

HEALTH

HEALTH SYSTEMS BRANCH

DIVISION OF CERTIFICATE OF NEED AND LICENSING

OFFICE OF CERTIFICATE OF NEED AND HEALTHCARE FACILITY LICENSURE

Hospital Licensing Standards

Infection Control: Sepsis Protocols

Adopted New Rule: N.J.A.C. 8:43G-14.9

Proposed: June 19, 2017, at 49 N.J.R. 1653(a).

Adopted: November 6, 2017, by Cathleen D. Bennett, Commissioner, Department of Health (with the approval of the Health Care Administration Board).

Filed: December 19, 2017, as R.2018 d.047, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 26:2H-1 et seq., particularly 26:2H-5 and 12.45.

Effective Date: January 16, 2018.

Expiration Date: December 18, 2024.

Summary of Public Comments and Agency Responses:

The Department received comments from the following:

1. Sean Benson, Vice President and General Manager, Specialized Surveillance, Wolters Kluwer Health, Minneapolis, Minnesota;

2. Michele Garcia, Association for Professionals in Infection Control and Epidemiology, Inc., of Southern New Jersey, Chapter 11, Marlton, NJ;

3. Thomas Heymann, Executive Director, Sepsis Alliance, Maplewood, NJ;

4. Aline M. Holmes, DNP, RN, Senior Vice President, Clinical Affairs, New Jersey Hospital Association (NJHA), Princeton, NJ;

5. Sarah Lechner, Vice President, Policy Development and Government Affairs, RWJBarnabas Health, West Orange, NJ;

6. Melinda R. Martinson, General Counsel, Medical Society of New Jersey, Lawrenceville, NJ;

7. Sharon Parrillo, BSN, RN, CIC, and 2017 President of the Association for Professionals in Infection Control and Epidemiology, Inc., of Northern New Jersey;

8. Linda Schwimmer, JD, President and CEO, New Jersey Health Care Quality Institute, Princeton, NJ;

9. Ann Twomey, President, Health Professionals and Allied Employees, AFT/AFL-CIO, Emerson, NJ;

10. K. Gilbert, Summit, NJ; and

11. Jessica Aubry, Blackwood, NJ

Joshua Bartell, Blackwood, NJ

Lisa Bartlett Davis, Sepsis Alliance, Colorado Springs, CO

Linda Brennan, Yonkers, NY

Linda Brennan, Rory Staunton Foundation, New York, NY

Jaimie Cramer, Hammonton, NJ

Rose Culliney, Sewell, NJ

Cynthia DeMonte, Astoria, NY

Kimberly Edwards-Wunderlich, Pelham, NH

Geraldine Endicott, Mount Laurel, NJ

Susanna Fitzgerald, South Bound Brook, NJ
William Fitzgerald, South Bound Brook, NJ
Deb Kelly
Ellen Labanowski, Cranford, NJ
Maryellen Magee, Marlton, NJ
Sandra Mclean, Blackwood, NJ
Eileen McMahon, Spring Lake, NJ
Megan Mortillite, Williamstown, NJ
Tara Nadzadi, Gibbstown, NJ
Sherita Nzali, Berlin, NJ
Celestial Piedra, Avenel, NJ
Justina Piedra, Avenel, NJ
Nick Purcell, East Windsor, NJ
Patricia Purcell, East Windsor, NJ
Jacqui Snype, Athleague, Roscommon, Ireland
Ranee Speece, Cedarbrook, NJ
Ranee Speece, West Berlin, NJ
Holly Streeter, Sewell, NJ
Harold Tamke, Matawan, NJ
Brittany Taylor, Williamstown, NJ
Dylan Taylor, Sewell, NJ
Freddy Taylor, Sewell, NJ
Frederick Taylor, Sewell, NJ

Frederick Taylor, Jr., Sewell, NJ

Nicole Taylor, Blackwood, NJ

Nicole Taylor, Williamstown, NJ

Terry Taylor, Sewell, NJ

Theresa Taylor, Sewell, NJ

Elizabeth Therrien, Tulsa, OK

Danielle Z, West Deptford, NJ

Quoted, summarized, and/or paraphrased below, are the comments and the Department's responses. The numbers in parentheses following the comments below correspond to the commenter numbers above.

