DATA DICTIONARY FOR SEVERE SEPSIS OR SEPTIC SHOCK

Version 5.1

February 14, 2018

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:
https://ny.sepsis.ipro.org

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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 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 should not use CMS method of selecting cases and add 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.

- All cases of severe sepsis or septic shock are to be reported to the NYSDOH portal even if they fall out of CMS reporting requirements. In these instances, there will still be clinical documentation that confirms severe sepsis or septic shock. Any patient diagnosed with severe sepsis or septic shock discharged within the reporting quarter should be reported regardless of coding/DRG assignment.
- It is expected that cases with clinical signs and symptoms of septic shock (severe sepsis with either lactate >=4 and/or persistent hypotension despite fluid resuscitation) are reported with ***Septic Shock Present=1***.
- CMS Version 5.4 will be used for guidance for CMS aligned variables effective January 1, 2018 for the NYSDOH data collection (https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228776364473). 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 progress to 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.
- If a patient had multiple episodes of severe sepsis and/or septic shock during the same hospital admission, use the first episode for data abstraction.

- 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."
- For alphanumeric fields submit up to 15 characters. There is no left padding.
- Data will not be collected using form or grid methods but will be accepted using more current data collection methodologies such as NHSN data submission. Data will be accepted as a standard data file (e.g., a CSV file), which may be submitted as a batch of data or as a single case upload.
- 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.

CMS Specifications Manual for National Hospital Inpatient Quality Measures Discharges 01-01-18 (1Q18) through 06-30-18 (2Q18) Version 5.3a Link and Version 5.4 for discharges 7-31-18 through 12-31-18. Excerpts from these documents are included in this document in addition to providing the links. Please note that the NYSDOH data dictionary is using Version 5.4 as the over-riding document for alignment for the entire calendar year 2018 discharges. For example, for fluid assessment data collection the individual data elements collected in CMS Version 5.3a were removed by CMS in Version 5.4. The NYSDOH data collection for all cases in CY 2018 will use ONLY the data elements for this measures that are presented in Version 5.4.

https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228776364473

https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228776143120

A link to CMS specifications are included for convenience, as are the CMS SEP-1 summaries provided in this dictionary. Hospitals are responsible for ensuring they are using the most current CMS specifications and direction in place for the discharge timeframe.

In addition, the following links are provided, for convenience, and represent a few of the resources available. These links are not meant to be comprehensive, but are provided to assist hospitals.

- https://www.qualityreportingcenter.com/wp-content/uploads/2017/03/IQR-QA-Transcript_Sepsis-01.11.2017_vFINAL.508.pdf
- https://www.qualityreportingcenter.com/wp-content/uploads/2017/01/IQR_slides_SEP-1_v5-2_updates_20160111_vFINAL.508.pdf
- https://www.qualityreportingcenter.com/wp-content/uploads/2016/04/10-26-IQR-QA_SEP-1-Severe-Sepsis-Septic-Shock-Part-III_FINAL.508.pdf
- https://www.qualityreportingcenter.com/wp-content/uploads/2017/03/IQR_QA-Transcript_SEP-1-Early-Mgmt_20161116_vFINAL508.pdf
- https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228775749207
- https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228776143120
- https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772869636

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

Description:

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 initial administrative admission to the facility 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:	Date of Birth
Format – Length:	Date-8
SPARCS variable:	Yes
CMS SEP-1 variable:	No
Mandatory:	Yes

Description:

The date of birth of the patient.

Codes and Values:

Notes for Abstraction:

- Format must be YYYYMMDD = Year Month Day (example November 3, 1959=19591103).
- ***Date of Birth*** cannot have been after ***Admission Datetime***.

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

Description:

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

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 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 final discharge from the facility 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

Description:

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

Description:

The code that best describes the ethnicity of the patient.

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

Description:

The date and time that the person met the exclusion criteria.

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
- ***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

Description:

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)

Notes for Abstraction:

- Submit a number for each applicable intervention, separated by a colon.
- Example:
  - 1:2:4 represent options 1, 2, and 4
  - Each 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.
- 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

Description:

Indicate if the patient was excluded from the sepsis protocol.

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
  - And on the following day, the patient was made comfort care
  - Do not 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

Description:

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

Notes for Abstraction:

- 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.
- 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.

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

Description:

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:

Notes for Abstraction:

- 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

Description:

The gender of the patient.

Codes and Values:

M = Male
F = Female
U = Unknown

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

Description:

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

Description:

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:

Notes for Abstraction:

- 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

Description:

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:

Notes for Abstraction:

- 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

Description:

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

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

Description:

The code that best describes the race of the patient.

