90-590 Maine Health Data Organization

Public Hearing

September 6, 2018

Proposed Rule Summary of Changes
Chapter 270: Uniform Reporting System for Quality Data Sets

(Major Substantive Rule)

The Maine Health Data Organization is authorized by statute to collect quality data from health care practitioners and health care facilities to support the set of quality measures adopted by the Maine Quality Forum with the goal to improving the quality of healthcare in Maine.

The MHDO Board met on June 7, 2018 and authorized the MHDO to initiate rulemaking to Chapter 270.

The following represent the proposed changes to the rule and the rationale for these changes:

Section 1. Definitions:

1. Deleted the following definitions from Section 1: Ambulatory Surgical Facility; and Ventilator-Associated Pneumonia

   One of the goals of this proposed rule change is to update the definitions section of the rule by deleting those definitions that are no longer used in the rule. This section has not kept up with the previous revisions to the rule.

2. Added the following definitions to Section 1: Health care facility; Nursing facility; Surgical Site Infection; and External Validation

   MHDO added the first three definitions to accommodate new measures added to the Healthcare Associated Infections (HAI) data set and to clarify the types of facilities required to provide the MHDO and the Maine CDC access to state or federally mandated HAI data submitted to the U.S. CDC's National Healthcare Safety Network (NHSN). MHDO added the "External validation"

definition in conjunction with a new Section 2(I) requiring hospitals to cooperate with studies to confirm the accuracy of their HAI data reporting.

3. The following revisions were made to existing definitions in Section 1:

   - Added a plain language description to the definition of "Central line catheter-associated blood stream infection".
   - In Section 1(B), formerly 1(C):
     - Added the name of the CDC measure specifications manual, previously implied without having been named, under the definition of "Central line catheter-associated blood stream infection".
     - Removed "ambulatory surgical facilities" from the definition of "Central line catheter-associated blood stream infection", because they have never appeared in the list of facility types required to report those infections.
   - In Section 1(I), inserted "Maine" before "Department of Health and Human Services" to avoid ambiguity.

Section 2. Healthcare Associated Infection Quality Data Set Filing Description:

4. Revised Section 2(A) by:

   - Replacing "MHDO" with "US CDC's NHSN".

   The current version of Chapter 270 instructs hospitals to submit CLABSI infection data directly to MHDO while allowing the option to submit the infection data via NHSN, instead. This revision requires all hospitals to submit CLABSI infection data via NHSN, as nearly all Maine hospitals now do. While the MHDO data submission form limits CLABSI infection data to each calendar quarter's total number of CLABSI infections, NHSN collects data on each infection including basic patient symptoms, risk factors, type of pathogen, and the pathogen's antibiotic resistance. The added information helps Maine CDC identify outbreaks, track patterns, and advise hospitals on ways reduce future risk to patients.

   - Inserting, "in accordance with NHSN specifications".

   Chapter 270 already identifies NHSN as the Measure Steward for CLABSI infection indicators (i.e., as the organization responsible for maintaining and

publishing detailed measure specifications). The revision does not add or change any requirements, but provides simple clarity to the rule.

- Adding "adult and pediatric" and "and mixed acuity units" to HAI-1.

Changing "patients" to "adult and pediatric patients" adds clarity by aligning Chapter 270 with the long-existing federal and state specifications that all hospitals are already required to follow.

- Adding "and mixed acuity units" to HAI-1.

The MHDO measure specifications instruct smaller hospitals that do not have an ICU, medical, surgical or medical/surgical unit to substitute their mixed acuity unit, instead. However, if a hospital has a medical/surgical unit and a mixed acuity unit, but no ICU, then it limits their reporting to the medical/surgical unit only.

- Deleting the paragraph that exempts hospitals who report their HAI-1 and HAI-2 CLABSI data to NHSN from having to submit that data to MHDO.

Requiring all hospitals to report HAI-1 and HAI-2 data to NHSN (see the second bullet point under item 4, above) renders this paragraph obsolete and meaningless.

- Adding the new measure HAI-6 for the reporting of, "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."

The U.S. CDC's most recent *HAI Progress Report* found that while Maine hospitals are performing better than the national baseline on nearly all other types of HAIs, Maine hospital CAUTI rates were 54% worse than the national baseline.

