

SUMMARY: This Chapter defines health care quality data sets and the provisions for filing the data sets by health care providers to the Maine Health Data Organization.

The provisions include:

- Identification of the organizations required to report;
 - Establishment of requirements for the content, form, medium, and time for filing health care quality metrics data;
 - Establishment of standards for the data reported; and
 - Compliance provisions.
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1. Definitions

Unless the context indicates otherwise, the following words and phrases shall have the following meanings:

- A. **Clostridium difficile.** In addition to its other definitions established in medical literature, the term “Clostridium difficile” shall mean a spore-forming, gram-positive anaerobic bacillus that is one of the causes of infection of the large bowel. Clostridium difficile associated infection ranges from mild antibiotic associated diarrhea to severe life-threatening inflammation of the colon.
- B. **Central line catheter-associated blood stream infection.** A serious infection that enters the bloodstream due to a special type of catheter used to access a major vein close to the heart. For reporting purposes, hospitals are bound by or subject to the definition of “central line catheter-associated blood stream infection” as specified in the current version of the CDC NHSN Patient Safety Component Manual.
- C. **CMS.** “CMS” means the Centers for Medicare & Medicaid Services.
- D. **Executive Director.** “Executive Director” means the Executive Director of the MHDO or his/her successors.
- E. **External validation.** “External validation” means an audit process by an external agency to assure the accuracy and quality of healthcare associated infection data submitted to the NHSN and that the data meets the NHSN’s pre-determined specifications.
- F. **Health care facility.** “Health care facility” means any hospital, mental health facility, State institution, ambulatory surgical facility, nursing home, residential care facility, rest home, sanatorium, convalescent home, federally qualified health center, or rural health clinic, as defined by 22 M.R.S.A. Chapter 1683 §8702(4), renal dialysis facility as

defined by 22 M.R.S.A. Chapter 412 §2041(8), or intermediate care facility for persons with intellectual disabilities as defined by 22 M.R.S.A. Chapter 405 §1812-K.

- G. **Hospital.** "Hospital" has the same meaning as in 22 M.R.S.A. §328(14). 'Hospital' includes but is not limited to, acute care hospitals, Critical Access Hospitals, and rehabilitation hospitals.
- H. **IHI.** "IHI" means the Institute for Healthcare Improvement.
- I. **Measure Steward.** The identified responsible entity having a process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation.
- J. **ME CDC.** "ME CDC" means the Maine Department of Health and Human Services, Maine Center for Disease Control and Prevention.
- K. **Methicillin-resistant Staphylococcus Aureus (MRSA).** "Methicillin-resistant Staphylococcus Aureus" are bacteria that can cause infections and are resistant to one or more classes of antibiotics.
- L. **MHDO.** "MHDO" means the Maine Health Data Organization or its designee.
- M. **MQF.** "MQF" means the Maine Quality Forum as defined in Title 24-A, Chapter 87, §6951.
- N. **M.R.S.A.** "M.R.S.A." means Maine Revised Statutes Annotated.
- O. **National Healthcare Safety Network.** "National Healthcare Safety Network" (NHSN) means the US CDC's secure internet-based data collection system managed by the Division of Healthcare Quality Promotion.
- P. **NQF.** "NQF" means the National Quality Forum.
- Q. **Nursing Facility.** "Nursing Facility" means a facility as defined in 22 MRS §1812-A.
- R. **Surgical Site Infection (SSI).** An infection occurring after surgery in the same part of the patient's body where the surgery was performed. For reporting purposes, hospitals are bound by or subject to the definition of "surgical site infection" as specified by the current version of the CDC NHSN Patient Safety Component Manual.
- S. **US CDC.** "US CDC" means the United States Department of Health and Human Services, Centers for Disease Control and Prevention.

2. **Healthcare Associated Infection Quality Data Set Filing Description**

- A. For all patients identified as eligible cases in the specific denominator and numerator categories (minus exclusions) specified by NHSN, each hospital or their agent shall report data to the US CDC's NHSN for the following healthcare associated infection (HAI) quality metrics in accordance with NHSN specifications:

HAI-1 Central line catheter-associated blood stream infection rate for adult and pediatric patients in intensive care units, medical units, surgical units, medical/surgical units, and mixed acuity units (Measure steward – NHSN).

HAI-2 Central line catheter-associated blood stream infection rate for high-risk nursery patients (Measure steward – NHSN).

HAI-3 through HAI-5 have been purposefully deleted.

HAI-6 Catheter-associated urinary tract infection rates for adult and pediatric patients in intensive care units, medical units, surgical units, medical/surgical units, mixed acuity units and rehabilitation units beginning January 1, 2020. (Measure steward – NHSN).

