

Quality ID #393: HRS-9: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision
– National Quality Strategy Domain: Patient Safety
– Meaningful Measure Area: Healthcare Associated Infections

2019 COLLECTION TYPE:
MIPS CLINICAL QUALITY MEASURES (CQMS)

MEASURE TYPE:
Outcome – High Priority

DESCRIPTION:
Infection rate following CIED device implantation, replacement, or revision

INSTRUCTIONS:
This measure is to be submitted a minimum of **once per performance period** for patients with a CIED device implantation, replacement, or revision performed from January 1, 2019 through June 30, 2019 of the performance period. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding.

NOTE: *Include only patients that have had CIED implantation, replacement, or revision performed by **June 30**. This timeframe allows for evaluation of infection requiring within 180 days within the performance period. This will allow the evaluation of infection status post CIED implantation, replacement, or revision within the performance period.*

Infection rates for new implants shall be calculated and submitted separately from device replacements and revisions.

Additional submitting stratification categories may be useful; however, these stratifications are not required for purposes of QPP submission:

- Device class (e.g., pacemaker, ICD) and type (e.g., single chamber, dual chamber);
- Advanced renal disease (CKD stages 4 and 5, ESRD);
- Diabetes;
- CIED infection requiring device removal within 180 days prior to index CIED procedures; and
- CIED-related surgical procedure within 180 days prior to current CIED procedure.

Measure Submission Type:
Measure data may be submitted by individual MIPS eligible clinicians, groups, or third party intermediaries. The listed denominator criteria are used to identify the intended patient population. The numerator options included in this specification are used to submit the quality actions as allowed by the measure. The quality-data codes listed do not need to be submitted by MIPS eligible clinicians, groups, or third party intermediaries that utilize this modality for submissions; however, these codes may be submitted for those third party intermediaries that utilize Medicare Part B claims data. For more information regarding Application Programming Interface (API), please refer to the Quality Payment Program (QPP) website.

THERE ARE TWO SUBMISSION CRITERIA FOR THIS MEASURE:

- 1) Patients, regardless of age, with a new CIED

OR

- 2) Patients, regardless of age, with a replaced or revised CIED

SUBMISSION CRITERIA 1: PATIENTS WITH A NEW CIED

DENOMINATOR (SUBMISSION CRITERIA 1):

All patients with a new CIED from January 1, 2019 through June 30, 2019 of the performance period

Definition:

CIEDs encompassed for this measure are the following devices:

- Pacemaker devices (single or dual chamber);
- Implantable cardioverter-defibrillators (ICDs, single or dual chamber);
- Cardiac resynchronization devices (pacemaker or ICD); and
- Implantable loop recorders (ILRs)

Denominator Criteria (Eligible Cases) 1:

All patients, regardless of age

AND

Procedure code for implantation, replacement, or revision of a CIED (ICD-10-PCS): 0JH604Z, 0JH605Z, 0JH606Z, 0JH607Z, 0JH608Z, 0JH609Z, 0JH60PZ, 0JH634Z, 0JH635Z, 0JH636Z, 0JH637Z, 0JH638Z, 0JH639Z, 0JH63PZ, 0JH804Z, 0JH805Z, 0JH806Z, 0JH807Z, 0JH808Z, 0JH809Z, 0JH80PZ, 0JH834Z, 0JH835Z, 0JH836Z, 0JH837Z, 0JH838Z, 0JH83PZ, 0JPT0PZ, 0JPT3PZ, 0JWT0PZ, 0JWT3PZ

AND/OR

Patient encounter during performance period (CPT): 33202, 33203, 33206, 33207, 33208, 33212, 33213, 33214, 33215, 33216, 33217, 33218, 33220, 33221, 33222, 33223, 33224, 33225, 33226, 33227, 33228, 33229, 33240, 33249, 33262, 33263, 33264, 33270

AND

New CIED

AND NOT

DENOMINATOR EXCLUSION:

Procedure code for heart transplantation (ICD-10-PCS): 02YA0Z0, 02YA0Z1, 02YA0Z2

NUMERATOR (SUBMISSION CRITERIA 1):

The number of patients from the denominator admitted with an infection requiring device removal or surgical revision within 180 days following CIED implantation, replacement, or revision

Numerator Instructions:

INVERSE MEASURE - A lower calculated performance rate for this measure indicates better clinical care or control. The "Performance Not Met" numerator option for this measure is the representation of the better clinical quality or control. Submitting that numerator option will produce a performance rate that trends closer to 0%, as quality increases. For inverse measures, a rate of 100% means all of the denominator eligible patients did not receive the appropriate care or were not in proper control.