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

Description:

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

Notes for Abstraction:

- 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

Description:

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 non-freestanding 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.
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.
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.

Notes for Abstraction:

- 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.

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

Description:

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.
- Can be blank if ***Transfer Status*** is reported as a value of 2.
- Must be blank if *Transfer Status* is reported as a value of 1.
- When transferring a patient to or from an out of state facility, please submit the two digit state identifier (http://www.census.gov/geo/reference/ansi_statetables.html) 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 Variables**
Data Element Name:	Transfer Status
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Description:

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

Codes and Values:

1 = Not a Transfer – Patient was **neither** 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, and the hospital's sepsis protocol was not initiated 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, and the hospital's sepsis protocol was initiated or completed prior to transfer to the receiving acute care hospital. ***Note: You will need to enter the PFI of the receiving hospital.***

Notes for Abstraction:

- 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:	Unique Personal Identifier
Format – Length:	Varchar-10
SPARCS variable:	Yes
CMS SEP-1 variable:	No
Mandatory:	Yes

Description:

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 UPPERCASE 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

Description:

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 prior to, at the time of, or after the presentation of *Initial Hypotension*, *Initial Lactate Level Result* >=4 mmol/L, or physician/APN/PA *Documentation of Septic Shock*.

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 ordered volume of crystalloid fluids were ordered, initiated, and infused prior to, at the time of, or after the presentation of *Initial Hypotension*, *Initial Lactate Level Result* >=4 mmol/L, or *Documentation of Septic Shock*.

2 = (No) Less than the target ordered volume of crystalloid fluids were ordered, initiated, or infused prior to, at the time of, or after the presentation of *Initial Hypotension*, *Initial Lactate Level Result* >=4 mmol/L, or *Documentation of Septic Shock*, or unable to determine volume ordered.

3= (No) Crystalloid fluids were not initiated prior to, at the time of, or after the presentation of *Initial Hypotension*, *Initial Lactate Level Result* >=4 mmol/L, or *Documentation of Septic Shock*, or unable to determine whether or not they were administered.

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.

Notes for Abstraction:

- Must be completed if ***Septic Shock Present*** = 1 or ***Initial Hypotension*** = 1 or ***Lactate Level*** >= 4 mmol and patient >=18 years old.
    - If ***Adult Crystalloid Fluid Administration*** = 1 AND ***Septic Shock Present*** = 1, then *Repeat Volume Status and Tissue Perfusion Assessment Performed*

- Abstract crystalloid fluids started for the presence of *Initial Hypotension,* OR for the presence of an *Initial Lactate Level Result* >=4 mmol/L, OR physician/APN/PA *Documentation of Septic Shock*.
- Do not abstract crystalloid fluids started more than 6 hours prior to the presence of an *Initial Lactate Level Result* >=4 mmol/L or physician/APN/PA *Documentation of Septic Shock*.
- For the presence of *Initial Hypotension*, only abstract crystalloid fluids that were started in the timeframe of 6 hours prior through 3 hours after the initial hypotension.
- Crystalloid fluids at the targeted amount were infused prior to, at the time of, or after the time of septic shock. The fluids must be given no more than 6 hours prior to determination of septic shock.
- The targeted amount of crystalloid fluid to be infused is 30ml/kg. The amount which is administered must be within 10% of the calculated amount.
- If the provider documents that the patient has obesity defined as BMI >30, the clinician may choose to use ideal body weight to determine the volume of fluid to be infused. The clinican must clearly document the IBW was used to determine fluid volume.
- Use the weight for calculating the dose which is measured closest to the time of the crystalloid order.
- Acceptable fluids are crystalloid or balanced crystalloids including 0.9%saline, 0.9%sodium chloride, normal saline, Isolyte, Lactated Ringers, Normosol, PlasmaLyte.
- Crystalloid fluids or balanced crystalloid fluids that are given to dilute medications are acceptable to count towards the target ordered volume.
- Fluids may be given only IV or IO.
- You may include crystalloid fluids given prior to arrival at the hospital as long as the documentation of the time, volume of fluid provided, and the type of fluid is included in the patients' record and is within 6 hours of septic shock determination.
- To determine if the target ordered volume was completely infused, one of the following must be documented (written in the order or documented by nursing):
    - An infusion rate
    - Infusion duration or time over which to infuse
    - Infusion end or completion time
- 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."
- • 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."
- Use the actual or estimated weight documented closest to and prior to the order for crystalloid fluids.

- • If an actual or estimated weight is not documented prior to the crystalloid fluid order, use the actual or estimated weight recorded closest to and after the crystalloid fluid order.
- • If a weight is documented in a crystalloid fluid order, it should be used to determine the target ordered volume.

