the creation of risk adjusted mortality associated with sepsis.
 - Shapiro NI, et al. Mortality in Emergency Department Sepsis (MEDS) score: a prospectively derived and validated clinical prediction rule. Critical Care Medicine 2003; 31(3): 670-675.
- Severity variable vs. SIRS criterion:
 - Band count 5% is the severity variable collected for this data element.
 - o Band count 10% is a SIRS criterion.
- If the laboratory does not provide a report of percentage of bands, select "2". If bands are not elevated, select 0. If bands are elevated select "1".
- The clinical criteria timeframe for these data elements is within six hours before to six hours after the identification of severe sepsis and/or septic shock.

Dataset Segment:	Severity Adjustment Variables
Data Element Name:	Lower Respiratory Infection
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Was there infiltrate on the patient's chest radiograph, computed tomography scan, or the presence of clinical findings suggestive of lower respiratory infection?

Codes and Values:

0 = No 1 = Yes 2 = Unknown

- Must be completed.
- The clinical criteria timeframe for these data elements is within six hours before to six hours after the identification of severe sepsis and/or septic shock.

Dataset Segment:	Severity Adjustment Variables
Data Element Name:	Platelet Count (Thrombocytopenia)
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Was the platelet count at the time of *Severe Sepsis Present* <150,000 cells/mm³?

Codes and Values:

0 = No

1 = Yes

2 = Unknown

- Must be completed.
- The collection of low platelets associated with sepsis is captured to determine patient severity.
- Severity variable vs. organ dysfunction:
 - Platelets <150,000 is the severity variable collected for this data element.
 - Platelets <100,000 is a sign of organ dysfunction.
- The clinical criteria timeframe for these data elements is within six hours before to six hours after the identification of severe sepsis and/or septic shock.

Comorbidity Variables

Dataset Segment:	Comorbidity Variables
Data Element Name:	AIDS/HIV Disease
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Indicate if patient has AIDS or HIV infection. This is demonstrated by a history of the condition reported in the chart by any source, lab or radiologic results which would be considered diagnostic of the condition or notation in the chart indicating the patient has been/was diagnosed with the condition.

Codes and Values:

- 0 = Not present on admission
- 1 = Present on admission
- 2 = Not known upon admission, but discovered prior to presentation of severe sepsis
- 3 = Not known upon admission but discovered after the presentation of severe sepsis

Notes for Abstraction:

Dataset Segment:	Comorbidity Variables
Data Element Name:	Chronic Liver Disease
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Indicate if patient has chronic liver disease as defined as the presence of cirrhosis or other liver disease accompanied by elevated bilirubin > 2mg/dL and serum albumin < 3.5g/dL, documentation of prior or present esophageal or gastric varices, portal hypertension, previous hepatic encephalopathy or ascites with notation of liver disease. This is demonstrated by a history of the condition reported in the chart by any source, lab or radiologic results which would be considered diagnostic of the condition or notation in the chart indicating the patient has been/was diagnosed with the condition.

Codes and Values:

- 0 = Not present on admission
- 1 = Present on admission
- 2 = Not known upon admission but discovered prior to presentation of severe sepsis
- 3 = Not known upon admission but discovered after the presentation of severe sepsis

- Must be completed.
- For patients with Hepatitis B or C without liver failure, clinical judgment should be used in determining the acute versus chronic stage of the liver disease.

Dataset Segment:	Comorbidity Variables
Data Element Name:	Chronic Renal Failure
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Indicate if patient has renal failure sufficient to require peritoneal dialysis or hemodialysis. This is demonstrated by a history of the condition reported in the chart by any source, lab or radiologic results which would be considered diagnostic of the condition or notation in the chart indicating the patient has been/was diagnosed with the condition.

Codes and Values:

- 0 = Not present on admission
- 1 = Present on admission
- 2 = Not known upon admission but discovered prior to presentation of severe sepsis
- 3 = Not known upon admission but discovered after the presentation of severe sepsis

Notes for Abstraction:

Dataset Segment:	Comorbidity Variables
Data Element Name:	Chronic Respiratory Failure
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Patient has chronic respiratory failure that requires use of mechanical ventilation. This is demonstrated by a history of the condition reported in the chart by any source, lab or radiologic results which would be considered diagnostic of the condition or notation in the chart indicating the patient has been/was diagnosed with the condition.

Codes and Values:

- 0 = Not present on admission
- 1 = Present on admission
- 2 = Not known upon admission but discovered prior to presentation of severe sepsis
- 3 = Not known upon admission but discovered after the presentation of severe sepsis

Notes for Abstraction:

Dataset Segment:	Comorbidity Variables
Data Element Name:	Congestive Heart Failure
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

An indication of congestive heart failure with evidence of treatment; include compensated and uncompensated congestive heart failure. This is demonstrated by a history of the condition reported in the chart by any source, lab or radiologic results which would be considered diagnostic of the condition or notation in the chart indicating the patient has been/was diagnosed with the condition.

Codes and Values:

- 0 = Not present on admission
- 1 = Present on admission
- 2 = Not known upon admission but discovered prior to presentation of severe sepsis
- 3 = Not known upon admission but discovered after the presentation of severe sepsis

Notes for Abstraction:

Dataset Segment:	Comorbidity Variables
Data Element Name:	Diabetes
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Indicate if patient was diagnosed and/or treated for diabetes or notation of a HbA1c of 6.5% or higher. Include patients on any pharmacologic therapy; exclude diet controlled, history of pregnancy related diabetes, and acute hyperglycemia without known history of diabetes. This is demonstrated by a history of the condition reported in the chart by any source, lab or results which would be considered diagnostic of the condition or notation in the chart indicating the patient has been/was diagnosed with the condition.

Codes and Values:

- 0 = Not present on admission
- 1 = Present on admission
- 2 = Not known upon admission but discovered prior to presentation of severe sepsis
- 3 = Not known upon admission but discovered after the presentation of severe sepsis

Notes for Abstraction:

Dataset Segment:	Comorbidity Variables
Data Element Name:	ICU
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Indicate if the patient was admitted to the Intensive Care Unit (ICU; MICU; SICU; CCU).