1. COMMENT: A commenter expresses "strong support for New Jersey's proposed rule revising the [State's] hospital licensing standards to include new evidence-based protocols to identify and treat cases of sepsis" and "applaud[s] New Jersey's leadership in taking steps to improve sepsis detection and treatment in hospitals, and release of the proposed new rule is timely. A report released just last month by the Agency for Health Research and Quality ... found that cases of sepsis in hospitals tripled between 2005 [through] 2014. An earlier study presented at the American Thoracic Society's annual conference in May 2014 concluded that sepsis contributes close to half of all hospital deaths in the United States. Early detection and quick treatment for sepsis in the hospital setting is particularly important to prevent complications and hospital readmissions. A 2015 study published in the American Journal of Respiratory and Critical Care Medicine found that older adults are three times more likely to develop sepsis in the first three months after leaving a hospital than at

any other time, and that the risk of sepsis is 30 [percent] higher for patients whose original hospital stay involved care for infections such as pneumonia. And a research letter published in February of this year in the Journal of the American Medical Association concluded that sepsis is associated with more hospital readmissions than myocardial infarction and heart failure. Requiring hospitals to establish, implement[,] and periodically update evidence-based protocols for the early identification and treatment of patients with sepsis has shown to be a particularly effective strategy to lower the number of inpatient deaths. [The States] of New York and Illinois both adopted similar protocols in 2013 and 2016, respectively. A recent study published in the New England Journal of Medicine concluded that the use of such protocols in New York hospitals was associated with lower risk-adjusted in-hospital mortality.” (1)

2. COMMENT: A commenter is “in alignment with the aims of the proposed new rule ... which seeks to protect patients from the dangers of sepsis through assuring effective protocols for its early identification and treatment.” (2)

3. COMMENT: A commenter “welcomes and applauds the ... commitment [of the Department] to saving lives and preventing serious injury from sepsis.” The commenter “also [recognizes] the tremendous work already done in the [State] by the New Jersey Hospital Association[, which] has achieved an 11 [percent] reduction in sepsis mortality and generated impressive increases in the use of hospital-wide screening tools and adoption of hospital-wide sepsis protocols. The challenge will be to secure 100 [percent] participation across the [State], provide necessary resources and support to ensure that [New Jersey] hospitals can enjoy sustainable success, ensure that new [rule does] not create unintended negative consequences, and make the

[State's] residents aware of sepsis as a medical emergency so they know to seek treatment as early as possible (a critical component for successful sepsis treatment).” The commenter “supports the promulgation of N.J.A.C. 8:43G-14.9 that would require [New Jersey] hospitals to institute a sepsis protocol and require training of hospital personnel among other things.... This rule is an important step toward leveraging the good work that has been done already to make sepsis a rare cause of death and disability in ... New Jersey. [The commenter] looks forward to working with the [Department], the New Jersey Hospital Association, New Jersey’s hospitals, [State]-wide community leaders, and the ... public to ensure that New Jersey becomes a national leader in sepsis prevention, early identification[,] and treatment.” (3)

4. COMMENT: A commenter states, “Over the past two and a half years, [the] NJHA and its Institute for Quality and Patient Safety, have led the New Jersey Sepsis Learning Action Collaborative (the Collaborative) to a 13 percent decrease in [Statewide] sepsis mortality by providing support to hospitals in the assessment, design and implementation of comprehensive practices that allow for both early sepsis identification and rapid treatment of septic patients. Through the Collaborative’s efforts, [the] NJHA has and will continue to:

[(1)] Provide acute and post-acute healthcare organizations with updates on evidence-based guidelines and strategies to identify and manage sepsis in both adult and pediatric populations;

[(2)] Consult with subject matter experts in the field of sepsis and critical care medicine to create education and training opportunities for clinicians;

[(3)] Measure, monitor and provide [State]- and hospital-level feedback reports for sepsis mortality and associated outcomes ([that is,] sepsis-related readmissions); and

[(4)] Engage patients and families in a better understanding of sepsis-related harm and prevention efforts.”

