

**Indiana State Department of Health
Health Care Quality and Regulatory Commission**

**Healthcare Associated Infection Reporting Rule
LSA # 11-102**

**Summary of Public Comments
on the Proposed Rule and
Recommendations for the Final Rule**

September 8, 2011

Indiana State Department of Health
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The Healthcare Associated Infection Reporting Rule was preliminary adopted by the Indiana State Department of Health (ISDH) Executive Board on May 11, 2011. A *Notice of Public Hearing* was subsequently published in the Indiana Register and a public hearing conducted on August 19, 2011 at the ISDH.

During the comment period, the ISDH requested meetings with interested individuals and organizations concerning the reporting of healthcare associated infections (HAI). These meetings were conducted on March 16, May 4, June 8, and July 6. The purpose of the meetings was to review Centers for Medicare and Medicaid Services (CMS) reporting regulations and Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) reporting standards.

The proposed rule was disseminated following preliminary adoption and comments on the proposed rule were requested. The ISDH received written comments on the proposed rule and received oral comments at the public hearing. The written and oral comments have been compiled into an official comment record of the rule promulgation. The ISDH received and reviewed two additional written comments after the close of the public hearing.

The ISDH appreciates the comments received on this proposed rule. The comments have been helpful towards preparation of a proposed final rule. The ISDH carefully reviewed and considered each comment. This document is a summary of comments received during the comment period and the recommendation of the staff in response to comments.

Most of the comments received discussed same or similar issues. For brevity sake, the comments have usually been excerpted or paraphrased. For each issue raised, the ISDH only included a representative sample of comments concerning that issue.

Sincerely,

Terry Whitson
Assistant Commissioner
Indiana State Department of Health

**Indiana State Department of Health
Summary of Public Comments
Healthcare Associated Infection Reporting Rule – LSA # 11-102**

COMMENTS ON USING THE HEALTH AND HUMAN SERVICES (HHS) ACTION PLAN TO PREVENT HEALTHCARE ASSOCIATED INFECTIONS

The HHS Action Plan had input from APIC, CDC, HICPAC, SHEA and other expert groups. Therefore, the document has legitimacy in terms of its scientific base.

We are asking for your consideration in modifying the HAI reporting rule so that it parallels the HHS / CMS requirements that are currently in place.

Our hospitals are in line with the HHS action plan and are in the process of developing a surveillance plan to support it.

ISDH STAFF REVIEW AND RECOMMENDATION: In June 2009, the U.S. Department of Health and Human Services (HHS) released its Action Plan to Prevent Healthcare Associated Infections. The Action Plan was not intended by HHS as a final plan but rather a first phase of an evolving plan. In the fall of 2010, the HHS Office of Healthcare Quality solicited public comment on draft phase two modules. Those comments are under review by HHS. A completely revised HAI Action Plan, including Phases 1 and 2, is expected to be released for public comment in 2011 with an updated HAI Action Plan to be released in the future.

In September 2009, the ISDH received a grant from CDC. The grant was intended to implement three components of the Action Plan:

- Development of a state healthcare associated infection (HAI) prevention plan;
- Development of a state surveillance program to include HAI reporting; and
- Implementation of a collaborative state prevention initiative.

An Indiana Plan was developed by a collaborative team of statewide interests and accepted by CDC. The Plan called for the mandatory reporting of healthcare associated infections by hospitals. The ISDH then developed and implemented the Indiana Healthcare Associated Infection Initiative to provide best practices and quality improvement resources.

As the CDC initiative has developed, changes to the HHS Action Plan (2009) have occurred. The National Healthcare Safety Network (NHSN) has continued to evolve with improved definitions and identification processes. The Centers for Medicare and Medicaid Services (CMS) became the implementation mechanism for the reporting requirements. The HHS Action Plan of June 2009 therefore is no longer totally consistent with current reporting standards and requirements.

On July 30, 2010, CMS published a regulation requiring hospitals to report selected healthcare associated infections as part of CMS' provider enrollment requirements. The regulation required hospitals to report central line associated bloodstream infections effective January 1, 2011, and surgical site infections effective January 1, 2012.

In early August 2011, CMS issued a second HAI reporting regulation. The regulation specified the surgical site infection categories, added catheter associated urinary tract infection reporting beginning January 1, 2012, and added *Clostridium difficile* reporting beginning January 1, 2013. These reporting requirements differ slightly from the original HHS Action Plan.