Dataset Segment:	**Adherence Variables**
Data Element Name:	Antibiotic 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 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 or 3 hours following the presentation of severe sepsis, or unable to determine.

Notes for Abstraction:

- 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.
- 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 that same antibiotic on another form.
- 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.
- Do not abstract antibiotics from narrative charting unless there is no other documentation that reflects that the same antibiotic was given during the specified timeframe.
- If the antibiotic name, route, date or time is missing, disregard that dose.
- Pre-hospital records (e.g., ambulance records, nursing home records) that are considered part of the medical record should be used for abstracting antibiotics.

Pediatric

CMS SEP-1 does not require the reporting of pediatric cases therefore the approach to this data element will be similar to the approach outlined by CMS for the adult cases however, the time window of the antibiotic administration for pediatric cases will differ. The pediatric accommodations to the clinical criteria are outlined below.

Pediatric accommodation to ***Antibiotic Administration***:

- The Codes and Values for the time window will be modified according to the 1 hour pediatric bundle.
    - 1 = (Yes) A broad spectrum or other antibiotic was administered intravenously in the time window 24 hours prior to or 1 hour following the presentation of severe sepsis.
    - 2 = (No) No antibiotic was administered intravenously in the time window 24 hours prior to or 1 hour following the presentation of severe sepsis, or unable to determine.

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

Description:

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:

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 ***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 antibiotics was started within the 24 hours prior to presentation of severe sepsis, and none of those same antibiotics were started more than 24 hours prior to presentation, abstract the earliest dose started in the 24 hours prior to presentation of severe sepsis.
- If one or more antibiotics were administered within 24 hours prior to severe sepsis presentation, abstract the earliest date and time that 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 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.

- 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.
- 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.
- Specific documentation by one person that another person administered the antibiotic is acceptable for determining the date and time of administration.
- Pre-hospital records (e.g., ambulance records, nursing home records) that are considered part of the medical record should be used for abstracting antibiotics.

Pediatric

CMS SEP-1 does not require the reporting of pediatric cases therefore the approach to this data element will be similar to the approach outlined by CMS for the adult cases however, the time window of the antibiotic administration datetime for pediatric cases will differ.

Pediatric accommodation to ***Antibiotic Administration Datetime***:

- The time window will be modified according to the 1 hour pediatric bundle.
- The time window for abstracting the datetime will be 24 hours prior to and 1 hour following the presentation of severe sepsis.

Dataset Segment:	**Adherence Variables**
Data Element Name:	Antibiotic Administration Selection
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 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.

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* are 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.
  - 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.”

- 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:
    - Identify the date of the culture results (must be within 5 days prior to the antibiotic start time).
    - 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.
- 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.
  - Any one of the treatments below is initiated within 3 hours following severe sepsis presentation:
    - Oral vancomycin with or without oral or IV metronidazole (Flagyl)
    - Rectal vancomycin with or without IV metronidazole (Flagyl)
    - 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

Pediatric

CMS SEP-1 does not require the reporting of pediatric cases. The approach to this data element will be similar to the approach outlined by CMS for the adult cases; however, the time window of the antibiotic administration for pediatric cases will differ. The pediatric accommodations are outlined below in the "Notes for Abstraction" section.

Pediatric accommodation to ***Antibiotic Administration Selection***:

- The time window will be modified according to the 1 hour pediatric bundle.
- The time window for abstracting the datetime will be within 1 hour following the presentation of severe sepsis.
- The same tables for antibiotic monotherapy and combination therapy from CMS SEP-1 should be used as a reference when reporting this data element.
- In certain facilities, a combination of antibiotics may be the default order set based on infection source in a pediatric patient, and one antibiotic in that combination may be considered appropriate for monotherapy according to the adult SEP-1 table.
- If the approved monotherapy antibiotic in that combination was started within 1 hour following the presentation of severe sepsis, then "1 = (Yes) …" may be reported. If not, then the notes and guidelines from the CMS SEP-1 should be referenced in reporting ***Antibiotic Administration Selection***.

Dataset Segment:	**Adherence 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.

Definition: 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

Notes for Abstraction:

- 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 observation from an outpatient setting of the hospital, use the datetime the patient arrived at the ED or on the floor for 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.
- 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.
- For "Direct Admits" 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.

Suggested Data Sources:

ONLY ACCEPTABLE SOURCES:

Emergency Department record
Nursing admission assessment/admitting note
Observation record
Procedure notes
Vital signs graphic record

Dataset Segment:	**Adherence Variables**
Data Element Name:	Blood Culture Collection
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 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. **The only exceptions 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 viral, parasitic, or fungal infections. Please report ALL infections.**

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.