The commenter “supports the ... proposed rule that would require hospitals to establish, implement[,] and periodically update evidence-based sepsis protocols for the early identification and treatment of patients in various levels of sepsis (sepsis and septic shock) and to train staff with clinical responsibilities in the sepsis protocols.” The commenter “also supports the [Department’s] recommendation to allow hospitals to develop their own protocols based on current national and international best practices, rather than mandating a strict protocol for all facilities to follow. This is especially important because of the ever-evolving research on the care of patients with sepsis, here in the United States and internationally. Hospitals must be allowed to adjust their protocols as needed based on the most current evidence at that time, rather than be locked into a protocol that may quickly become outdated.” (4)

5. COMMENT: A commenter “appreciates the Department’s continuing efforts to improve patient safety and encourage collaboration within the field....” (5)

6. COMMENT: A commenter “recognizes the success of [the NJHA’s] Institute for Quality [and] Patient Safety and the Surviving Sepsis Campaign’s 2015 Sepsis Learning—Action Collaborative [and] fully supports the ... proposed new rule that will require hospitals to establish, implement, and periodically update evidence-based

sepsis protocols for the early identification and treatment of patients with sepsis and to train staff in the sepsis protocols.” (6)

7. COMMENT: A commenter supports “the best practices of hospitals having robust sepsis screening, treatment protocols, staff training[,] and quality improvement programs....” (7)

8. COMMENT: A commenter “commends the ... Department ... for issuing [a] proposed [new rule] establishing mandated sepsis protocols and training for New Jersey hospitals, [urges] adoption[,] and [recommends] additional [rulemaking] to strengthen [the] impact [of the proposed new rule] on reducing the mortality rate and patient harm from failure to identify and treat sepsis in a timely manner....

Sepsis prevalence in New Jersey is a cause of concern for all. Nearly 300,000 people in the United States die every year from sepsis. The potentially life-threatening nature of the infection does not discriminate — killing and maiming young and old, healthy and sick alike. The swiftness with which the infection spreads through the body and affects organs means that early detection and treatment is vital to survival and cure. As attention on sepsis has increased, international and national guidelines for sepsis management have been designed and tested. Clinical studies show that quick identification and administration of antibiotics and other treatment improves survival. International guidelines recommend the administration of broad-spectrum antibiotics within [one] hour of sepsis recognition and fluids within three hours. The three-hour Severe Sepsis and Septic Shock: Management Bundle (Composite Measure) has been adopted by the Centers for [Medicare and Medicaid Services] (CMS) as part of its inpatient Quality Reporting and will be part of the publicly reported measures included in

2018 Hospital Compare with 2017 data. The National Quality Forum has endorsed two sepsis bundle measures citing an improvement of 8.75 [percent] of saving a patient over not following it. And [state] governments in Illinois (Gabby’s Law) and New York (Rory regulations) have responded with mandatory regulations for establishing and following sepsis protocols.”

The commenter “commends the [NJHA] for recognizing that [State] hospitals could improve performance in swift sepsis identification and treatment. By creating a Sepsis Learning Collaborative, ‘to spread evidence-based sepsis interventions beyond intensive care units and emergency departments to medical surgical patient populations’ through ‘a systems-based approach to harness the combined power of physician and nursing leadership, executive support, clinical expertise, unit-based engagement and information technology to reduce sepsis.’ [The] NJHA began the work to identify best practices and train hospital staff on sepsis early recognition screening and standardized sepsis treatment protocols.”

The commenter states that “it is essential to establish [a] mandatory protocol [rule] because[,] although the voluntary actions of the [NJHA’s] Sepsis Learning Collaborative have shown some progress, the rates of sepsis mortality in New Jersey continue to hover between 25 and 30 [percent] since 2015 (the year the Collaborative was established). The Collaborative’s data shows a slow slope of improvement; yet, the mortality rate varies over each quarter with some quarters showing improvement and other quarters indicating backsliding. Clearly, more must be done.