Codes and Values:

- 0 = Patient not admitted to ICU
- 1 = Patient admitted to ICU

- Must be completed.
- If *ICU* = 1, *ICU Admission Datetime* and *ICU Discharge Datetime* must be completed.
- Indicate if the patient was admitted at any time to the ICU during the hospital admission.

Dataset Segment:	Comorbidity Variables
Data Element Name:	ICU Admission Datetime
Format – Length:	Datetime-16
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Situational

The date and time the patient was first admitted to the Intensive Care Unit (ICU).

Codes and Values:

- Formatting:
 - Format must be YYYY-MM-DD hh:mm

 YYYY-MM-DDThh:mm is also valid
 - YYYY = four-digit year
 MM = two-digit month (01=January, etc.)
 DD = two-digit day of month (01 through 31)
 hh = two digits of hour (00 through 23) (am/pm NOT allowed)
 mm = two digits of minute (00 through 59)
 - 3. Example: 11:42 pm November 3, 1959=1959-11-03 23:42
 - a. 1959-11-03T23:42 is also valid
 - 4. Midnight = 00:00, not 24:00
- If *ICU* = 1, then must be completed.
- If *ICU* = 0, then must be blank.
- Cannot have been after *Discharge Datetime*.
- Indicate if the patient was admitted at any time to the ICU during the hospital admission, and specify that date and time. If there is a different between actual admission and order time, the order time to ICU should be reported.
- If there are multiple ICU admissions within the same hospital admission (due the patient being transferred in & out multiple times), use the first ICU admission date and time.
- "Indicate if the patient was admitted to the Intensive Care Unit (ICU)" means if the patient was admitted at any time during the stay. Specify the date and time in the 'ICU Admission Datetime' data element.

Dataset Segment:	Comorbidity Variables
Data Element Name:	ICU Discharge Datetime
Format – Length:	Datetime-16
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Situational

The date and time that the patient was first discharged from the Intensive Care Unit (ICU) or expired.

Codes and Values:

- Formatting:
 - 1. Format must be YYYY-MM-DD hh:mm
 - a. YYYY-MM-DDThh:mm is also valid
 - YYYY = four-digit year
 MM = two-digit month (01=January, etc.)
 DD = two-digit day of month (01 through 31)
 hh = two digits of hour (00 through 23) (am/pm NOT allowed)
 mm = two digits of minute (00 through 59)
 - 3. Example: 11:42 pm November 3, 1959=1959-11-03 23:42
 - a. 1959-11-03T23:42 is also valid
 - 4. Midnight = 00:00, not 24:00
- If *ICU* = 1, then must be completed.
- If *ICU* = 0, then must be blank.
- ICU Discharge Datetime may not precede ICU Admission Datetime.
- If there is a difference between discharge order and actual discharge time, report actual discharge date and time.

Dataset Segment:	Comorbidity Variables
Data Element Name:	Immune Modifying Medications
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Indicate if patient is taking disease modifying medications/therapies (drugs and biologics) for collagen diseases, corticosteroids, chemotherapeutic agents through any modality (oral, IV, IM, etc.) known to specifically adversely impact the function of the immune system as primary therapeutic goal or unintended side effect, including steroids (excluding inhaled or topical steroids), radiotherapy, chemotherapy. This is demonstrated by a history of the condition reported in the chart by any source, lab or radiologic results which would be considered diagnostic of the condition or notation in the chart indicating the patient has been/was diagnosed with the condition.

Codes and Values:

- 0 = Not present on admission
- 1 = Present on admission
- 2 = Not present on admission but started prior to presentation of severe sepsis
- 3 = Not present on admission but started after the presentation of severe sepsis

- Must be completed.
- As steroid usage (dosage/type) can vary depending on the patient's acute or chronic conditions, clinical judgment should be used in answering this variable.

Dataset Segment:	Comorbidity Variables
Data Element Name:	Infection Etiology (Hospital Acquired Infection)
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Indicate if the severe sepsis or septic shock was the result of a hospital acquired infection that was obtained sometime during that current admission.

Codes and Values:

- 0 = No
- 1 = Yes
- 2 = Unknown

- Must be completed.
- ONLY indicate "1 = Yes" if <u>ALL</u> of the following conditions are met:
 - The infection is a hospital acquired infection (HAI)
 - The HAI was acquired from <u>your</u> facility
 - o The HAI was acquired from your facility during this current admission
- If only 1 or 2 of the above conditions are met, then either "0 = No" or "2 = Unknown" must be chosen (depending on the particular circumstance).
- All severe sepsis & septic shock cases presenting as such to the ED should be reported as "0 = No" unless the patient arrived at the ED for a different reason, acquired a HAI in the ED, and resultantly developed severe sepsis or septic shock.
- Example:
 - o The patient presented to the ED from a nursing home
 - And the patient presented with severe sepsis (or septic shock) secondary to pneumonia (diagnoses)
 - And the infection (pneumonia) was "hospital acquired" from the nursing home
 - This is <u>not</u> reported as "1 = Yes" this should be reported as "0 = No"
 - If the patient arrives at the hospital with severe sepsis/septic shock, then the infection causing that condition was not hospital acquired (as defined for these reporting purposes).

• If the patient arrives at a hospital with severe sepsis or septic shock, then the condition was not hospital acquired (e.g. arrives from a nursing home).

Dataset Segment:	Comorbidity Variables
Data Element Name:	Lymphoma/Leukemia/Multiple Myeloma
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Indicate if patient has malignant neoplasm of lymphatic and hematopoietic tissue including those neoplasms which may be in clinical remission. This is demonstrated by a history of the condition reported in the chart by any source, lab or radiologic results which would be considered diagnostic of the condition or notation in the chart indicating the patient has been/was diagnosed with the condition.

Codes and Values:

- 0 = Not present on admission
- 1 = Present on admission
- 2 = Not known upon admission but discovered prior to presentation of severe sepsis
- 3 = Not known upon admission, but discovered after the presentation of severe sepsis

Notes for Abstraction:

Dataset Segment:	Comorbidity Variables
Data Element Name:	Mechanical Ventilation
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Indicate whether the patient had mechanical ventilation support during the hospital stay. Do not report patients with only CPAP for sleep apnea as having mechanical ventilation.