Numerator Options:

Performance Met:

Patient admitted within 180 days, status post CIED implantation, replacement, or revision with an infection requiring device removal or surgical revision **(G9410)**

OR

Performance Not Met:

Patient not admitted within 180 days, status post CIED implantation, replacement, or revision with an infection requiring device removal or surgical revision **(G9411)**

OR

SUBMISSION CRITERIA 2: PATIENTS WITH A REPLACED OR REVISED CIED

DENOMINATOR (SUBMISSION CRITERIA 2):

All patients with replacement or revision of a CIED from January 1, 2019 through June 30, 2019 of the performance period

Definition:

CIEDs encompassed for this measure are the following devices:

- Pacemaker devices (single or dual chamber);
- Implantable cardioverter-defibrillators (ICDs, single or dual chamber);
- Cardiac resynchronization devices (pacemaker or ICD); and
- Implantable loop recorders (ILRs)

Denominator Criteria (Eligible Cases) 2:

All patients, regardless of age

AND

Procedure code for implantation, replacement, or revision of a CIED (ICD-10-PCS): 0JH604Z, 0JH605Z, 0JH606Z, 0JH607Z, 0JH608Z, 0JH609Z, 0JH60PZ, 0JH634Z, 0JH635Z, 0JH636Z, 0JH637Z, 0JH638Z, 0JH639Z, 0JH63PZ, 0JH804Z, 0JH805Z, 0JH806Z, 0JH807Z, 0JH808Z, 0JH809Z, 0JH80PZ, 0JH834Z, 0JH835Z, 0JH836Z, 0JH837Z, 0JH838Z, 0JH83PZ, 0JPT0PZ, 0JPT3PZ, 0JWT0PZ, 0JWT3PZ

AND/OR

Patient encounter during performance period (CPT): 33202, 33203, 33206, 33207, 33208, 33212, 33213, 33214, 33215, 33216, 33217, 33218, 33220, 33221, 33222, 33223, 33224, 33225, 33226, 33227, 33228, 33229, 33240, 33249, 33262, 33263, 33264, 33270

AND

Replaced or revised CIED

AND NOT

DENOMINATOR EXCLUSION:

Procedure code for heart transplantation (ICD-10-PCS): 02YA0Z0, 02YA0Z1, 02YA0Z2

NUMERATOR (SUBMISSION CRITERIA 2):

The number of patients from the denominator admitted with an infection requiring device removal or surgical revision within 180 days following CIED implantation, replacement, or revision.

Numerator Instructions:

INVERSE MEASURE - A lower calculated performance rate for this measure indicates better clinical care or control. The "Performance Not Met" numerator option for this measure is the representation of the better clinical quality or control. Submitting that numerator option will produce a performance rate that trends closer to 0%, as quality increases. For inverse measures, a rate of 100% means all of the denominator eligible patients did not receive the appropriate care or were not in proper control.

Numerator Options:

Performance Met:

Patient admitted within 180 days, status post CIED implantation, replacement, or revision with an infection requiring device removal or surgical revision (**G9412**)

OR

Performance Not Met:

Patient not admitted within 180 days, status post CIED implantation, replacement, or revision with an infection requiring device removal or surgical revision (**G9413**)

RATIONALE:

The rate of implantable cardioverter-defibrillator (ICD) infections has been increasing faster than that of device implantation and is associated with substantial morbidity, mortality, and financial cost. A recent study including over 200,000 ICD implant patients found 2 percent of patients undergoing ICD implantation experienced a device-related infection. Patients who developed an ICD infection were likely to have more comorbidity burden, warfarin use, and

coronary sinus lead, device upgrade/malfunction as the last surgery, peri-ICD implant complications, and non-EP trained operator. The evidence demonstrates the need to measure performance in this area.