For example, according to the Collaborative data, almost 70 [percent] of hospitals still do not include ‘sepsis or previous infection’ in their readmission risk screening,

despite studies showing that these patients are most likely to decline and are at high risk of complications or developing sepsis upon discharge. [The proposed new rule at N.J.A.C. 8:43G-14.9] will add the force of law to ensure better compliance with the internationally and nationally endorsed protocols.” (8)

9. COMMENT: A commenter “commends the ... Department ... for proposing a rule to require hospitals to establish evidence-based protocols to prevent sepsis.” The commenter “likewise applaud[s] the success of the New Jersey 2015 Sepsis Learning—Action Collaborative in reducing severe sepsis mortality by nearly 11 percent by September 2016 among the participating hospitals [Statewide], resulting in nearly 400 lives saved from septic shock.”

The commenter “agree[s] that better screening, identification[,] and treatment will save lives, improve outcomes[,] and reduce costs. The cost of sepsis in lives and quality of life is staggering. The national incidence rate of sepsis is growing by eight percent each year. Sepsis was the seventh leading cause of death in New Jersey in 2015, increasing by nearly 10 percent in just one year. Identifying and treating patients early will not only save lives, but will reduce the enduring physical and psychological effects of severe sepsis among survivors, including disabling pain, amputations, decreased cognitive functioning, hallucinations, and kidney and respiratory problems. [(Citation omitted.)] One study found that severe sepsis is associated with enduring cognitive and functional limitations among the elderly. [(Citation omitted.)]

The cost of sepsis to the economy and in healthcare dollars is also astonishing. The Healthcare Cost and Utilization Project of the Agency for Healthcare Research and Quality [of the United States] Department of Health and Human Services found that in

2013, sepsis was the most expensive condition treated in hospitals in the United States, accounting for over \$23.7 billion, 6.2 percent of the aggregated annual cost of all hospitalizations. [(Citation omitted.)] Not counted in these estimates are the costs to families in terms of lost income and nursing home care.

Implementing this rule makes sense. It would require hospitals to establish, implement, and update evidence-based protocols based on guidelines provided by the National Quality Forum, the Hospital Improvement Innovation Network of the Health Research and Educational Trust and the Surviving Sepsis Campaign.

The training requirements described (clinical staff must receive training in sepsis protocols within six months of the effective date of the rule, within six months of hire, and annually thereafter) are appropriate.”

The commenter is “encouraged that the Department ... considers sepsis a priority.” (9)

10. COMMENT: Commenters submitted, alone and in combination, the following statements:

“I want mandatory, life-saving sepsis protocols in New Jersey hospitals!”

“Treat sepsis earlier.”

“Please do whatever you can to make sepsis treatment in hospitals a higher priority. Thank you.”

“Please pass this proposal. Long overdue.”

“[New Jersey hospital] staff ... need to be educated about sepsis. Please help NJ save lives.”

“I agree that everyone should know about [sepsis].”

“Stop. Think. Sepsis.”

“Please pass this protocol and stop unnecessary deaths from sepsis.”

“Enact Rory’s Law” (a reference to a New York statewide mandate requiring all hospitals to adopt sepsis protocols, also known as “Rory’s Regulations,” promoted by the Rory Staunton Foundation).

“According to the New England Journal of Medicine, these protocols have saved thousands of lives in [New York. Every state] needs to implement! Congrats on taking the lead!!!”

“I am trying to get a mandatory sepsis protocol law passed in [another state]. Please pass this in NJ! Sepsis was the seventh leading cause of death — Very possibly much higher if death certificates cited sepsis accurately, they often say complications of pneumonia, UTI, etc. but if you die from an infection, you die from sepsis. Hospitals should implement — Please train them to get a proper physical exam and medical history.... The New Jersey hospital — Why do we have to initiate mandatory protocols in every [state]? I am currently fighting for the same in [another state]. It’s silly we have to fight in every [state] when it should have been done years ago and many families wouldn’t have watched their loved ones suffer and die. Please pass this law! ... Thank you and God bless!”

“I WANT SEPSIS AWARENESS for every single person who works in an ER and hospital. I want every ER doctor to KNOW they have to MOVE FAST when sepsis is a possibility and TIME IS ESSENTIAL! I want it on every admission form they complete — ‘COULD IT BE SEPIS? — yes or no.’ ... Post-Sepsis Syndrome is real, and continues long after the infection is resolved.... I would hope that awareness would

help others be treated quickly so that it might not have as devastating an effect on them.... I want more people to survive and I want greater awareness and faster treatment for patients. Please help save lives. Please make ‘Could it be Sepsis?’ the first thing an ER doctor thinks. And make the second thing they think ‘Get me antibiotics ASAP.’ Thank you.”