Adding the new measure to Chapter 270 would allow Maine CDC to access NHSN CAUTI data for all acute care and rehabilitation hospitals, and expand its ability to track patterns of infection, identify outbreaks, target and prioritize technical assistance, and reduce public risk of infection. Publicly reporting healthcare-associated CAUTI infection rates on

www.comparemaine.org will allow patients and their families to make informed choices, and provide greater incentive to reduce CAUTI infection rates to at-or-below the national baseline level.

5. Throughout the past six years, Maine hospitals have maintained a statewide weighted-average compliance rate of 90%-or-better for all three measures below, and a majority of hospitals have achieved perfect compliance rates. It is time to retire the collection of these data by deleting section 2(B) and focus on identifying quality measures where compliance and/or infection rates are not as good.

   - HAI-3: Percent compliance with all five evidence-based interventions for patients with intravascular central catheters in intensive care units;
   - HAI-4: Percent compliance with the four insertion-related evidence-based interventions for patients with intravascular central catheters placed preoperatively, in pre-operative areas, operating rooms, and recovery areas; and
   - HAI-5: Percent compliance with all five evidence-based interventions for patients with mechanical ventilation in intensive care units.

6. Inserting a new Section 2(B) that requires hospitals, beginning Jan. 1, 2020, to collect data on two Surgical Site Infection (SSI) measures for submission via the NHSN:

   - HAI-7: Surgical Site Infection rate for patients undergoing inpatient knee prosthesis (arthroplasty of knee) surgical procedures (KPRO); and
   - HAI-8: Surgical Site Infection rate for patients undergoing inpatient hip prosthesis (arthroplasty of hip) surgical procedures (HPRO).

   Although there is no current federal or state mandate to submit SSI data for KRPO or HPRO, nearly all Maine hospitals are reported to be doing so. Unlike several other surgical SSI measures, KPRO and HPRO SSI rates are highly valid indicators of healthcare associated infection, because both surgeries are performed in sterile parts of the human body. Adding HAI-7 and HAI-8 to Chapter 270 will allow the State to gauge and publicly report on www.comparemaine.org the extent of KPRO and HPRO SSIs for the first time.

7. Revised Section 2(C) by:

   - Limiting "MRSA LabID Event data" to "MRSA blood specimen LabID Event data" to conform with the current NHSN measure specifications already in use by Maine hospitals.
   - Changing "inpatients (facility-wide)" to "all facility-wide inpatients (FacWideIN)" to grammatically conform with language used in the NHSN measure specifications.
   - Removing, "no later than January 1, 2014.", given that the measure is now in existing use.

8. Revised Section 2(D) by:

   - Italicizing the words, "Clostridium difficile" to conform with proper usage.
   - Changing "inpatients (facility-wide)" to "all facility-wide inpatients (FacWideIN)" to grammatically conform with language used in the NHSN measure specifications.
   - Changing, "in accordance with NHSN" to "in accordance with NHSN specifications" to match the language in Section 2(C).
   - Removing, "beginning when rule becomes effective.", given that the measure is now in existing use.

9. Added a new Section 2(E) to require all Maine nursing facilities to submit to MHDO *Clostridium difficile* LabID Event data for all facility-wide residents in accordance with NHSN specifications beginning July 1, 2020.

   Although there is anecdotal data to suggest that HAIs present serious issues in the nursing home setting, there is no statewide systematic collection and reporting of HAI data in the nursing home setting. Extending Chapter 270's scope to this health care setting would allow the Maine CDC, MHDO and the nursing homes themselves to measure and gauge the extent and geographic distribution of a serious and frequently antibiotic-resistant pathogen known to be found in nursing home settings. It would also permit the Maine CDC to target and prioritize its resources to advise and assist nursing facilities in their *C. difficile* prevent efforts.

10. Replaced the old Sections 2(E), 2(F) and 2(G) with new Sections 2(F), 2(G) and 2(H):

- The new Section 2(F) authorizes the Maine CDC access to any HAI Chapter 270 data submitted to MHDO for use in data validation, public health surveillance and internal or external performance improvement purposes.
- The old Sections 2(F) and 2(G) required all Maine acute care hospitals to authorize the Maine CDC and MHDO to access and use any Chapter 270 HAI data submitted to the NHSN.
- The old Section 2(E) required hospitals mandated by the CMS Prospective Payment System Inpatient Quality Report Program to submit HAI data to NHSN, for any measure not specified in Chapter 270, to:
- authorize the Maine CDC to access that data, "for data validation, public health surveillance and internal or external performance improvement purposes"; and
- authorize MHDO to access that data for facility-level public reporting purposes.