Codes and Values:

0 = No mechanical ventilation

1 = Mechanical ventilation

- Must be completed.
- If *Mechanical Ventilation* = 1, then *Mechanical Ventilation Datetime* must be completed.
- Any type of mechanical/assisted ventilation (invasive or non-invasive) is acceptable.
- If a patient was **only** intubated for surgery and was able to be extubated, then mechanical ventilation would not apply.
- Examples of acceptable use:
 - BIPAP (except when used only for sleep apnea)
 - \circ $\;$ The patient arrived and remained on mechanical ventilation
 - The patient was intubated, specifically associated with initiation of mechanical ventilation
 - The patient was intubated for surgery and was unable to be extubated post-surgery
- Mechanical ventilation includes all types of assisted ventilation except CPAP or BiPAP for sleep apnea.

Dataset Segment:	Comorbidity Variables
Data Element Name:	Mechanical Ventilation Datetime
Format – Length:	Datetime-16
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Situational

The date and time that the patient was first started on mechanical ventilation.

Codes and Values:

- Formatting:
 - Format must be YYYY-MM-DD hh:mm

 YYYY-MM-DDThh:mm is also valid
 - YYYY = four-digit year
 MM = two-digit month (01=January, etc.)
 DD = two-digit day of month (01 through 31)
 hh = two digits of hour (00 through 23) (am/pm NOT allowed)
 mm = two digits of minute (00 through 59)
 - 3. Example: 11:42 pm November 3, 1959=1959-11-03 23:42
 - a. 1959-11-03T23:42 is also valid
 - 4. Midnight = 00:00, not 24:00
- If *Mechanical Ventilation* = 1, then must be completed.
- If *Mechanical Ventilation* is blank or contains a value of 2, then must be blank.
- Cannot have been after *Discharge Datetime*.
- The datetime of the clinician's <u>order</u> for mechanical ventilation is not acceptable.
- Any type of mechanical/assisted ventilation (invasive or non-invasive) is acceptable, except:
 - BIPAP is acceptable, except in use for sleep apnea.
- If the patient arrives on mechanical ventilation, use *Arrival Datetime*.
- Intubation datetime may be used if specifically associated with the initiation of mechanical ventilation for the patient.
- If a patient was intubated for surgery and was unable to be extubated post-surgery, then use the surgery intubation datetime. If a patient was **only** intubated for surgery and was able to be extubated, then mechanical ventilation would not apply.
- The intubation datetime can be used for Mechanical Ventilation Datetime if it is specifically associated with the initiation of mechanical ventilation for the patient. Any type of

mechanical ventilation (invasive or noninvasive) is acceptable, except CPAP or BIPAP that is used specifically for sleep apnea. An order date/time for mechanical ventilation is not acceptable.

• If the patient arrives in the ED and is already receiving and continues to receive ventilation support, the arrival date and time would be used for Mechanical Ventilation Datetime.

Dataset Segment:	Comorbidity Variables
Data Element Name:	Metastatic Cancer
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Indicate if patient has any solid, malignant neoplasm with evidence of metastasis beyond the primary involved organ, including involvement of lymph nodes (exclude lymphoma/leukemia/multiple myeloma) and including brain tumor. This is demonstrated by a history of the condition reported in the chart by any source, lab or radiologic results which would be considered diagnostic of the condition or notation in the chart indicating the patient has been/was diagnosed with the condition.

Codes and Values:

- 0 = Not present on admission
- 1 = Present on admission
- 2 = Not known upon admission but discovered prior to presentation of severe sepsis
- 3 = Not known upon admission, but discovered after the presentation of severe sepsis

- Must be completed.
- Malignant brain tumor may also be counted as a comorbidity under Metastatic Cancer.

Dataset Segment:	Comorbidity Variables
Data Element Name:	Organ Transplant
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Indicate if patient had an organ transplant including heart, lung, kidney, liver, pancreas, stem cell/bone marrow. Exclude corneal or skin transplant/grafting. This is demonstrated by a history of the condition reported in the chart by any source, lab or radiologic results which would be considered diagnostic of the condition or notation in the chart indicating the patient has been/was diagnosed with the condition.

Codes and Values:

- 0 = Not present on admission
- 1 = Present on admission
- 2 = Not present on admission but received transplant prior to presentation of severe sepsis
- 3 = Not present on admission but received transplant after the presentation of severe sepsis

Notes for Abstraction:

Dataset Segment:	Comorbidity Variables
Data Element Name:	Site of Infection
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Indicate the suspected or diagnosed site of infection.

Codes and Values:

- 1 = Urinary
- 2 = Respiratory
- 3 = Gastrointestinal
- 4 = Skin
- 5 = Central Nervous System
- 6 = Other
- 7 = Unknown

- Must be completed.
- If there are multiple suspected or diagnosed sites of infection, the most likely source of infection should be chosen.
- If the site of infection cannot be determined then choose 7=Unknown.

Sepsis Data Submission Data Types and Constraints

Data Typing:

date	YYYY-MM-DD
datetime	YYYY-MM-DD hh:mm OR YYYY-MM-DDThh:mm
enumerated	defined list of possible values, single choice
set	defined list of possible values, composite choice with each choice separated
	by a colon.
varchar	variable ascii character
int	integer
decimal	fixed point (precision, scale)

Data Constraints:

- comma signals specified available values (A,Z allows only A or Z)
- dash signals range of values (A-Z allows any letter from A through Z)
- minlength is the minimum ASCII character length of the element IF the element is submitted. Where blanks are allowed, minlength is moot.
- maxlength denotes the total allowed space per element, but is not fixed width. Do not leftpad or zero-fill.

The most up to date *Table of Elements* defining data submission data element names, data element min and max lengths and, data element constraints for each data element may be downloaded at <u>https://ny.sepsis.ipro.org</u>.

Blanks:

There may be cases for which data elements can include a blank field. Cases with blank fields depend upon situational responses to related data elements. Please read the data dictionary for each data element carefully.

Change Log

Version 7.1

This is effective for discharges on or after January 1, 2020.