CLINICAL RECOMMENDATION STATEMENTS:

In recognition that there is an absence of applicable physician-level performance measures for the profession of cardiac electrophysiology, the Heart Rhythm Society (the international professional society focused on the care of patients with heart rhythm disorders) convened a Performance Measures Development Task Force to consider and develop potential physician-level measures for cardiac electrophysiologists. The task force consisted of thought leaders in 1) implantation of cardiac implantable electronic devices (CIEDs) including pacemakers, implantable cardioverter defibrillators (ICDs), cardiac resynchronization devices (pacemaker or ICD); and implantable loop recorders (ILRs), 2) cardiovascular health policy, 3) performance measures development, 4) clinical outcomes, and population science.

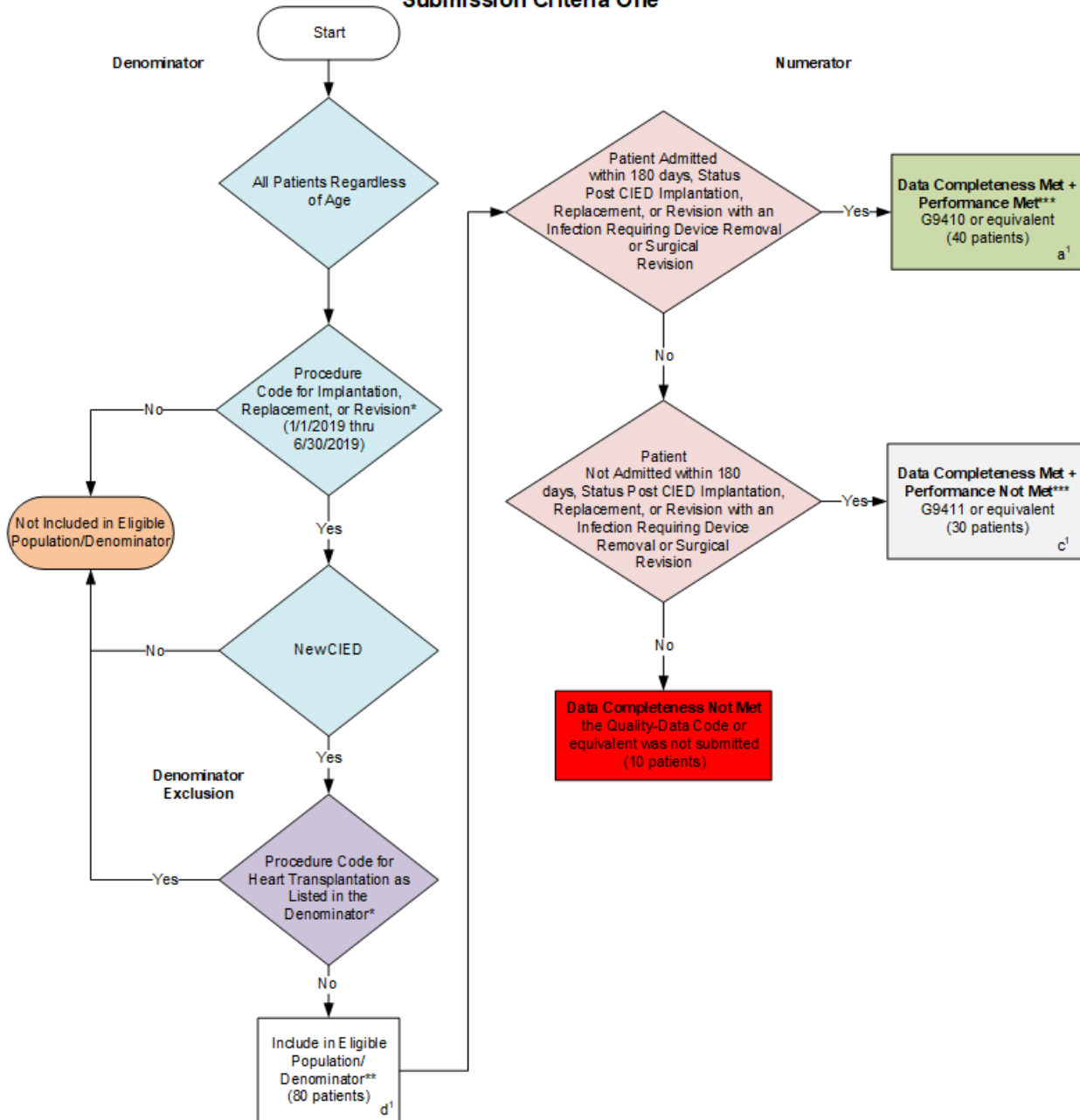
The process for consideration of the evidence included review of the relevant literature referenced within this document and in the knowledge of the members of the task force (Voigt et al, 2006; Cabell et al, 2004; Voigt et al, 2010; Greenspon et al, 2011; Sohail et al, 2011; Nery et al, 2010; Ferguson et al, 1996; Uslan et al, 2007; Lee et al, 2010; Klug et al, 2007; Alter et al, 2005; Al-Khatib et al, 2008; de Oliveira et al, 2009; Uslan et al, 2011; Borleffs et al, 2010; Sohail et al, 2007; Bloom et al, 2006; Baddour et al, 2010; Le KY et al, 2011; Johansen et al, 2011; Al-Khatib et al, 2005; Tarakji et al, 2010).