Indiana State Department of Health
Summary of Public Comments
Healthcare Associated Infection Reporting Rule – LSA # 11-102

The intent of the ISDH was to craft a state rule that was consistent with federal reporting requirements. When the ISDH began the rule promulgation process in April 2011, there was uncertainty as to how the HHS Action Plan would be implemented and the timing of federal reporting requirements. The July 2010 CMS regulation indicated the first two infections for reporting but did not provide specifics about surgical site infection reporting. In order to start the rule promulgation process and ensure the beginning of reporting in 2012, the ISDH recommended an inclusive preliminary rule that included all healthcare associated infections. This provided the ISDH with the capacity to adapt the final rule to conform to revised CMS reporting standards.

For the proposed final state rule, the ISDH is not following the HAI Action Plan of June 2009 since HHS, CDC, and CMS have already deviated from that plan. While comments to the proposed rule requested that the ISDH follow the HHS Action Plan, the ISDH believes that the intent of the comments was that the ISDH adopt a rule consistent with the federal reporting requirements. Many comments referred to CMS reporting requirements or interchanged HHS and CMS. The proposed final rule follows the CMS reporting requirements for central line associated bloodstream infections, surgical site infections, and catheter associated urinary tract infections. CMS is requiring the reporting of these infections beginning in either 2011 or 2012.

Although it is included in the recent CMS reporting regulation, the ISDH did not include the reporting of *Clostridium difficile* in the proposed final rule. CMS is not requiring it to be reported until 2013. At this time, it is uncertain whether the August 2011 CMS regulation will be the final federal regulation related to the reporting of *Clostridium difficile*. The ISDH believes that it is prudent to wait before adopting that reporting requirement. The ISDH would like to see the implementation of the reporting system and allow providers time to learn the NHSN system. Once CMS finalizes additional reporting requirements, the ISDH will consider adding those requirements through a new rule promulgation.

The ISDH agrees with the intent of the comments that the final state rule should follow federal reporting standards and requirements. Because the implemented CMS regulations have deviated slightly from the original HHS Action Plan, the proposed final rule does not follow the HHS Action Plan but rather follows the CMS HAI reporting regulations.

COMMENTS ON NATIONAL HEALTHCARE SAFETY NETWORK (NHSN)

NHSN is the electronic repository used for HHS data and uses CDC guidelines and definitions. NHSN standardized definitions should be used to identify and report HAIs. Duplicate reporting will allow Infection Preventionists less time for intervention activities. The rule should not include reporting HAI data that is not accepted at NHSN.

Mandatory reporting through one database (NHSN) can be accomplished. Having to report some infections to a different database would add increased burden to a department that needs to focus resources on initiatives to prevent infections, not simply report them.

Some cases that meet the ISDH definition for central line associated bloodstream infections would not meet the NHSN definition. Using different sets of definitions would be both confusing and time-consuming.

**Indiana State Department of Health
Summary of Public Comments
Healthcare Associated Infection Reporting Rule – LSA # 11-102**

ISDH STAFF REVIEW AND RECOMMENDATION: The preliminary rule required reporting solely through the CDC National Healthcare Safety Network (NHSN). Comments supported reporting through NHSN in order to eliminate duplicate reporting. The ISDH agrees with those comments. The proposed final rule retains reporting solely through NHSN. Because hospitals will be reporting through NHSN as part of CMS requirements, there will be no duplication of reporting.

In the preliminary rule, the ISDH included definitions of the healthcare associated infections. The ISDH obtained those definitions from CDC and NHSN documents available at the time of preparing the proposed preliminary rule. Comments to the preliminary rule indicated that the proposed definitions were not consistent with NHSN definitions. In reviewing current NHSN standards, CDC has tweaked some definitions based on current laboratory processes in order to improve accuracy and consistency of infection identification.

The intent of the preliminary rule was for hospitals to report healthcare association infections using the NHSN system and its definitions. The ISDH agrees with comments that the proposed definitions are no longer current with NHSN standards. To resolve this discrepancy, the ISDH determined that there was no need to include definitions of healthcare associated infections in the state rule. The proposed final rule requires reporting through the NHSN system. That system provides the user with current definitions and laboratory standards for reporting healthcare associated infections. In the proposed final rule, the ISDH therefore deleted the definitions and simply retained reporting through the NHSN system.

COMMENTS ON WHAT INFECTIONS TO INCLUDE IN REPORTING

The HHS plan has 5-year national prevention targets phased in so as to have the science catch up best practices as well as to formulate standardized definitions. Using the tiered plan of HHS for HAI reporting will allow reporting to progress in tandem with NHSN's ability to assimilate the data.

Inconsistent and inaccurate reporting will most likely occur among facilities since definitions for some major surgical site infections and ventilator associated pneumonia have not been established in the NHSN guidelines.