- B. For all patients identified as eligible cases in the specific denominator and numerator categories specified by NHSN, each hospital, or their agent, shall submit to the US CDC's National Healthcare Safety Network (NHSN), data for the following healthcare associated infection (HAI) quality metrics in accordance with NHSN specifications, beginning with all qualifying surgical procedures performed on or after January 1, 2020:

HAI-7 Surgical Site Infection rate for patients undergoing inpatient knee prosthesis (arthroplasty of knee) surgical procedures (KPRO) (Measure steward – NHSN); and

HAI-8 Surgical Site Infection rate for patients undergoing inpatient hip prosthesis (arthroplasty of hip) surgical procedures (HPRO) (Measure steward – NHSN).

- C. Each hospital shall submit to the US CDC's National Healthcare Safety Network (NHSN) MRSA blood specimen Lab ID Event data, for all facility-wide inpatients (FacWideIN) in accordance with NHSN specifications. (Measure steward - NHSN).
- D. Each hospital shall submit to the US CDC's NHSN data for *Clostridium difficile* Lab ID Events for all facility-wide inpatients (FacWideIN) in accordance with NHSN specifications. (Measure steward - NHSN).
- E. Each nursing facility shall make a quarterly submission to the MHDO of data, separated by month, for *Clostridium difficile* Lab ID Events for all facility-wide residents (FacWideIN) in accordance with NHSN specifications beginning July 1, 2020. (Measure steward - NHSN).
- F. The Maine CDC shall have access to any healthcare associated infection measure data submitted under state mandate directly to MHDO in lieu of NHSN, and the Maine CDC shall be authorized to use this data for data validation, public health surveillance and performance improvement purposes.
- G. In lieu of reporting data directly to MHDO, each-health care facility shall authorize Maine CDC to have access to the NHSN for facility-specific reports of data submitted for any healthcare associated infection measure under a state or federal mandate, and shall authorize the Maine CDC to use this data for data validation, public health surveillance and performance improvement purposes. Such data accessed and used by Maine CDC is

not considered MHDO data but is protected by 22 M.R.S.A. §42(5) to the extent it is individually identifiable.

- H. Each health care facility shall also authorize the MHDO to have access to the NHSN for facility-specific reports of data submitted for any healthcare associated infection measure under a state or federal mandate, for the purpose of public reporting.
- I. The MQF and Maine CDC shall develop and implement an external validation process to assure the accuracy of healthcare associated infection data submitted to the NHSN. Each hospital selected to participate in a State external validation study shall cooperate with the State's third-party external validation contractor and provide any hospital medical records or data required to complete the study.
- J. Any hospital selected for a federal validation study is exempt from state-level validation for that year and measure(s) with the understanding that the hospital must submit a copy of the federal validation report summary to the MQF within 14 days of their receipt of the final federal report. The MQF is authorized to use information from the federal validation report summary for the purpose of public reporting.

3. **Nursing-Sensitive Patient-Centered Health Care Quality Data Set Filing Description.**

American Nurses Association (ANA) measures (NSPC-2 & NSPC-3): Each hospital or their agent shall report data to the MHDO for NSPC-2 and NSPC-3 as defined by NDNQI, National Database for Nursing Quality Indicators, *Guidelines for Data Collection on the American Nurses Association's National Quality Forum Endorsed Measures, May 2010* or as updated by the ANA.

The Joint Commission measures (NSPC-1): Each hospital or their agent shall report data to the MHDO for NSPC-1 as currently defined by the Joint Commission, *Implementation Guide for the NQF Endorsed Nursing Sensitive Care Measure Set*.

For each nursing-sensitive patient-centered (NSPC) health care outcome measure, the NSPC metrics are:

- NSPC – 1 Percentage of inpatients who have a hospital-acquired Stage 1 or greater pressure ulcer (Measure steward – The Joint Commission);
- NSPC – 2 Number of patient falls per patient days (Measure steward: ANA); and
- NSPC – 3 Number of patient falls with injuries per patient days (Measure steward- ANA)

4. **Submission Requirements.**

- A. **File submission.** With the exception of data submitted via NHSN, each hospital and nursing facility or their agent shall file all applicable data sets by using the current version of the electronic forms provided by the MHDO at its website at mhdo.maine.gov/quality_data.htm. Data files must be submitted to the MHDO Hospital Data Portal via the secure web upload interface. E-mail attachments shall not be accepted. File naming conventions are specified in the Portal User Manual.