The number of CIED-related infections in the United States continues to increase out of proportion to the increase in the CIED implantation rates (Voigt et al, 2006; Cabell et al, 2004; Voigt et al, 2010). This infection burden is associated with increased mortality, prolonged hospital stays and high financial costs (Greenspon et al, 2011; Sohail et al, 2011; Ferguson et al, 1996). Collectively, the incidence of CIED infection has ranged from 0.3 to 2.9% across the literature evaluated (Greenspon et al, 2011; Sohail et al, 2011; Nery et al, 2010; Uslan et al, 2007; Lee et al, 2010; Klug et al, 2007; Alter et al, 2005; Al-Khatib et al, 2008; Uslan et al, 2011; Bloom et al, 2006; Baddour et al, 2010; Johansen et al, 2011). In the vast majority of patients, CIED infection is preventable, and an association between a higher volume of ICD implants and a lower rate of infections has been demonstrated (Tarakji et al, 2010). This is why a performance measure that could lower the risk of CIED infection is critically needed.

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**2019 Clinical Quality Measure Flow for Quality ID #393:
HRS-9: Infection Within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation,
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Submission Criteria One****



*See the posted Measure Specification for specific coding and instructions to submit this measure. This measure flow illustrates denominator eligible encounters as requiring a ICD-10-PCS AND/OR an encounter. The measurement period is for patients with a CIED device implantation, replacement, or revision performed from January 1, 2019 through June 30, 2019 of the performance period.