Exclusion of using MRSA data acquired through the communicable disease reporting rule from the plan. The Communicable Disease Reporting Rule requires the reporting to ISDH of severe *Staphylococcus aureus* in a previously healthy person. The HHS plan includes reporting of MRSA bloodstream infections starting in January 2013.

Surgical site infections (SSI) are not reported by location through NHSN. The ISDH is proposing that we only report SSI infections for ICU. This cannot be done through NHSN.

ISDH STAFF REVIEW AND RECOMMENDATION: There were comments about the inclusion of specific healthcare associated infections as part of state reporting requirements. As discussed above, the intent of the ISDH was for state reporting requirements to parallel federal reporting requirements to standardize reporting and eliminate duplication. The proposed final rule deletes reporting for those infections not included in CMS reporting regulations and parallels the federal reporting requirements.

**Indiana State Department of Health
Summary of Public Comments
Healthcare Associated Infection Reporting Rule – LSA # 11-102**

Comments referred to the HHS Action Plan for reporting MRSA infections beginning in January 2013. The August 2011 CMS regulations did not include MRSA reporting for 2013. In the proposed final rule, the ISDH therefore did not include MRSA reporting.

The preliminary rule included the reporting of surgical site infections by ICU location. The August 2011 CMS regulations clarifies the reporting of surgical site infections and includes facility-wide reporting for infections arising from abdominal hysterectomies and colorectal surgeries. The NHSN system has also been updated to reflect these changes. The proposed final rule therefore changes the reporting of surgical site infections to be consistent with the most recent CMS requirements.

COMMENTS ON REPORTING BY ALL HOSPITALS

The rule will require reporting by all hospitals, which will be new to many and require significant education and training in a short period of time. We encourage the ISDH to pursue funding and team with the Indiana Hospital Association to provide this training.

We support all Indiana hospitals allowing the ISDH to obtain Indiana information about HAIs.

ISDH STAFF REVIEW AND RECOMMENDATION: The preliminary rule included the reporting of healthcare associated infections by all hospitals. Comments agreed with that proposal. There were no comments opposed to reporting by all hospitals. The ISDH therefore has retained the reporting of healthcare associated infections by all hospitals in the proposed final rule.

Comments suggested the need for training as part of implementation of the proposed rule. The ISDH recognizes that the NHSN system is new to many providers. The ISDH also recognizes that some hospitals have utilized the NHSN system since its inception over five years ago so are very familiar with the system. As part of the Indiana Healthcare Associated Infection Initiative, the ISDH provided training on NHSN in July 2010 to approximately 40 hospitals. As part of its contract, the CMS Quality Improvement Organization for Indiana will be assisting providers with NHSN and implementing prevention processes. To further assist providers in utilizing the NHSN system and standards, the ISDH is planning training on NHSN for hospitals in late 2011.

COMMENTS ON SURVEILLANCE, VALIDATION, and INTERVENTIONS

APIC-Indiana supports your efforts to report healthcare associated infections and, as new HHS requirements are promulgated, we look forward to working with you on incorporating these into the surveillance process.

We are not sure how ISDH plans to use the data they collect on Indiana hospitals. If there are plans to publish the data publically, we encourage ISDH to develop a method for validating hospital's HAI rates. Without such external validation, some hospitals may report falsely low rates in order to preserve their public reputation. Such false reporting would undermine the goal of reducing HAIs

Indiana State Department of Health
Summary of Public Comments
Healthcare Associated Infection Reporting Rule – LSA # 11-102

Reporting alone does not reduce infections, targeted intervention does. Intervention requires data, analysis, action plans, implementation, and evaluation. It will be difficult to have any focus on improvement if the limited time Infection Control has is spent on data collection, on too many fronts at the same time, and reporting alone.

ISDH STAFF REVIEW AND RECOMMENDATION: There was widespread support for the reporting of healthcare associated infections in comments. The concerns cited were that reporting should not inhibit the ability of the providers to focus on infection prevention. The ISDH is currently nearing the completion of a two-year Indiana Healthcare Associated Infection Initiative involving approximately 130 health care facilities. As part of the initiative, the ISDH has provided facilities with access to numerous resources to assist in prevention efforts. The ISDH expects that the recent HHS Partnerships for Patients initiatives will provide additional assistance and resources for facilities in the prevention of infections.

In late 2010, the ISDH hired its first HAI Epidemiologist. While that individual left the agency to return to school, the ISDH has refilled the position and has continuing funding for the position for the immediate future. The ISDH plans for the Epidemiologist along with the licensing program to develop and implement a validation and surveillance system.