Notes for Abstraction:

- 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.
- If there is supportive documentation that a blood culture was collected in the appropriate time window 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." Select Value "1."
- Do not use physician orders to determine a blood culture was collected, as they do not demonstrate collection of the blood culture.

Suggested Data Sources:

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

Pediatric

CMS SEP-1 does not require the reporting of pediatric cases. The approach to this data element will be similar to the approach outlined by CMS for the adult cases; however, the time window of the blood culture collection for pediatric cases will differ. The pediatric accommodations to the clinical criteria are outlined below in the "Notes for Abstraction" section. **The same exception for failed/contaminated laboratory specimens will apply to pediatric cases; failed attempts or contaminated specimens cannot be reported as collected.**

Pediatric accommodation to ***Blood Culture Collection***:

- The Codes and Values for the time window will be modified according to the 1 hour pediatric bundle.
    - 1 = (Yes) A blood culture was collected in the time window 48 hours prior to and 1 hour following the presentation of severe sepsis.
    - 2 = (No) A blood culture was not collected in the time window 48 hours prior to and 1 hour following the presentation of severe sepsis or unable to determine.

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

Description:

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. **The only exceptions 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.

Notes for Abstraction:

- 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, then an "acceptable delay" did not occur. If an "acceptable delay" never occurred, then there would be no documentation of any "acceptable delay". Therefore, the option stating "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.
- If there was no delay in the collection of a blood culture, then an "acceptable delay" did not occur. Choose Value "2" in this circumstance. See measure specifications to determine how the values are used for a measure.
- Only the following situations demonstrate an acceptable delay, resulting in the blood culture being 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 and within 24 hours of that antibiotic dose develop severe sepsis and then have a blood culture drawn.
- Within 24 hours prior to severe sepsis presentation, antibiotics were started in the hospital for an infection before severe sepsis was identified as present or suspected and a blood culture was drawn after the initial antibiotic dose.
- Within 24 hours prior to severe sepsis presentation antibiotics were started prior to arrival to the hospital and a blood culture was drawn after arrival to the hospital.
- A physician/APN/PA documented reason for the delay, such as waiting to start the antibiotic or to draw the blood culture could cause a delay which would be detrimental to the patient.
- 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."

Pediatric

CMS SEP-1 does not require the reporting of pediatric cases, but the approach to this data element will be similar to the approach outlined by CMS for the adult cases. This data element would be reported for pediatric cases just as it would be for adult cases. **The same exception for failed/contaminated laboratory specimens will apply to pediatric cases; failed attempts or contaminated specimens cannot be reported as collected.**

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

Description:

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.

Pediatric

CMS SEP-1 does not require the reporting of pediatric cases, but the approach to this data element will be similar to the approach outlined by CMS for the adult cases however, the time window of the blood culture collection for pediatric cases will differ. The pediatric accommodations to the clinical criteria are outlined below in the "Notes for Abstraction" section. **The same exception for failed/contaminated laboratory specimens will apply to pediatric cases; failed attempts or contaminated specimens cannot be reported as collected.**

Pediatric accommodation to ***Blood Culture Collection Datetime***:

- The time window will be modified according to the 1 hour pediatric bundle.
- The time window for abstracting the datetime will be 48 hours prior to and 1 hour following 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

Description:

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 for *Initial Hypotension*, *Initial Lactate Level Result* >=4 mmol/L, or physician/APN/PA *Documentation of Septic Shock*.

Although pediatric patients are not addressed in SEP-1, this data element aligns to ***Pediatric Crystalloid Fluid Administration*** for pediatric patients and requires 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.

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 either ***Adult or Pediatric Crystalloid Fluid Administration*** = 1, then ***Crystalloid Fluid Administration Datetime*** must be completed, else must be blank.
- Cannot have been after ***Discharge Datetime***.
- .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*, an *Initial Lactate Level Result* >=4 mmol/L, 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.

Dataset Segment:	**Adherence Variables**
Data Element Name:	Initial Hypotension
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 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 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:

1 = (Yes) Initial hypotension was present 6 hours prior to or within 6 hours following Severe Sepsis presentation.
2 = (No) Initial Hypotension was not present 6 hours prior to or within 6 hours following Severe Sepsis presentation or unable to determine from medical record documentation.