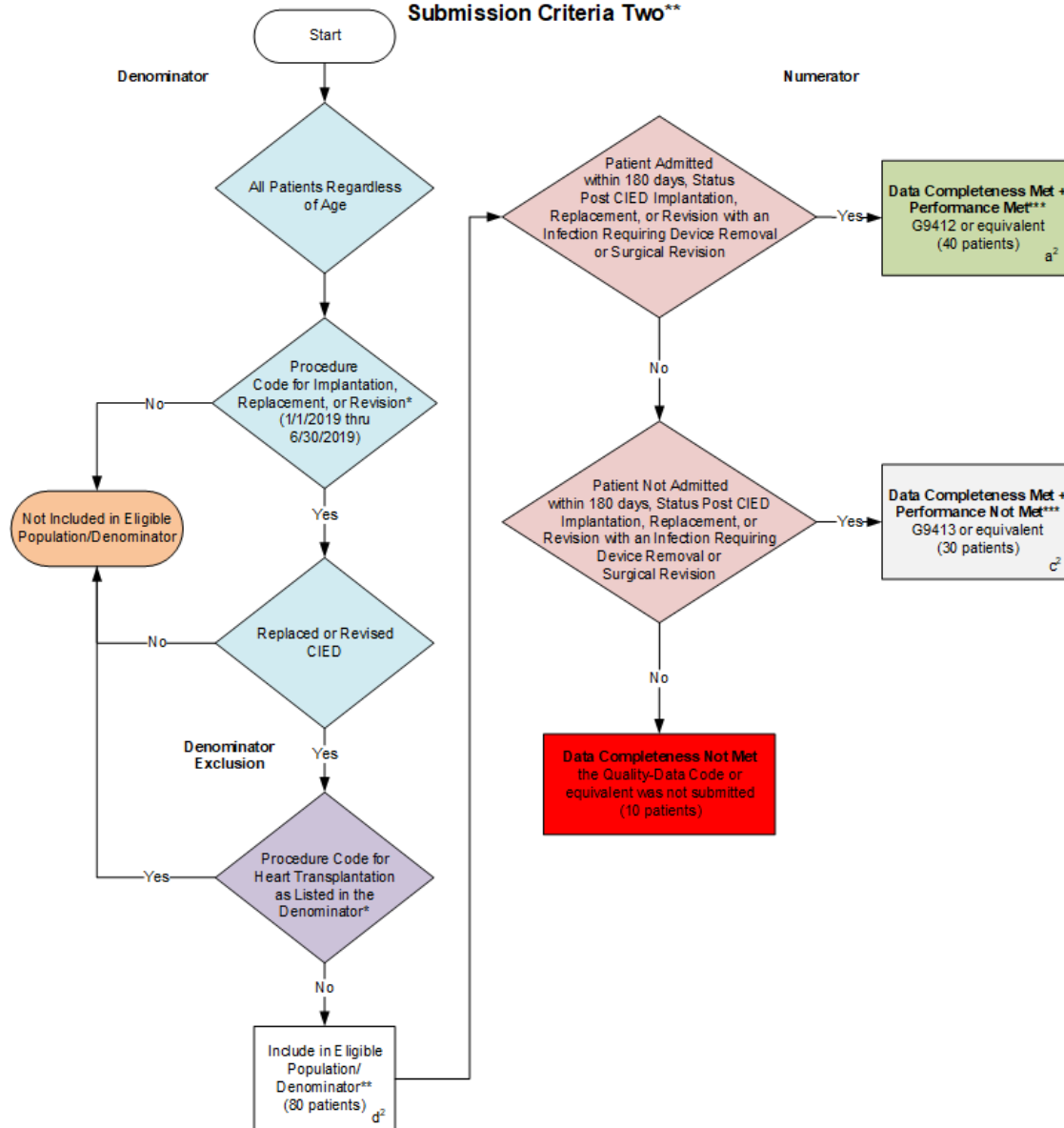
**This measure has two Submission Criteria that are combined for calculation of one data completeness and one performance rate.

***A lower calculated performance rate for this measure indicates better clinical care or control.

NOTE : Submission Frequency: Patient-process

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**2019 Clinical Quality Measure Flow for Quality ID #393:
HRS-9: Infection Within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation,
Replacement, or Revision
Submission Criteria Two****



*See the posted Measure Specification for specific coding and instructions to submit this measure. This measure flow illustrates denominator eligible encounters as requiring a ICD-10-PCS AND/OR an encounter. The measurement period is for patients with a CIED device implantation, replacement, or revision performed from January 1, 2019 through June 30, 2019 of the performance period.
 **This measure has two Submission Criteria that are combined for calculation of one data completeness and one performance rate.
 ***A lower calculated performance rate for this measure indicates better clinical care or control.
 NOTE : Submission Frequency: Patient-process

**2019 Clinical Quality Measure Flow for Quality ID #393:
HRS-9: Infection Within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation,
Replacement, or Revision**

SAMPLE CALCULATIONS:

Data Completeness=

$$\frac{\text{Performance Met (a}^1\text{+a}^2\text{=80 patients) + Performance Not Met (c}^1\text{+c}^2\text{=60 patients)}}{\text{Eligible Population / Denominator (d}^1\text{+d}^2\text{= 160 patients)}} = \frac{140 \text{ patients}}{160 \text{ patients}} = 87.50\%$$

Performance Rate=

$$\frac{\text{Performance Met (a}^1\text{+a}^2\text{=80 patients)}}{\text{Data Completeness Numerator (140 patients)}} = \frac{80 \text{ patients}}{140 \text{ patients}} = 57.14\%$$

*See the posted Measure Specification for specific coding and instructions to submit this measure.