- B. Filing Periods.** Data generated in accordance with the provisions of Sections 2 and 3 shall be submitted no later than the date of the 15th of the 5th month following the end of each calendar quarter in which the service occurred. The filing periods are as follows:

1 st Quarter	January, February, March	August 15th
2nd Quarter	April, May, June	November 15th
3rd Quarter	July, August, September	February 15 th
4 th Quarter	October, November, December	May 15 th

5. Standards for Data; Notification; Response

- A. Standards.** The MHDO or its designee shall evaluate each file submission in accordance with the following standards:
1. When more than one licensed health care facility is operated by the reporting organization, the information required by this Chapter must be reported for each health care facility separately. When a provider of health care operates in more than one location, the MHDO may require that information be reported separately for each location.
 2. Coding values indicating “data not available”, “data unknown”, or the equivalent will not be accepted. However, those health care facilities that do not have relevant patient populations for any section of metrics may submit a letter to the MHDO stating there are no appropriate data available and therefore they will not be submitting data for that section of metrics. This will be an annual requirement for those health care facilities not submitting data.
- B. Notification.** Upon completion of this evaluation, the MHDO will notify each health care facility whose data submissions do not satisfy the standards for any filing period within 90 days of the quarterly submission deadline. This notification will identify the specific file and the data elements within them that do not satisfy the standards.
- C. Resubmission.** Each health care facility notified under subsection 5.B. will resubmit the data within 30 days of the notification by making the necessary changes to satisfy the standards.
- D. Replacement of Data Files.** No health care facility may amend its data submission more than one year after the end of the quarter in which the discharge or service occurred unless it can be established by the health care facility that exceptional circumstances occurred. Any resubmission of data after the elapse of the one year period must be approved by the MHDO Board.

6. Public Access

Information collected, processed and/or analyzed under this rule shall be subject to release to the public or retained as confidential information in accordance with 22 M.R.S.A. §8707 (or §8714 when effective) and Code of Maine Rules 90-590, Chapter 120: *Release of Information to the Public*, unless prohibited by state or federal law.

7. Waivers to Data Submission Requirements

If a health care facility due to circumstances beyond its control is temporarily unable to meet the terms and conditions of this Chapter, a written request must be made to the Executive Director of the MHDO as soon as it is practicable after the health care facility has determined that an extension is required. The written request shall include: the specific requirement to be waived; an explanation of the cause; the methodology proposed to eliminate the necessity of the waiver; and the time frame required to come into compliance. The Executive Director shall present the request to the MHDO Board at its next regularly scheduled meeting where the request shall be approved or denied.

8. Compliance

The failure to file, report, or correct quality data in accordance with the provisions of this Chapter may be considered a violation under 22 M.R.S.A. §8705-A and Code of Maine Rules 90-590, Chapter 100: *Enforcement Procedures*.

In the event that a measure steward announces a modification to a measure required under Chapter 270, health care facilities must continue to collect data based on specifications of the existing version of the measure up until the date that the measure steward requires reporting based on the modified version.

9. Summary Tables of Reporting Requirements by Facility Unit Type

A. Healthcare Associated Infection Measures

Measures	Hospitals							Nursing Facilities
	Adult and Pediatric Units						Neonatal NICU	
	ICU	Medical	Surgical	Medical/Surgical	Mixed Acuity	Rehab		
HAI-1 CLABSI	√	√	√	√	√			
HAI-2 CLABSI							√	
HAI-6 CAUTI	√	√	√	√	√	√		
HAI-7 KPRO SSI	<i>Applies to all KPRO surgical patients</i>							
HAI-8 HPRO SSI	<i>Applies to all HPRO surgical patients</i>							
MRSA	Facility-wide inpatients (FacWideIN)							
<i>C. difficile.</i>	Facility-wide inpatients (FacWideIN), excluding any nursery or NICU							√

B. Nursing Sensitive Indicator Measures

All three Nursing Sensitive Indicators apply to the following list of units:

- Critical Access Hospitals
 - All units
- Adult and pediatric hospital units
 - Critical care
 - Step-down
 - Medical
 - Surgical
 - Medical/Surgical
 - Mixed Acuity
- Rehabilitation units
 - Adult

STATUTORY AUTHORITY:

22 MRS §§ 8704 sub-§4, §8708-A, §8712, §8761, 24-A MRS §6951(2), (3)

EFFECTIVE DATE (filing 2005-279, major substantive):

August 6, 2005 – Sections 1, 2, 5-10

October 1, 2005 – Sections 3, 4

AMENDED (filing 2006-210, major substantive):

May 24, 2006 – Sections 1, 2, 4-10

January 1, 2007 – Section 3

AMENDED (filing 2007-325, major substantive):

September 8, 2007 - Sections 1-5, 7-11

January 1, 2008 - Section 6

AMENDED (filing 2008-228, major substantive):

June 22, 2008 – Sections 1-6, 8-12

January 1, 2009 – Section 7

AMENDED:

November 5, 2009 – filing 2009-581 (EMERGENCY, major substantive)

July 2, 2010 – filing 2010-217, major substantive

May 23, 2012 – filing 2012-106, major substantive

August 17, 2013 – filing 2013-176, major substantive

June 1, 2016 – filing 2016-072, major substantive

TBD – filing 2019-XX, major substantive