Notes for Abstraction:

- Must be completed unless ***Excluded from Protocol*** = 1.
- The criteria for determining that Initial Hypotension was present are as follows:
  - Either 6 hours prior to or within 6 hours following Severe Sepsis presentation of two low blood pressure readings from different measurements of either:
    - systolic blood pressures <90, or
    - mean arterial pressures (MAP) <65 or
    - 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.
- If there is physician/APN/PA documentation prior to or within 24 hours after *Severe Sepsis Presentation Time* indicating hypotension or low blood pressure (SBP <90 mmHg or MAP <65 mmHg) is due to the following, it should not be used. Inferences should not be made.
  - It is required that the same physician/APN/PA documentation must also include either the abnormal value or reference the abnormal value.

        - Normal for that patient
        - Is due to a chronic condition
        - Is due to a medication
- If there is physician/APN/PA documentation prior to or within 24 hours after *Severe Sepsis Presentation Time* indicating hypotension or low blood pressure (SBP <90 mmHg or MAP <65 mmHg) is due to the following, the criteria value should be used.
    - Acute condition
    - Acute injury on a chronic condition
- If there is physician/APN/PA documentation prior to or within 24 hours of *Severe Sepsis Presentation Time* indicating the acute condition is due to a non-infectious source/process, it should not be used (Refer to *Severe Sepsis Present* to determine if a condition is an infection).
- 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.
- Blood pressure readings documented in the operating room (OR) should not be used.
- Do not use low BPs documented from an orthostatic BP evaluation.
- 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 low blood pressure(s) recorded, the low blood pressure value(s) should not be used. The documentation must be within 24 hours following the low blood pressure value(s).

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

Description:

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 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 within the time period.

- Use the time documented for when hypotensive blood pressure was taken or obtained. If time taken or obtained is not available, use recorded or documented date.

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

Description:

This is the actual lactate level that was reported by the lab for the initial lactate associated with the sepsis episode.

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.

Notes for Abstraction:

- 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:
    - 7.81 is rounded to 7.8
    - 7.85 is rounded to 7.9
    - 7.97 is rounded to 8
    - **NOT CORRECT**: 7.85 is truncated to 7.8 (this should be rounded to 7.9)
- If there are multiple lactate levels, only abstract the level drawn closest to the time of presentation of severe sepsis. If there is a lactate level both before and after presentation of severe sepsis that are the same time apart, use the level prior to presentation. That lactate level is the initial lactate level for purposes of this data element.
- 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, then ***Adult Crystalloid Fluids Administration*** MUST be completed.

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

Description:

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 Lactate Level Collection
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 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. **The only exceptions are with respect to failed laboratory 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 presentation of severe sepsis.

Codes and Values:

1 = (Yes) An initial lactate level was drawn in the time window between 6 hours prior to and 3 hours following the presentation of severe sepsis.
2 = (No) An initial lactate level was not drawn in the time window between 6 hours prior to and 3 hours following the presentation of severe sepsis, or unable to determine.

Notes for Abstraction:

- 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:
  - ***Initial Lactate Level Collection Datetime***
  - ***Initial Lactate Level***
  - ***Repeat Lactate Level Collection***
  - ***Repeat Lactate Level Collection Datetime***
- If ***Excluded from Protocol*** = 1, may be blank, else must be completed.
- 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).
- 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.
- 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.
- In the NYSDOH data collection, the lactate result must actually be present in the medical record.
- The NYSDOH data collection does not permit the submission of failed or contaminated specimens.

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

Description:

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:
  - ***Initial Lactate Level Collection Datetime***
  - ***Initial Lactate Level***
- If ***Initial Lactate Level Collection*** is blank or contains a value of 2, then the following MUST be blank:
  - ***Initial Lactate Level Collection Datetime***
  - ***Initial Lactate Level***
- Cannot have been after ***Discharge Datetime***.
- If there are multiple lactate levels, only abstract the level drawn closest to the time of presentation of severe sepsis. If there is a lactate level both before and after presentation

of severe sepsis that are the same time apart, use the level prior to presentation. That lactate level is the initial lactate level for purposes of this data element.

- Use documentation specifying the date 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 or reported, unless there is a notation of “drawn” or “collected” next to the order, including a 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).

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

Description:

If Pediatric (age<18), indicate if at least 20ml/kg isotonic saline or colloid was given.

Codes and Values:

0 = At least 20ml/kg isotonic saline or colloid were not given
1 = At least 20ml/kg isotonic saline or colloid were given
2 = Volume of fluids given is unknown

Notes for Abstraction:

- Must be completed if patient < 18 years old.