This measure flow illustrates denominator eligible encounters as requiring a ICD-10-PCS AND/OR an encounter.

The measurement period is for patients with a CIED device implantation, replacement, or revision performed from January 1, 2019 through June 30, 2019 of the performance period.

**This measure has two Submission Criteria that are combined for calculation of one data completeness and one performance rate.

***A lower calculated performance rate for this measure indicates better clinical care or control.

NOTE : Submission Frequency: Patient-process

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The measure diagrams were developed by CMS as a supplemental resource to be used in conjunction with the measure specifications. They should not be used alone or as a substitution for the measure specification.

**2019 Clinical Quality Measure Flow Narrative for Quality ID #393:
HRS-9: Infection Within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation,
Replacement, or Revision**

Please refer to the specific section of the Specification to identify the denominator and numerator information for use in submitting this Individual Specification. NOTE: A lower calculated performance rate for this measure indicates better clinical care or control.

This measure includes 2 Submission Criteria.

Submission Criteria 1:

- 1) Start with Denominator
- 2) All Patients Regardless of Age
- 3) Check Patient Procedure:
 - a. If Procedure Code for Implantation, Replacement, or Revision as Listed in Denominator equals No, do not include in Eligible Population. Stop Processing
 - b. If Procedure Code for Implantation, Replacement, or Revision as Listed in Denominator equals Yes, proceed to check New CIED.
- 4) Check New CIED:
 - a. If New CIED equals No, do not include in Eligible Population. Stop Processing.
 - b. If New CIED equals Yes, proceed to check Procedure Code for Heart Transplantation.
- 5) Check Procedure Code for Heart Transplantation:
 - a. If Procedure Code for Heart Transplantation as Listed in the Denominator equals No, include in Eligible Population.
 - b. If Procedure Code for Heart Transplantation as Listed in the Denominator equals Yes, do not include in Eligible Population. Stop Processing.
- 6) Denominator Population:
 - a. Denominator Population is all Eligible Patients in the Denominator. Denominator is represented as Denominator in the Sample Calculation listed at the end of this document. Letter d¹ equals 80 patients in the Sample Calculation.
- 7) Start Numerator
- 8) Check Patient Admitted within 180 days, Status Post CIED Implantation, Replacement, or Revision with an Infection Requiring Device Removal or Surgical Revision:
 - a. If Patient Admitted within 180 days, Status Post CIED Implantation, Replacement, or Revision with an Infection Requiring Device Removal or Surgical Revision equals Yes, include in Data Completeness Met and Performance Met.
 - b. Data Completeness Met and Performance Met letter is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter a¹ equals 40 patients in the Sample Calculation.

- c. If Patient Admitted within 180 days, Status Post CIED Implantation, Replacement, or Revision with an Infection Requiring Device Removal or Surgical Revision equals No, proceed to check Patient Not Admitted within 180 days, Status Post CIED Implantation, Replacement, or Revision with an Infection Requiring Device Removal or Surgical Revision.
- 9) Check Patient Not Admitted within 180 days, Status Post CIED Implantation, Replacement, or Revision with an Infection Requiring Device Removal or Surgical Revision:
- a. If Patient Not Admitted within 180 days, Status Post CIED Implantation, Replacement, or Revision with an Infection Requiring Device Removal or Surgical Revision equals Yes, include in Data Completeness Met and Performance Not Met.
 - b. Data Completeness Met and Performance Not Met letter is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter c¹ equals 30 patients in the Sample Calculation.
 - c. If Patient Not Admitted within 180 days, Status Post CIED Implantation, Replacement, or Revision with an Infection Requiring Device Removal or Surgical Revision equals No, proceed to check Data Completeness Not Met.
- 10) Check Data Completeness Not Met:
- a. If Data Completeness Not Met, the Quality Data Code or equivalent was not submitted. 10 patients have been subtracted from the Data Completeness Numerator in the Sample Calculation.