The "change log" for version 7.0 contained an error. The <u>change log</u> for version 7.0 should have read:

- Adult Crystalloid Fluid Administration:
 - Added "Unable to Determine" to Allowable Value 3 (No)

Version 7.0

This is effective for discharges on or after January 1, 2020 through June 30, 2020. The NYSDOH is aligning with CMS in releasing two dictionaries for 2020 therefore hospitals will receive a revised dictionary for July 1, 2020 discharges.

The following data elements were modified or changed:

- Ethnicity:
 - Description statement has been modified.
- Excluded Datetime: new content was added to the description.
- *Excluded Explain*: new content was added to the notes for abstraction.
- *Excluded Reason:* new content was added to the notes for abstraction.
- Race:
 - Description statement has been modified.
- *Adult Crystalloid Fluid Administration*: content in the notes for abstraction was rearranged to the following:
 - o Added "Unable to Determine" to Allowable Value 2 (No)
 - o Added CMSv5.7 examples for clarification
- Antibiotic Administration: redundant content relevant to antibiotic administration datetime was removed from this section. Refer to the notes for abstraction in the Antibiotic Administration Datetime variable.
- Antibiotic Administration Selection:
 - Added "Unable to Determine" to Allowable Value 2 (No)
 - o Added CMS examples & Appendix for acceptable antibiotic selection
- *Arrival Datetime* variable listed under adherence variables was moved to the demographic variables section.
- Blood Culture Collection: content in the notes for abstraction was rearranged.
- **Blood Culture Collection Acceptable Delay:** content in the notes for abstraction was rearranged and a value was modified.
 - o Added "Unable to Determine" to Allowable Value 2 (No)
- Crystalloid Fluid Administration Datetime:
 - CMS examples added for clarification
 - o CMS details on acceptable fluids added

- Initial Hypotension:
 - Added: "Of note, while hospital abstractors are not expected to calculate MAP, the reviewer may calculate a MAP (MAP= (SBP+2*DBP)/3) if the data submission reflective of hypotension cannot otherwise be validated, in order to validate an entry of severe sepsis/septic shock, initial hypotension and/or persistent hypotension" to the notes for abstraction
- Initial Hypotension: added "obtained" to the notes for abstraction.
- Initial Lactate Level Collection: content in the notes for abstraction was rearranged
 Added the time window for abstraction in the definition.
- Initial Lactate Level Collection Datetime: content in the notes for abstraction was rearranged.
- *Persistent Hypotension:* Added new CMSv5.7 changes to the notes for abstraction.
- *Repeat Lactate Level Collection*: redundant content relevant to repeat lactate level collection datetime was removed from this section. Refer to the notes for abstraction in the *Repeat Lactate Level Collection Datetime* variable.
- Repeat Volume Status and Tissue Perfusion Assessment Performed:
 - Modified measures to: If Adult Crystalloid Fluid Administration = 1 AND Septic Shock Present = 1 AND Persistent Hypotension = 1 or 2, then Repeat Volume Status and Tissue Perfusion Assessment Performed must be completed.
- Repeat Volume Status and Tissue Perfusion Assessment Performed Datetime:
 - Added new CMSv5.7 changes to the notes for abstraction
- Septic Shock Present: content in the notes for abstraction was rearranged.
- Septic Shock Presentation Datetime:
 - \circ $\;$ Added the time window for abstraction in the definition
 - Added new CMSv5.7 changes to the notes for abstraction
- Severe Sepsis Present:
 - Added CMS example of choosing a Value "2": "Patient does not have Septic Shock, and Severe Sepsis was met by Physician/APN/PA documentation that Septic Shock was present."
- Severe Sepsis Presentation Datetime:
 - o Added CMS details on direct hospital admits
 - Added CMS details on determining the earliest datetime of septic shock present when the only documentation of septic shock being present is in a physician/APN/PA note that septic shock was present
- Transfer Facility Identifier:
 - Must be blank if *Transfer Status* is reported as a value of 1 or 2.
- *Triage Datetime* variable listed under adherence variables was moved to the demographic variables section.
- Vasopressor Administration:
 - o Added "Unable to Determine" to Allowable Value 2 (No)
- Altered Mental Status:
 - Rearranged content to specify the timeframe for abstraction in the description statement.

• *Site of Infection:* content in the notes for abstraction was rearranged.

Version 6.3

This is effective for discharges on or after January 1, 2019. The *Sepsis Submission Data Types and Constraints* (see page 129) has been corrected in data format as specified in V 6.2 for *Date of Birth* to include dashes.

The following *Notes for Abstraction* were <u>modified</u>:

- Adult Crystalloid Fluid Administration, Crystalloid Fluid Administration Datetime, and Initial Lactate Level
 - Corrected *Notes for Abstraction* to reflect the 2019 Measure Specifications which require fluid administration completion if Septic Shock Present=1 or Initial Hypotension=1.

Version 6.2

This is effective for discharges on or after January 1, 2019. The following data element was <u>modified</u>:

- Date of Birth
 - The date format was changed to an ISO certified ten (10) digit date.

Version 6.1

This is effective for discharges on or after January 1, 2019. Links to the most recent CMS data dictionaries were included.

The following data elements were modified:

- Pregnancy Status
 - Additional value added

The following CMS SEP-1 data elements were <u>modified</u> to include clarification regarding infection with sole source viral, parasitic, or fungal infection:

- Blood Culture Collection
- Septic Shock Present
- Severe Sepsis Present
- Site of Infection

Version 6.0

CMS released upcoming changes to the SEP-1 data elements effective 7/1/2019 (CMS SEP1 Version 5.6). **The NYSDOH is aligned with CMS Sep1 Version 5.6 as of January 1, 2019**. This is different than the CMS 7/1/2019 effective date.

Please see below changes and be sure to follow CMS specifications for SEP1, CMS Version 5.6 found at

https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnet Tier3&cid=1228776844612.

"Points to remember during data collection" were updated including the CMS link to the 2019 CMS SEP1 Dictionaries.

The NYSDOH has released a separate pediatric data dictionary which should be used to report all severe sepsis and septic shock discharges for 2019 onward in patients <18 years of age at admission.