Some of these commenters supplemented their statements with compelling personal stories of the experiences of themselves and/or their family members in having had sepsis. Their comments describe situations that may have had better outcomes if sepsis indicia were recognized and treated earlier, as exemplification of the need for New Jersey to implement protocols for early recognition of, and response to, sepsis. The Department is not reiterating these stories as they could expose the individually identifiable health information of the commenters and others. (11)

RESPONSE TO COMMENTS 1 THROUGH 10: The Department acknowledges the commenters’ support of the proposed new rule.

The Department acknowledges the initiatives of certain commenters to develop, recommend, support, and/or voluntarily participate in, the Statewide assessment, design, and implementation of sepsis screening tools and model protocols.

The Department notes data that the Center for Health Statistics of the Department compiles in its *Complete Health Indicator Report of Deaths due to Septicemia (Sepsis)* (last updated July 10, 2017) (NJ Sepsis Report), available from the New Jersey State Health Assessment Data (NJSHAD) System at https://www26.state.nj.us/doh-shad/indicator/complete_profile/SepticemiaDeath.html.

The NJ Sepsis Report states that as of 2015, the “age-adjusted death rate due to

septicemia is lower than it was a decade ago but appears to be on the rise again. In New Jersey, nearly 2,000 deaths each year are due to septicemia ... The New Jersey age-adjusted death rate due to septicemia is 1.6 times that of the nation ... It is one of only two leading [causes] of death for which New Jersey's rate is higher than that of the [United States]. New Jersey has the fourth highest age-adjusted death rate due to septicemia among all 50 states and [the District of Columbia]. The three highest states are all in the southeast ... New Jersey is the northernmost [state] in a contiguous cluster of states with high sepsis mortality in the Southeastern and mid-Atlantic [United States]." (Internal citations omitted.) The NJ Sepsis Report states that the State sepsis mortality rate in 2012 was 16 percent, in 2013 was 17 percent, in 2014 was 16.5 percent, and in 2015 was 17.9 percent.

As the comments support the proposed new rule at N.J.A.C. 8:43G-14.9, the Department will make no change on adoption in response to the comments.

11. COMMENT: A commenter states that the establishment of proposed new N.J.A.C. 8:43G-14.9 "within ... Subchapter 14 Infection Control [of the Hospital Licensing Standards at N.J.A.C. 8:43G] is inconsistent with past successful efforts within New Jersey to address sepsis. The New Jersey 2015 Sepsis Learning—Action Collaborative facilitated by The Institute for Quality and Patient Safety (IQPS) of the New Jersey Hospital Association (NJHA) in partnership with the Surviving Sepsis Campaign demonstrated the effectiveness of leveraging hospitals' [quality] programs and processes to convene multidisciplinary working groups within their organizations to address the challenge of sepsis." The commenter "therefore [recommends] that the oversight of ... [the] proposed [new rule] be assigned to the Subchapter 27 Continuous

Quality Improvement [of the Hospital Licensing Standards,] allowing ... a multidisciplinary approach under the direction of [quality improvement] staff which would include expert guidance from [infection prevention] staff.” (2)

12. COMMENT: A commenter states that “the development, implementation, and monitoring of [hospital] programs [establishing best practices for robust sepsis screening, treatment protocols, staff training, and quality improvement] must be handled with a multidisciplinary approach [that includes,] at minimum[,] nursing, medicine, pharmacy, laboratory, staff development[,] and continuous quality monitoring under the direction of [quality improvement] staff, with consultation and expert guidance provided by [infection control staff] as required.” The commenter opposes the proposed establishment of new N.J.A.C. 8:43G-14.9 within Subchapter 14 Infection Control of the Hospital Licensing Standards, “as this places the responsibility of the” proposed new rule at N.J.A.C. 8:43G-14.9 under hospitals’ infection control programs. The commenter recommends that “oversight of [the proposed new rule] and its proposed requirements be assigned to ... Subchapter 27 Continuous Quality Improvement [of the Hospital Licensing Standards], allowing ... a multidisciplinary approach to implementation and monitoring.” (7)