**2019 Clinical Quality Measure Flow Narrative for Quality ID #393:
HRS-9: Infection Within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation,
Replacement, or Revision**

Please refer to the specific section of the Specification to identify the denominator and numerator information for use in submitting this Individual Specification. NOTE: A lower calculated performance rate for this measure indicates better clinical care or control.

This measure includes 2 Submitting Criteria.

Submission Criteria 2:

- 1) Start with Denominator
- 2) All Patients Regardless of Age
- 3) Check Patient Procedure:
 - a. If Procedure Code for Implantation, Replacement, or Revision as Listed in Denominator equals No, do not include in Eligible Population. Stop Processing.
 - b. If Procedure Code for Implantation, Replacement, or Revision as Listed in Denominator equals Yes, proceed to check Replaced or Revised CIED.
- 4) Check Replaced or Revised CIED:
 - a. If Replaced or Revised CIED equals No, do not include in Eligible Population. Stop Processing.
 - b. If Replaced or Revised CIED equals Yes, proceed to check Procedure Code for Heart Transplantation.
- 5) Check Procedure Code for Heart Transplantation:
 - a. If Procedure Code for Heart Transplantation as Listed in the Denominator equals No, include in Eligible Population.
 - b. If Procedure Code for Heart Transplantation as Listed in the Denominator equals Yes, do not include in Eligible Population. Stop Processing.
- 6) Denominator Population:
 - a. Denominator Population is all Eligible Patients in the Denominator. Denominator is represented as Denominator in the Sample Calculation listed at the end of this document. Letter d² equals 80 patients in the Sample Calculation.
- 7) Start Numerator
- 8) Check Patient Admitted within 180 days, Status Post CIED Implantation, Replacement, or Revision with an Infection Requiring Device Removal or Surgical Revision:
 - a. If Patient Admitted within 180 days, Status Post CIED Implantation, Replacement, or Revision with an Infection Requiring Device Removal or Surgical Revision equals Yes, include in Data Completeness Met and Performance Met.
 - b. Data Completeness Met and Performance Met letter is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter a² equals 40 patients in the Sample Calculation.

- c. If Patient Admitted within 180 days, Status Post CIED Implantation, Replacement, or Revision with an Infection Requiring Device Removal or Surgical Revision equals No, proceed to check Patient Not Admitted within 180 days, Status Post CIED Implantation, Replacement, or Revision with an Infection Requiring Device Removal or Surgical Revision.
- 9) Check Patient Not Admitted within 180 days, Status Post CIED Implantation, Replacement, or Revision with an Infection Requiring Device Removal or Surgical Revision:
- a. If Patient Not Admitted within 180 days, Status Post CIED Implantation, Replacement, or Revision with an Infection Requiring Device Removal or Surgical Revision equals Yes, include in Data Completeness Met and Performance Not Met.
 - b. Data Completeness Met and Performance Not Met letter is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter c² equals 30 patients in the Sample Calculation.
 - c. If Patient Not Admitted within 180 days, Status Post CIED Implantation, Replacement, or Revision with an Infection Requiring Device Removal or Surgical Revision equals No, proceed to check Data Completeness Not Met.
- 10) Check Data Completeness Not Met:
- a. If Data Completeness Not Met, the Quality Data Code or equivalent was not submitted. 10 patients have been subtracted from the Data Completeness Numerator in the Sample Calculation.

SAMPLE CALCULATIONS:

Data Completeness=

$$\frac{\text{Performance Met (a}^1\text{+a}^2\text{=80 patients)} + \text{Performance Not Met (c}^1\text{+c}^2\text{=60 patients)}}{\text{Eligible Population / Denominator (d}^1\text{+d}^2\text{= 160 patients)}} = \frac{140 \text{ patients}}{160 \text{ patients}} = 87.50\%$$

Performance Rate=

$$\frac{\text{Performance Met (a}^1\text{+a}^2\text{=80 patients)}}{\text{Data Completeness Numerator (140 patients)}} = \frac{80 \text{ patients}}{140 \text{ patients}} = 57.14\%$$