The following data element was newly added to the NYSDOH Data Dictionary

• Pregnancy Status was added

The following CMS SEP-1 data elements were modified:

- Blood Culture Collection Acceptable Delay
- Antibiotic Administration
- Antibiotic Administration Selection
- Adult Crystalloid Fluid Administration
- Adult Crystalloid Fluid Administration Datetime
- Initial Hypotension
- Initial Lactate Level
- Initial Lactate Level Collection
- Initial Lactate Level Collection Datetime
- Persistent Hypotension
- Repeat Volume Status and Tissue Perfusion Assessment Performed
- Septic Shock Present
- Septic Shock Present Datetime
- Severe Sepsis Present
- Severe Sepsis Present Datetime

The following non-CMS aligned data elements were <u>modified</u> in notes and/or values:

- Source of Admission
- Payer
- Bandemia
- *ICU* was modified to include ICU inclusion categories.
- *Metastatic Cancer* was modified to include brain tumor.

Version 5.1

CMS released upcoming changes to the SEP-1 data elements effective 7/1/2018 (CMS SEP1 Version 5.4). These changes align with some of the changes already put in place in the NYSDOH Data Dictionary 5.0 (e.g., initial hypotension datetime). CMS also removed many fluid assessment variables and introduced a single fluid assessment variable. The Department aligned with the upcoming CMS changes as of January 1, 2018 rather than awaiting the CMS 7/1/2018 effective date. These changes significantly reduce data collection burden (e.g., fluid assessment as a single data element rather than multiple). Please see below changes and be sure to follow CMS specifications for SEP1, CMS Version 5.4 found at

https://www.jointcommission.org/specifications manual for national hospital inpatient quality measures.aspx .

The following CMS SEP-1 data elements were <u>newly added</u> to the NYSDOH Data Dictionary

- *Arrival Datetime* was added (*Earliest Datetime* was removed to align with CMS arrival time. These data elements appear to be the same in definition).
- Repeat Volume Status and Tissue Perfusion Assessment Performed
- Repeat Volume Status and tissue Perfusion Assessment Datetime

The following data element was modified as described below:

- Initial Hypotension Datetime was added to the NYSDOH Data Dictionary in version 5.0 and is now aligned with the CMS addition of this data element in version 5.1.
- Notes were added to *Points to Remember during data collection* to assist in data collection clarity.

We have added to the summary notes for abstraction for following data elements however we caution that these are not all inclusive for CMS aligned data elements. Be sure to follow CMS *notes for abstraction* for completed abstraction notes for aligned data elements.

- Excluded Datetime
- Excluded Reason
- Blood Culture Collection
- Blood Culture Acceptable Delay
- Blood Culture Datetime
- Adult Crystalloid Fluid Administration
- Antibiotic Administration Datetime
- Antibiotic Administration Selection
- Persistent Hypotension
- Metastatic Cancer
- Initial Lactate Level Collection
- Initial Hypotension Datetime

The following CMS SEP-1 data elements were <u>removed from</u> the NYSDOH Data Dictionary in early alignment with CMS SEP-1 Version 5.4.

- Bedside Cardiovascular Ultrasound
- Bedside Cardiovascular Ultrasound Datetime
- Capillary Refill Examination
- Capillary Refill Examination Datetime
- Cardiopulmonary Evaluation
- Cardiopulmonary Evaluation Datetime
- Central venous oxygen measurement
- Central venous oxygen measurement datetime
- Central venous pressure measurement
- Central venous pressure measurement datetime
- Fluid challenge performed
- Fluid challenge performed datetime
- Passive Leg Raise Examination
- Passive Leg Raise Examination Datetime
- Peripheral Pulse Evaluation
- Peripheral Pulse Evaluation Datetime
- Skin Examination
- Skin Examination Datetime
- Vital Signs Review
- Vital Signs Review Datetime

The following data elements were removed from data collection.

• Earliest Datetime was removed and replaced with Arrival Datetime.

The <u>change log</u> for Version 5.0 failed to list the following data elements as removed. The data elements were correctly removed from the dictionary but were not listed as removed in the change log.

- Protocol Initiated
- Protocol Not Initiated Reason

The data element *Exclude Explain* included the removal of two values in Version 5.0 which were not noted in the change log. The adjustment of the Format-length now accommodates this change.

Version 5.0

The following data elements were removed from data collection.

- Left ED Datetime
- Destination After ED
- Protocol Initiated Place
- Protocol NI Reason Additional Detail
- Protocol Type
- Initial Lactate Level unit
- Blood Culture Result
- Blood Culture Pathogen

The following data elements were added to data collection.

- Initial Hypotension Datetime
- Elevated Lactate Reason
- Sepsis Identification Place

The following data elements were modified in data collection.

- *Initial Lactate Level* requirement was modified to require reporting in MMOL. This was done to reduce data collection burden by enabling skip logic for additional data elements when the value is > 2 mmol.
- Significant data collection reporting requirement logic (i.e., "Notes for Abstraction") was
 modified to align with the NYSDOH Measurement Specifications. For example, Fluid
 assessment variables are required to be answered if fluids were required AND the correct
 amount of fluid volume was reported as given; persistent hypotension is not required to be
 answered if initial hypotension is not present. Please pay attention to both the measurement
 specifications and the specific data element "Notes for Abstraction" to be sure you are
 reporting data elements as required.
- A great amount of detail was added in "Notes for Abstraction" including incorporating relevant FAQs and CMS summary notes. Please read the data elements in detail prior to collecting and reporting data. While we have provided summary information on CMS specifications, the NYSDOH Data Dictionary is not meant to be comprehensive. You will need to refer to CMS specifications for complete details.
- Links to select CMS resources were included but are not meant to be inclusive. They are provided as a convenience to hospitals.
- Data elements were reordered for alphabetical presentation within category.

Version 5.0 is effective for discharges on or after January 1, 2018.

Version 4.1

Critical clarification:

• To be clear: NYSDOH is ONLY aligning with select CMS SEP-1 data elements. The denominator for the NYSDOH data submission still requires reporting ALL cases of severe sepsis or septic shock INCLUDING cases identified through coding AND/OR other avenues (e.g., concurrent case identification; retrospective review; and so forth). Hospitals are NOT to be using the CMS method of selecting cases and adding DOH data elements to those cases. This would be an incorrect interpretation of the 2017 modification; the NYSDOH requires reporting ALL severe sepsis and septic shock cases regardless of how they are identified.