Dataset Segment:	**Adherence Variables**
Data Element Name:	Persistent Hypotension
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 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
    - mean arterial pressure <65mm, or

    - decrease of systolic BP of >40mm where the provider determined that the drop occurred as a result of the infection.
- If the fluid order is for a volume that exceeds the 30ml/kg target, the time period for measuring persistent hypotension can begin when the infusion of target volume has been reached, as long as the time can be calculated based on the rate of fluid administration.
- If the end time of the target ordered volume of crystalloid fluids cannot be determined, select Value “3.”
- If crystalloid fluids were administered but at a volume less than the target ordered volume, choose Value “4.”
- Determining presence of persistent hypotension (low is SBP <90 or MAP <65): o 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.”

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

Description:

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. **The only exceptions 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."
- 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 Lactate Level Collection Datetime
Format – Length:	Datetime-16
SPARCS variable:	No
CMS SEP-1 variable:	Yes
Mandatory:	Situational

Description:

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
  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 ***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

Description:

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:
    1) 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.
    2) Physician/APN/PA documentation indicating or attesting to performing or completing a review of at least five of the following seven 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).
- 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.

3) 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).
        - 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, 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

Description:

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:
  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***.

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 latest 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

Description:

Adult

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) There is documentation of Septic Shock.
2 = (No) There is no documentation of Septic Shock, 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.
- 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 in the hour after the conclusion of the target ordered volume of *Crystalloid Fluid Administration*, evidenced by two consecutive documented recordings of:
systolic blood pressure (SBP) <90, or
mean arterial pressure <65 or
a decrease in systolic blood pressure by >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.

b. *Severe Sepsis Present*
AND
Tissue hypoperfusion evidenced by *Initial Lactate Level Result* is >=4 mmol/L

- If criteria for Septic Shock are not met, but there is physician/APN/PA documentation of Septic Shock, choose Value "1."

Pediatric

CMS SEP-1 does not require the reporting of pediatric cases therefore the approach to this data element will be similar but not the same as the approach outlined by CMS for the adult cases. Similar to SEP-1, all clinical criteria must be met **within 6 hours of each other**. The pediatric accommodations to the clinical criteria are outlined below in the "Notes for Abstraction" section.

Notes for Abstraction:

- ***Septic Shock Present*** for pediatric patients will utilize the same CMS SEP-1 notes for abstraction that do not pertain to clinical criteria (e.g. timeline parameters, suggested data sources.)

- ***Septic Shock Present:***

Pediatric accommodation to clinical criteria for septic shock:

Current internationally recognized standards for definition apply. At this time, refer to Tables 2 & 4 from the following published manuscript: Pediatr Crit Care Med. 2005 Jan; 6(1):2-8. International pediatric sepsis consensus conference: definitions for sepsis and organ dysfunction in pediatrics:

1. Sepsis; and,
2. Cardiovascular organ dysfunction (despite at least 20ml/kg fluid administration)

- The crystalloid fluid administration will be based on the pediatric patient's weight (in kg) and the 20ml/kg ratio.
- Pediatric patients should be categorized as having septic shock if unable to differentiate between severe sepsis and 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

Description:

Adult

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: The earliest datetime on which the final criterion was met to establish the presence of septic shock.

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***.
- The date/time that should be used is the time that the last criterion was met determining that septic shock was present.
- In patients with multiple episodes of septic shock, use the date/time from the first episode.

- If septic shock was determined by provider note, use the earliest date and time this was documented, which could be time of arrival to the ED if the note states there was septic shock on arrival.
- If septic shock was determined by severe sepsis with persistent hypotension after fluid administration, use the later time of either severe sepsis presentation or persistent hypotension. Use the date/time of the last consecutive BP reading that identifies the presence of persistent hypotension.
- If septic shock was determined by severe sepsis with elevated initial lactate of 4 or higher, use the later time of either severe sepsis presentation or when initial lactate result was available. (Not time drawn)

Pediatric

CMS SEP-1 does not require the reporting of pediatric cases therefore the approach to this data element will be similar but not the same as the approach outlined by CMS for the adult cases. Similar to SEP-1, all clinical criteria must be met **within 6 hours of each other**. The pediatric accommodations to the clinical criteria are outlined below in the "Notes for Abstraction" section.

Pediatric accommodation to clinical criteria for septic shock:

Current internationally recognized standards for definition apply. At this time, refer to Tables 2 & 4 from the following published manuscript: Pediatr Crit Care Med. 2005 Jan; 6(1):2-8. International pediatric sepsis consensus conference: definitions for sepsis and organ dysfunction in pediatrics:

1. Sepsis; and,
2. Cardiovascular organ dysfunction (despite at least 20ml/kg fluid administration)

- The crystalloid fluid administration will be based on the pediatric patient's weight (in kg) and the 20ml/kg ratio.
- Pediatric patients should be categorized as having septic shock if unable to differentiate between severe sepsis and septic shock.
- ***Septic Shock Presentation Datetime*** for pediatric patients will utilize the same CMS SEP-1 notes for abstraction that do not pertain to clinical criteria (e.g. timeline parameters, suggested data sources, etc.)