RESPONSE TO COMMENTS 11 AND 12: The Department acknowledges the commenters’ concerns, but disagrees with the assertion that it should codify the proposed new rule within Subchapter 27, Continuous Quality Improvement, of the Hospital Licensing Standards at N.J.A.C. 8:43G. A hospital’s continuous quality improvement program undertakes oversight, monitoring, and data collection and analyses of hospital practices, which it shares with other hospital departments to drive

improvements. See N.J.A.C. 8:43G-27.5. Continuous quality improvement programs do not develop and institute clinical protocols; rather, they analyze the effectiveness and outcomes of those protocols to offer evidentiary support to inform other hospital departments' review and updating of their discipline-specific processes. *Ibid.* A hospital's infection control program has the clinical subject matter expertise to establish clinical protocols addressing sepsis prevention, identification, and response; therefore, Subchapter 14, Infection Control, is the proper subchapter within which to codify the proposed new rule.

For the foregoing reasons, the Department will make no change on adoption in response to the comments.

13. COMMENT: A commenter states "that there are several critical success factors to driving dramatic and sustainable reductions in sepsis mortality and morbidity [and encourages] the [Department] to work with New Jersey's health constituencies to properly address the following:

(1) The implementation of sepsis protocols at all hospitals and the regular reporting of outcomes so progress can be tracked across the [State], and poorer performing hospitals can be identified and supported[;]

(2) The training (and regular re-training) of all hospital staff on protocols and the identification and treatment of sepsis[;]

(3) The education of primary care providers in identification and treatment of sepsis (70 [percent] of sepsis patients have chronic ailments or recently were treated by a medical provider, making primary care a critical opportunity for patient education and early identification of sepsis)[;]

(4) The training of first responders to identify sepsis (nearly one half of sepsis cases travel in an ambulance, creating a life-saving opportunity for early diagnosis and expedited transition to the hospital emergency team)[;]

(5) The education of care transition providers (home health, skilled nursing, rehabilitation and others) to identify and treat or refer sepsis patients to urgent medical care[; and]

(6) The education of the ... public to identify sepsis as a medical emergency (as many as 92 [percent] of sepsis cases originate in the community making early patient identification a key to rapid treatment).” (3)

14. COMMENT: A commenter recommends that, in “addition to concerns with hospital treatment of sepsis, ... skilled nursing facilities [that] take patients with sepsis have a specific protocol for them.” (10)

15. COMMENT: A commenter recommends that the Department add to the proposed new rule a requirement that hospitals educate “consumers and patients about the warning signs of sepsis upon admission and discharge. According to the NJHA Sepsis Learning Collaborative, 60 [percent] of New Jersey hospitals do not provide patients with sepsis education prior to discharge. Because as many as 92 [percent] of sepsis cases start in the community, educating consumers to act quickly to seek medical care is essential. Even in an inpatient setting, a family member or caregiver can be a crucial partner with nursing staff in looking for early signs of sepsis.” (8)

16. COMMENT: A commenter recommends the deletion of proposed new N.J.A.C. 8:43G-14.9(c), at which “the Department lists categories of clinical staff who should receive training, for example clinical practitioners, registered professional

nurses, etc. [This] language should not be so prescriptive and believes that *all* healthcare professionals should be educated on the identification of patients at risk for or who have developed sepsis”

The commenter states that proposed new N.J.A.C. 8:43G-14.9(e) would require “hospitals to establish, maintain[,] and make available to the Department a record identifying staff who need to be trained and staff who have been trained. This is needlessly burdensome to hospitals, who may have a thousand or more staff, and we are unsure as to what the Department would do with all of these records. Hospital-wide staff education is already covered in [existing N.J.A.C.] 8:43G-5.7 and 5.9. [Existing N.J.A.C.] 8:43G-5.9(b)5 covers education on statutory requirements and ... (b)6 covers areas identified by quality assurance programs. Additionally, [existing N.J.A.C.] 8:43G-5.9(c) already requires ‘Implementation of the plan shall include records of attendance for each program and composite records of participation for each staff member.’” (4)