The following fluid assessment data elements were not included in Version 4.0 in error. The same expectations apply to these as were applied for the fluid assessment data elements outlined in the 4.0 version. These variables are CMS SEP-1 data elements, and therefore data collection will follow CMS SEP-1 specifications. They are required for data collection beginning with discharges on or after January 1, 2017.

- Central venous oxygen measurement
- Central venous oxygen measurement datetime
- Central venous pressure measurement
- Central venous pressure measurement datetime
- Fluid challenge performed
- Fluid challenge performed datetime

Version 4.1 is effective for discharges on or after January 1, 2017.

Version 4.0

Important CMS SEP-1 alignment instructions:

- Numerous data elements in this data dictionary have been changed to align with CMS SEP-1. All notes and guidelines provided by CMS should be referenced for the correct abstraction and submission of all data for those data elements. The only exception is with respect to failed/contaminated laboratory specimen collection (e.g. blood culture, lactates, etc.). Currently the NYSDOH is not allowing any failed attempts or contaminated specimens to be reported as collected.
- Please see below for the list of the various data elements. The codes and values for the new CMS-aligned data elements have changed from the former NYSDOH codes and values.

For these data elements, please **DO NOT USE** the previous codes and values originally set by the NYSDOH. Instead, **USE** the CMS codes and values.

• Be sure to pay attention to the few select adherence variables for which treatment prior to arrival at your facility may be reported in your data capture. Follow CMS specifications INCLUDING the requirement to have the medical record documentation in YOUR medical record to support data reporting (e.g., outpatient clinic starts treatment and sends complete medical record documentation with the patient).

Examples:

- The septic patient was at a stand-alone ED (or dialysis facility or "fill in the hypothetical blank") and administered the 3 hour severe sepsis bundle. The stand-alone ED sent the chart with the patient (or it was integrated into the EHR/EMR of the admitting hospital and evidenced), and the physician at the admitting hospital documented the review of the care that was provided by the stand-alone ED. All the treatment data elements received prior to arrival (at the stand-alone ED) would count for reporting by the admitting hospital.
- A patient was in a GI outpatient suite, spiked a fever, became hypotensive, and sepsis was suspected. It's possible that the GI outpatient suite started an IV, drew all blood samples for labs, started fluid boluses, and gave an antibiotic prior to transferring to the ED. As long as the treatment components were clearly documented, evidenced, and merged with the admitting hospital's medical records, the treatment given prior to arrival could be reported by the admitting hospital. In this example, the GI suite's selection of antibiotic should be documented to ensure it meets CMS data element criteria.

The following data elements were <u>removed</u> from version 3.0 of the NYSDOH Data Dictionary:

- Protocol Datetime
- Fluids Assessment
- CVP Measured
- CVP Measured Datetime
- ScVO₂ Measured
- ScVO₂ Measured Datetime
- Septic Shock Diagnosis

The following data elements were already in the NYSDOH Data Dictionary but were <u>changed to</u> <u>align</u> with CMS SEP-1, displayed below using the "*New Data Element Name* (*Old Data Element Name*)" format:

- Initial Lactate Level Collection (Lactate Reported)
- Initial Lactate Level Collection Datetime (Lactate Reported Datetime)
- **Repeat Lactate Level Collection** (Lactate Re-ordered)
- **Repeat Lactate Level Collection Datetime** (Lactate Re-ordered Datetime)
- **Blood Culture Collection** (Blood Cultures Obtained)
- **Blood Culture Collection Datetime** (Blood Cultures Obtained Datetime)

- Antibiotic Administration (Antibiotics Given)
- Antibiotic Administration Datetime (Antibiotics Start Datetime)
- Adult Crystalloid Fluid Administration (Adult Fluids)
- **Pediatric Crystalloid Fluid Administration** (Pediatric Fluids)
- Crystalloid Fluid Administration Datetime (Fluids Completed Datetime)
- **Persistent Hypotension** (Hypotension)
- Vasopressor Administration (Vasopressors Given)
- Vasopressor Administration Datetime (Vasopressors Given Datetime)

The following new data elements (NYSDOH, not associated with CMS SEP-1) were added:

- Protocol Not Initiated Reason
- Protocol NI Reason Additional Detail

The following CMS SEP-1 data elements were <u>newly added</u> to the NYSDOH Data Dictionary, not having been in any previous versions. Having been added, these will maintain alignment with CMS SEP-1.

- Severe Sepsis Present
- Severe Sepsis Presentation Datetime
- Septic Shock Present
- Septic Shock Presentation Datetime
- Blood Culture Collection Acceptable Delay
- Antibiotic Administration Selection
- Initial Hypotension
- Bedside Cardiovascular Ultrasound
- Bedside Cardiovascular Ultrasound Datetime
- Capillary Refill Examination
- Capillary Refill Examination Datetime
- Cardiopulmonary Evaluation
- Cardiopulmonary Evaluation Datetime
- Passive Leg Raise Examination
- Passive Leg Raise Examination Datetime
- Peripheral Pulse Evaluation
- Peripheral Pulse Evaluation Datetime
- Skin Examination
- Skin Examination Datetime
- Vital Signs Review
- Vital Signs Review Datetime

The following data elements were <u>changed</u> as described below:

• *Ethnicity* and *Payer* codes and options were changed to align with SPARCS.