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

Description:

Adult

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.

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.

This can include physician, APN, PA, or pharmacist. Terms such as r/o UTI can be used unless later notes state no UTI is present.

b. Two or more manifestations of systemic infection according to the Systemic Inflammatory Response Syndrome (SIRS) criteria

1. Temp >38.3 or <36.0 C (>100.9 or <96.8 F)
2. Pulse >90 (do not use if rapid pulse is due to chronic Afib/flutter)
3. Resp >20
4. WBC > 12000 or <4000 or bands >10%

c. Organ dysfunction evidenced by one of the following (Note: If one of the items below is documented to be caused by a chronic condition or is normal for this patient, it should not be used.)

1. Systolic BP <90mm or Mean Art press <65mm unless hypotension is documented to be caused by a non-infectious cause such as blood loss.
2. Systolic BP decrease of more than 40mm (must not be caused by something other than infection)
3. Acute resp failure with need for **new** invasive or non-invasive ventilation. Can include mech ventilator, CPAP, or BIPAP or change from intermittent to continuous treatment.
4. Creat > 2.0. Do not use this for patients with ESRD on dialysis. In patients with CRF, may use increase in creat by 0.5 above baseline.
5. Urine output <0.5ml/kg/hr for 2 consecutive hours. (must measure output at least hourly)
6. Total Bilirubin above 2.0 mg/dl.
7. Platelet count <100,000
8. INR >1.5 or aPTT >60 sec. (do not use if patient is on anticoagulants causing the changes)
9. Lactate >2.0mmol/l (do not use if elevation is documented to be caused by seizures or other non-infectious cause)

- If clinical criteria for Severe Sepsis are not met, but there is physician/APN/PA documentation of Severe Sepsis, choose Value "1."

Pediatric

- CMS SEP-1 does not require the reporting of pediatric cases: therefore, the approach to this data element will be similar but not the same as the approach outlined by CMS for the adult cases. Presence of Severe Sepsis may be identified based upon clinical criteria or physician/APN/PA documentation of Severe Sepsis.

Similar to SEP-1, three clinical criteria all three clinical criteria must be met **within 6 hours of each other**.

Pediatric accommodations for the ***three clinical criteria components for severe sepsis***:

(Current internationally recognized standards for definition apply. At this time, refer to Tables 2 & 4 from the following published manuscript: Pediatr Crit Care Med. 2005 Jan; 6(1):2-8. International pediatric sepsis consensus conference: definitions for sepsis and organ dysfunction in pediatrics):

1. Proven or suspected infection; and,
2. Two or more pediatric SIRS criteria, one of which must be abnormal temperature or leukocyte count; and,
3. Organ dysfunction:

• For the organ dysfunction criteria, pediatric organ dysfunction is noted by the presence of:

- o Cardiovascular organ dysfunction

  OR

- o Acute respiratory distress syndrome (ARDS)

  OR

- o A combination of two other types of organ dysfunction (respiratory, neurologic, hematologic, renal, hepatic)

- Pediatric patients should be categorized as having septic shock if unable to differentiate between severe sepsis and septic shock.

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

Description:

Adult

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:
  5. Format must be YYYY-MM-DD hh:mm
     a. YYYY-MM-DDThh:mm is also valid
  6. 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)
  7. Example: 11:42 pm November 3, 1959=1959-11-03 23:42
     a. 1959-11-03T23:42 is also valid
  8. 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***.
- The date/time that should be used is the time that the last criteria was met determining that severe sepsis was present.
- In patients with multiple episodes of severe sepsis, use the date/time from the first episode.

- If severe sepsis was determined by provider note, use the earliest date and time this was documented which could be time of arrival to the ED if the note states there was septic shock on arrival. Unless a time of severe sepsis is included in the note, use the time that the note was opened or started.
- If severe sepsis is determined by clinical criteria, use the date/time that the last element meeting criteria for severe sepsis was documented.
- If there is no provider documentation of severe sepsis, and clinical criteria for severe sepsis are not documented, but the provider documents that septic shock is present, enter the date/time that septic shock was documented.

Pediatric

- CMS SEP-1 does not require the reporting of pediatric cases therefore the approach to this data element will be similar but not the same as the approach outlined by CMS for the adult cases. Presence of Severe Sepsis may be identified based upon clinical criteria or physician/APN/PA documentation of Severe Sepsis.