17. COMMENT: A commenter suggests “strengthening the rule in the following ways[:]

The Department ... should require hospitals to provide training records on an annual basis, rather than upon request by the Department. This should include the curricula content and the name and qualifications of the trainer. The Department should have the authority to cite and fine the hospital for failing to provide these records in a timely manner

The Department should review the content of the curricula to ensure that the hospitals are following best practices and the latest guidelines provided by the entities listed above.” (9)

RESPONSE TO COMMENTS 13 THROUGH 17: Proposed new N.J.A.C. 8:43G-14.9(c) would identify by position title the minimum staff to whom hospitals would have to provide sepsis protocol training. It would not prohibit hospitals from either offering the opportunity to, or requiring, other or all healthcare professionals at a facility to receive the training. The Department acknowledges that facilities need flexibility in establishing clinical protocols that may change rapidly as the science changes. A hospital's internal procedures for the development of clinical protocols and training curricula are matters that are properly within the hospital's control in its exercise of clinical and business judgment. The Department can review curricula as pertinent to Department investigations or surveys.

As with respect to other types of training records that N.J.A.C. 8:43G requires hospitals to maintain, the proposed new rule would require hospitals to make sepsis protocol training records available to the Department upon request, as may be pertinent to Department investigations or surveys. Existing rules at N.J.A.C. 8:43E-3.4 establish civil monetary penalties for licensed health care facilities' noncompliance with Department rules; thus, additional rulemaking to establish sanctions for noncompliance would be redundant.

The Department declines to mandate by rule that hospitals provide sepsis awareness training for all hospital patients upon discharge, but does not prohibit or discourage this activity as both a recommended practice and a beneficial service to the community. Existing N.J.A.C. 8:43G-11.5 requires hospitals to engage in discharge planning that is appropriate to each patient's needs, and to give patients, and/or their caregivers, written instructions for follow-up care. Depending on patient-specific factors

such as diagnoses and comorbidities upon admission and at discharge, hospitals, in the exercise of clinical and business judgment, might determine that alerting patients who are at risk of post-discharge sepsis, and their caregivers, to sepsis warning signs and indicators should be part of hospitals' discharge instructions.

The Department anticipates engaging in ongoing evaluation of the effectiveness of the proposed new rule over time in reducing sepsis morbidity and mortality rates in hospitals, with a view toward, among other matters, the appropriateness of expanding the applicability of the rule to other types of licensed health care facilities. The Department declines to expand the applicability of the rule to other types of licensed health care facilities until it has had the opportunity to conduct this evaluation.

The Department acknowledges the recommendation that it should work with other agencies, providers, and the public, to offer sepsis awareness programming.

For the foregoing reasons, the Department will make no change on adoption in response to the comments.

18. COMMENT: A commenter recommends that the Department revise proposed new N.J.A.C. 8:43G-14.9(f)2 and 3 because "they are not appropriate references for the management of patients with sepsis. Rather, the following references to peer-reviewed clinical practice guidelines, specifically those developed by the *Surviving Sepsis Campaign*, Society of Critical Care Medicine and the American College of Critical Care Medicine, should be added, as they are the most current guidelines at any given time:

Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock: 2016. *Crit Care Med* 2017; 45(3): 486-552.

<http://www.survivingsepsis.org/Guidelines/Pages/default.aspx>.

American College of Critical Care Medicine Clinical Practice Parameters for Hemodynamic Support of Pediatric and Neonatal Septic Shock. *Crit Care Med* 2017; 45(6):1061–1093.

http://journals.lww.com/ccmjournals/Fulltext/2017/06000/American_College_of_Critical_Care_Medicine.18.aspx. (4)

RESPONSE: Proposed new N.J.A.C. 8:43G-14.9(f) would not mandate adherence to specific published guidelines or protocols. Rather, it would refer hospitals to the entities identified therein as resources that develop, make available, and periodically update, evidence-based sepsis guidelines that hospitals might elect to consider in the development of their own protocols. Moreover, proposed new N.J.A.C. 8:43G-14.9(f) would not prohibit hospitals from considering evidence-based guidelines that other resource entities make available. Therefore, the Department will make no change on adoption in response to the comment.