- *Triage Datetime* was changed to situational status to account for the few instances in which a patient was a direct admission and never entered the ED. This data element captures the triage start date and time. If the patient developed sepsis on the floor but at some previous point arrived through the ED, *Triage Datetime* is to be reported.
- *Admission Datetime* was changed to match the administrative admission of the patient to inpatient status at the hospital. This is now a SPARCS alignment variable.
- *Earliest Datetime* description was modified to capture the earliest arrival date and time to the facility, whether to the ED or directly to an inpatient unit (direct admission). This data element is mandatory for all cases, as it is not linked to the ED but seeks the earliest arrival datetime for all patients.
- Initial Lactate Level and Initial Lactate Level Unit are data elements with modification only to the name (originally named Lactate Level and Lactate Level Unit). The expectations for reporting of lactate level and level unit remain the same.
- Adult Fluids and Pediatric Fluids were changed to Adult Crystalloid Fluid Administration and Pediatric Crystalloid Fluid Administration, respectively. For adults, this data element was aligned with CMS SEP-1 and is to be reported according to their guidelines. For peds, the fluid volume requirements remain unchanged, but additional fluid assessment data elements are now necessary for reporting.
- *Fluids Completed Datetime* was changed to *Crystalloid Fluid Administration Datetime*. The original data element (*Fluids Completed Datetime*) required the documentation of the completion of fluids (the end date and time) for what would have been the sufficient amount of crystalloid fluids (30ml/kg for adult and 20ml/kg for peds).
 - The new data element (*Crystalloid Fluid Administration Datetime*) was aligned with CMS SEP-1 and requires the **start date and time** for the number of bags that would deliver sufficient fluid volume using the same fluid volume to weight ratio (30ml/kg for adults).
 - Although pediatric patients are not addressed in SEP-1, for pediatric patients this data element will now require the start date and time for the number of bag(s) that would deliver sufficient fluid volume based on the pediatric patient's weight (in kg) and the 20mg/kg ratio.
 - For both adult and pediatric patients, if the hospital reported that sufficient crystalloid fluids were given, the 7 fluid assessment data elements (and datetimes) must also be completed.
 - It's understood that not all of the fluid assessment data elements will be applicable for pediatric patients. It is expected that at least one will apply. Therefore, facilities should accordingly submit a Yes/No response for each data element as appropriate, and complete the corresponding data element datetime if a "Yes" response is chosen.
 - Those 7 fluid assessment data elements are as follows:
 - Bedside Cardiovascular Ultrasound
 - Capillary Refill Examination
 - Cardiopulmonary Evaluation

- Passive Leg Raise Examination
- Peripheral Pulse Evaluation
- Skin Examination
- Vital Signs Review
- Hypotension originally referred to 2 physiologic conditions (hypotension and elevated lactate level) that were or were not responsive to fluid administration. This data element was changed to *Persistent Hypotension* (as mentioned in a prior list), and this now only refers to persistent hypotension or new hypotension present after fluid administration. This data element now aligns with CMS SEP-1. Also, the *Initial Hypotension* data element was added to align with CMS SEP-1 and provides additional insight into the patient's status with respect to low blood pressure and treatment.
- The new data element *Protocol Not Initiated Reason* must be completed if a hospital reported that a protocol was not initiated. Regardless of protocol initiated status, the appropriate adherence variables must be submitted by the hospitals for all adherence treatment data elements unless the patient was excluded from the protocol and documented as such. An additional data element *Protocol NI Reason Additional Detail* was added to allow hospitals to add additional details if desired in explanation for cases for which a protocol was not initiated in a patient for whom exclusion was not selected.
- The Codes and Values for the comorbidity data elements (*Chronic Respiratory Failure*, *Congestive Heart Failure, Chronic Renal Failure, Chronic Liver Disease, Diabetes*) were rephrased to say "...discovered..." instead of "...developed...," since conditions that develop during a hospital admission would be considered acute and not chronic.

The "Edit Applications" section was renamed as "Notes for Abstraction" and provides additional notes and examples (for some) to aid data abstraction and submission.

The relevant FAQ's from the Sepsis Data Collection Portal and topics from the Helpdesk were integrated throughout this revision of the Data Dictionary. The introduction page "Points to remember for data collection" was also updated to reflect these changes.

Version 4.0 is effective for discharges on or after January 1, 2017.

Version 3.0

Data elements *Earliest Time, Triage Datetime, Left ED Datetime,* and *Destination after ED* were updated in definition. These data elements are to be reported regardless of whether or not a protocol was initiated. These variables are all mandatory data elements; all cases reported must include responses to these data elements. This is effective for discharges on or after January 1, 2016.

Sepsis Data Submission Data Types and Constraints section was updated to incorporate the changes described above. The end table specifying potentially blank data elements for data submission was removed. This data specification is available within each data element.

Version 2.0

Data element *Excluded Reason* updated in codes and values. The Department has clarified that non-discharged newborns, including newborns/infants in the NICU that had not been previously discharged from the initial birth stay, are NOT to be reported to the sepsis clinical data portal. Code 5 = Patient is a newborn or infant in the NICU that had not been previously discharged from initial birth stay has been removed from the dictionary and is effective for discharges on or after October 1, 2015. Hospitals should NOT report these cases to the sepsis data portal, which were previously considered excluded cases. Cases reported prior to this effective date will be removed from the database and hospital reports. Newborns that are discharged and then readmitted ARE to be reported to the sepsis data portal.

Data elements *Infection Etiology* and *Platelet Count* include subheading changes to Hospital Acquired Infection and Thrombocytopenia, respectively, to represent more accurate data descriptions. The data elements have NOT been changed therefore there is no change to data capture.

Version 1.44

Data element *Hypotension* updated in description. More detail has been provided to specify that the data code and value should be answered using the six hour window of the patient having severe sepsis or septic shock. This change does not require a modification to your data template and is effective for discharges on or after July 1, 2015.

Version 1.43

Data element *Excluded Explain* updated in codes and values to remove: 7 = Mechanical Ventilation. This change does not require a modification to your data template and is effective for discharges on or after April 1, 2015.

Version 1.42

Data element *Hypotension* updated in codes and values to: 2 = No hypotension. This change does not require a modification to your data template and is effective for discharges on or after January 1, 2015.

Version 1.41

Data element *Excluded Reason* updated in codes and values to permit the submission of more than one reason for excluding the patient from the protocol. This change is effective for discharges on or after January 1, 2015. Remember that when *Excluded Reason* = 1 (even if it is one of multiple reasons selected), then data element *Excluded Explain* must be completed. Data element *Transfer Facility Identifier* corrected to reflect that this is not a SPARCS variable. Additionally, the edit application was modified to provide direction for out of state transfer patients. When transferring a patient to or from an out of state facility, please submit the two digit state identifier (<u>http://www.census.gov/geo/reference/ansi_statetables.html</u>) to represent the transfer facility state.

Data element *Vascular or Intraosseous Access Datetime* removed from the Data Dictionary as per documentation provided in Version 1.3 and 1.4.