Similar to SEP-1, all three clinical criteria must be met **within 6 hours of each other**.

Pediatric accommodations for the ***three clinical criteria components for severe sepsis***:

(Current internationally recognized standards for definition apply. At this time, refer to Tables 2 & 4 from the following published manuscript: Pediatr Crit Care Med. 2005 Jan; 6(1):2-8. International pediatric sepsis consensus conference: definitions for sepsis and organ dysfunction in pediatrics):

1. Proven or suspected infection; and,
2. Two or more pediatric SIRS criteria, one of which must be abnormal temperature or leukocyte count; and,
3. Organ dysfunction:
   - For the organ dysfunction criteria, pediatric organ dysfunction is noted by the presence of:
     - o Cardiovascular organ dysfunction
       OR
     - o Acute respiratory distress syndrome (ARDS)
       OR
     - o A combination of two other types of organ dysfunction (respiratory, neurologic, hematologic, renal, hepatic)

- Pediatric patients should be categorized as having septic shock if unable to differentiate between severe sepsis and septic shock.

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

Description:

The date and time that the triage assessment of the patient was started. 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:

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***.
- 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:	**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.

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

Description:

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
  - 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)
  - 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

Notes for Abstraction:

- 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:

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

Notes for Abstraction:

- 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.
- 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:	Bandemia
Format – Length:	Enumerated-1
SPARCS variable:	No
CMS SEP-1 variable:	No
Mandatory:	Yes

Description:

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

Notes for Abstraction:

- 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 variabl collected for this data element.
    - Band count – 10% is a SIRS criterion.
- If the laboratory does not provide a report of percentage of bands if bands are not elevated, select 0.
- 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

Description:

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

Notes for Abstraction:

- 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

Description:

Was the platelet count at the time of *severe sepsis presentation* <150,000 cells/mm^3?

Codes and Values:

0 = No
1 = Yes
2 = Unknown

Notes for Abstraction:

- 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

Description:

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:

- Must be completed.

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

Description:

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

Notes for Abstraction:

- 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

Description:

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:

- Must be completed.

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

Description:

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:

- Must be completed.

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

Description:

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:

- Must be completed.

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

Description:

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:

- Must be completed.

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

Description:

Indicate if the patient was admitted to the Intensive Care Unit (ICU).

Codes and Values:

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

Notes for Abstraction:

- 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

Description:

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

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 ***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 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

Description:

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

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 ***ICU*** = 1, then must be completed.
- If ***ICU*** = 0, then must be blank.
- ***ICU Discharge Datetime*** may not precede ***ICU Admission Datetime***.

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

Description:

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

Notes for Abstraction:

- 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

Description:

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

Notes for Abstraction:

- Must be completed.
- ONLY indicate "1 = Yes" if **ALL** of the following conditions are met:
  - The infection is a hospital acquired infection (HAI)
  - The HAI was acquired from your facility
  - 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:
  - 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 **not** 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

Description:

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:

- Must be completed.

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

Description:

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

Notes for Abstraction:

- 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)
    - 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

Description:

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

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 ***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 order 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

Description:

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). 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:

- 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

Description:

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:

- Must be completed.

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

Description:

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

Notes for Abstraction:

- Must be completed.
- If there are multiple suspected or diagnosed sites of infection, the most likely source of infection should be chosen.
- Option "7 = Unknown" should be chosen for cases where the site of infection cannot be determined.
- If there are more than one 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.
- If severe sepsis or shock was part of the patient's final diagnosis (beyond the bacterial vs. viral/fungal infection) then this case would need to be reported to the NYSDOH. All cases of severe sepsis or septic shock are to be reported regardless of the source of infection.

Sepsis Data Submission Data Types and Constraints

Data Typing:

date	YYYYMMDD
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 left-pad 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 https://ny.sepsis.ipro.org.

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 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 newly added 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 removed from 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 change log 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 removed from version 3.0 of the NYSDOH Data Dictionary:

- ***Protocol Datetime***
- ***Fluids Assessment***
- ***CVP Measured***
- ***CVP Measured Datetime***
- ***$ScVO_2$ Measured***
- ***$ScVO_2$ Measured Datetime***
- ***Septic Shock Diagnosis***

The following data elements were already in the NYSDOH Data Dictionary but were changed to align 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 newly added 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 changed 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 (http://www.census.gov/geo/reference/ansi_statetables.html) 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 diagnosed 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 https://ny.sepsis.ipro.org. 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.
Example *datetime* now correctly reads 23:42.
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 ***$ScVO_2$ Measured*** and ***$ScVO_2$ Measured Datetime*** amended description to include SVO_2.
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