The intent of the old Section 2(E) is now incorporated in the new Sections 2(G) and 2(H).

- The new Section 2(G) requires health care facilities to authorize Maine CDC to access any HAI data they have submitted to NHSN under state or federal mandate and to authorize Maine CDC to use that data for data validation, public health surveillance and internal or external performance improvement purposes.
- The new Section 2(H) covers health care facilities to authorize MHDO to access the same data described in the new 2(G) and requires each facility to authorize MHDO to use that data for facility-specific public reporting purposes.

  The new language in 2(G) and 2(H) would have the immediate effect of requiring outpatient dialysis centers to authorize the Maine CDC and MHDO to access the HAI-related data that CMS requires they submit to NHSN.

11. Added Section 2(I) requiring MHDO and Maine CDC to develop and implement an external validation process to perform an annual audit the accuracy of HAI data submitted by hospitals to the U.S. CDC NHSN. The MHDO has commissioned external validation studies in past years, based on the U.S. CDC's published recommendations and guidelines. In addition to verifying data accuracy and correcting errors, the studies provide hospital

staff with valuable feedback and advice on how to avoid future errors and allow the Maine CDC to identify common issues of concern to target future training and technical assistance. Section 2(I) authorizes the MHDO to publically report general results as has been done in past years.
In addition, Section 2(J) responds to stakeholder requests to exempt a hospital from a state validation study, if it has been chosen in the same year to participate in a CMS-mandated federal validation study for the same HAI measure.

Section 4. Submission Requirements:

12. Deleted Sections 4(A) and 4(B) and replaced them with a new Section 4(A):

- The old Sections 4(A) and 4(B) are outdated. Section 4(A) refers to submitting data on floppy disks and CD-ROMS. Section 4(B) requires a no-longer-needed hard copy sheet or separate computer file to identify the date submitter's name, hospital, email address and phone number.
- The new 4(A) replaces the old 4(A) and 4(B) by requiring any data submitted directly to MHDO by using the current version of the electronic data form provided for download at the MHDO website. It also requires that the data files be submitted via the MHDO Hospital Data Portal via the portal's secure web upload interface, and that the data form file names conform to the specifications in the Portal User Manual.

13. Renamed Section 4(C) to 4(B) and deleted its closing paragraph:

- The closing paragraph required that Chapter 270 data reported via NHSN be submitted monthly and per the surveillance system specifications posted on the NHSN website. The paragraph is made redundant by the revised Sections 2(A) and 2(B) which instruct hospitals or nursing homes to report HAI quality measure data, "in accordance with NHSN specifications."

Section 5. Standards for Data; Notification; Response:

14. Deleted Section 5(A.1)

- This section instructed hospitals to conform to the data, "transmittal sheet layouts as specified at the MHDO website," is obsolete.

15. Inserted a new Section 5(A.1)

    - Requires providers operating multiple health care facilities or in multiple locations to submit separate data reports for each. This requirement conforms with a similar requirement in MRSA 22 §8708 sub-§3 regarding "clinical data" reported to MHDO.

16. Deleted Section 5(A.2)

    - The deleted section is redundant. It repeats the same instructions in Section 3 that hospitals report their Nursing Sensitive Indicator data as defined by each indicator's measure steward.

17. Renumbered Section 5(A.3) as Section 5(A.2) and replaced "hospitals" with "health care facilities".

18. In Sections 5(B), 5(C), 5(D), replaced either "hospital" or "hospital and ambulatory surgery facility" with "health care facility".

Section 7. Waivers to Data Submission Requirements *and* Section 8. Compliance

19. In Sections 7 and 8, replaced either "hospital" or "hospital and ambulatory surgery facility" with "health care facility".

Section 9. Summary of Tables of Reporting Requirements by Facility Unit Type.

20. Added a new Section 9

    - Section 9A provides a summary table to identify which types of hospital units are included in each individual HAI quality indicator and to note that nursing facilities are covered by the *C. difficile* LabID event indicator

    - Section 9B lists the types of hospital units included in all three of the Nursing Sensitive Indicators.

    - The unit types listed in Section 9 conform to the unit types listed or described under the individual reference to each measure in Sections 2 and 3.