Version 1.4

Demographic data element *Transfer Status* has been updated in codes and values to streamline data collection. This change is effective for discharges on or after October 1, 2014. Demographic data element *Transfer Facility Identifier* has been added to capture the sending or receiving Permanent Facility Identifier for all severe sepsis or septic shock transfer cases. This change is effective for discharges on or after October 1, 2014.

An introductory section has been added to the Dictionary to highlight key points to remember during data collection.

Version 1.3

Element *Vascular or Intraosseous Access Datetime* will be removed from the Data Dictionary for all data collected as of October 1, 2014 onward. For the reporting period discharge dates July 1, 2014 through September 30, 2014 the data element will be optional and therefore, may be blank. Please note the current data structure will require a space allocation for the element in order to pass data validation for 7/1-9/30/2014 discharges but will no longer be reported as of October 1, 2014 discharges.

Element *Fluids Assessment* modified to include codes "6" and "7". "6"=Fluid response not evaluated. "7"=Fluid resuscitation not provided. This change is effective for discharges on or after July 1, 2014.

Element *Septic Shock Diagnosis* modified to exclude code "0" Patient was not diagnosed with either severe sepsis or septic shock. The element description was modified from "Indicate if the patient has been <u>diagnosed</u> with severe sepsis and/or septic shock". The new description states "Indicate if the patient had severe sepsis and/or septic shock." This change is effective for discharges on or after July 1, 2014.

Demographic data element *Transfer Status* has been added to require hospitals to designate if a patient has been received or discharged as a transfer patient. In recognition that this data element requires data collection of new information, this change is effective for discharges on or after October 1, 2014.

The link provided on page 2 of the Dictionary was updated to reflect the consolidated website <u>https://ny.sepsis.ipro.org</u>. Please note the original website will seamlessly redirect you to this site. The direct link is provided as a courtesy and requires no action on your part.

Version 1.21

Element *Excluded Explain* amended to capture additional exclusions. Code 1 was "IV or IO fluids (acute, decompensated congestive heart failure)", changed to "IV or IO fluids (acute, decompensated congestive heart failure, pulmonary edema and LVAD)"

Element *Insurance Number* updated to allow blanks if Element *Payer* is not Medicare (C), Medicaid (D), Commercial Insurance (F), or Blue Cross (G).

Element *Source of Admission* modified to include codes "A" and "D". "A"=Transfer from a Rural Primary Care Hospital. The patient was admitted to this facility as a transfer from a Rural Primary Care Hospital (RPCH) where he or she was an inpatient. "D"=Transfer from One Distinct Unit of the Hospital to another Distinct Unit of the Same Hospital Resulting in a Separate Claim to the Payer. Inpatient: The patient was admitted to this facility as a transfer from hospital inpatient within this facility resulting in a separate claim to the payer.

Version 1.2

All data element Format-Length values have been modified to align with data submission specifications. A section providing general data element specifications has been added with a reference to the location of the downloadable *Table of Elements,* or template. The data dictionary was also modified as necessary to denote revised mandatory versus situational fields. For example, all Severity Adjustment and Comorbidity Variables are noted as *mandatory* data elements. The *Index* was eliminated and replaced with a hyperlink *Table of Contents* to facilitate use of the dictionary.

Element *Insurance Number* updated to provide definition clarification and alignment with SPARCS. Element *Facility Identifier* updated to clarify that the PFI can range from four to six digits. Element *Source of Admission* amended to define code value 1 to specify "from home or from an assisted living facility", all other values and codes align with SPARCS. Element *Earliest Time* reverted to v1.0 description and further clarified edit applications. Element *Race* updated to reflect 4/2014 SPARCS definitions and, to permit multiple race codes to be captured for a patient. If multiple race codes are chosen, this data element will no longer align with SPARCS therefore the data element is not designated as a SPARCS variable. Element *Ethnicity* updated to reflect 2014 SPARCS definitions. Element *Excluded Explain* amended to exclude Codes and Values: *3=Antibiotics* therefore all subsequent Codes and Values were altered and the Format-Length was reduced.

Element *Blood Cultures Pathogen* amended to include Codes and Values: 7=Viral.

Element *ScVO₂ Measured* and *ScVO₂ Measured Datetime* amended description to include SVO₂.

Element *Site of Infection* amended to include Codes and Values: 7=Unknown.

Element *Mechanical Ventilation* amended to specify patients with CPAP for sleep apnea as not having mechanical ventilation for reporting purposes.

Element *Lactate Reordered* amended element definition to clarify re-measured.

Element *Lactate Reordered Datetime* amended definition to clarify re-measurement results datetime. Additionally, the edit application removed "cannot have been before *Lactate Reported Datetime*".

Element *Platelet Count* amended to add code value 3 = Protocol not initiated. Element *Bandemia* amended to add code value 3 = Protocol not initiated.

Element *Date of Birth* format amended to align completely with SPARCS.

Element *Payer* amended to align completely with SPARCS; additional codes and values added.

Element *Medical Record Number* amended to align completely with SPARCS; format length modified. Element *Admission Datetime* and *Discharge Datetime* were amended to note that they are not SPARCS aligned variables.

Element *Discharge Status* amended to align with April 2014 SPARCS definitions, codes and values. Element *Fluids Start Datetime* was deleted and replaced with *Fluids Completed Datetime*.

Version 1.1

Removed element First Name Removed element Last Name Removed element Social Security Number Added element Unique Personal Identifier Added element Patient Control Number Modified Notes for Abstraction for element Date Of Birth Modified all Date elements that have a related Time element to be combined Datetime elements (YYYY-MM-DD hh:mm) Removed all Time elements Modified element *Insurance Number* from AlphaNumeric-30 to AlphaNumeric-19 Modified element Adult Fluids to include additional code (9=Not Adult) Modified element *Pediatric Fluids* to include additional code (9=Not Pediatric) **Protocol Initiated** now specifies collection of severity adjustment and **Comorbidity Variables** in all cases. Admission Datetime now specifies cannot precede January 1, 2014 Discharge Datetime now specifies cannot precede April 1, 2014 *Excluded Explain* now specifies clinical reasons for exclusions *Excluded Explain* modified from AlphaNumeric 9 to AlphaNumeric 15 Septic Shock Diagnosis clarified for pediatric patients