19. COMMENT: A commenter “understands the Department’s desire to ensure that hospitals are addressing the ever-changing sepsis identification and treatment guidelines and appreciate[s] the Department’s recognition that mandating a particular protocol for adherence could hamper the industry.

Given that ‘medical understanding of the diagnosis, path, and treatment of sepsis is continually evolving,’ 49 N.J.R. [1653(a),] 1654, [the commenter seeks] to ensure that the Department’s proposal will provide hospitals with the latitude to adopt its clinical

processes based on best practices and emerging clinical research. Specifically, [the commenter requests] that the Department provide guidance allowing hospitals to quickly adopt changes to best practices in this space by updating order sets, process flows and algorithms, for example, instead of undertaking the onerous process of updating protocol or policy documents.

Flexibility to adapt within this emerging field is crucial, and, to be sure, requires hospitals and health systems to evaluate peer-reviewed research as it becomes available, and not rely on anecdotes from individual practitioners and group practices. Hospitals and health systems require certain levels of autonomy in selecting which protocol and processes to implement within their own facility or facilities. Additionally, ... the process [that] facilities must undertake to amend hospital protocols or policies is laborious and, at best, takes months to implement. In order to update these documents, a group or committee must draft updated documents, research and apply references to clinical best practices, refer to various internal departments — such as medical staff, surgical groups, and nursing — for review and finally comply with any medical executive committee requirements before the policy or protocol is adopted, circulated and implemented hospital-wide.

[Flexibility] is particularly important for certain population-specific variations, such as perinatal or pediatric populations, as these are emerging areas of research and until recently there has been little to no evidence-based research on indications and treatment. Even the three entities[, to which] the Department [refers] at N.J.A.C. 8:43G-14.9(f), have not, to date, issued guidelines in these areas. As accepted standards become available and evolve in this field [the commenter seeks] to be able to respond

to the evolution through a more nimble approach than the policy and protocol process currently allows. [The commenter] requests additional flexibility in responding to an ever-emerging field of medicine.” (5)

20. COMMENT: A commenter suggests that the Department “[strengthen] the rule” by requiring “[frontline] clinical workers with the appropriate education and experience [to] be included in hospital-based committees that meet to review, evaluate[,] and update the evidence-based protocols. These clinical staff should have input into the development, implementation, and evaluation of the training programs. Where represented by collective bargaining agents, the union shall name a representative to the committee to represent the frontline workers.” (9)

RESPONSE TO COMMENTS 19 AND 20: Proposed new N.J.A.C. 8:43G-14.9(a) would require hospitals to establish, implement, and periodically update, evidence-based protocols for the early identification and treatment of patients with sepsis and septic shock. A hospital’s internal procedures and decision-making processes for establishing and updating protocols and training curricula, such as the formation of committees, the identification of staff who might serve on such committees, and the inclusion or exclusion of collective bargaining representatives from participation on those committees, are appropriately matters within the hospital’s discretion and control in the exercise of clinical and business judgment, and/or might be determinable by reference to the terms of hospital or industry-specific collective bargaining agreements. The Department declines to specify by rule the processes by which hospitals would establish their sepsis protocols and training curricula.

It might be that a hospital determines to establish a protocol that requires adherence to, and/or “incorporates by reference,” whichever “order set, process flow, and/or algorithm” is then extant facility-wide, “as amended and supplemented,” in accordance with whatever process a hospital establishes to maintain the responsiveness of these order sets, process flows, and/or algorithms, to the medical and scientific communities’ evolving understanding of evidence-based best practices in the early identification and treatment of sepsis. This approach would be compliant with proposed new N.J.A.C. 8:43G-14.9(a), provided the order sets, process flows, and/or algorithms that a protocol incorporates by reference, as amended and supplemented, would address the minimum content requirements at proposed new N.J.A.C. 8:43G-14.9(b).

For the foregoing reasons, the Department will make no change on adoption in response to the comments.

21. COMMENT: A commenter “understands that the Department will receive comments urging the Department to require public reporting by hospitals to the Department of sepsis mortality rates.” The commenter “supports the reporting of quality metrics when performed in a meaningful way that provides useful information to patients and health care consumers. Related to sepsis reporting, CMS requires hospitals to submit data on sepsis bundle compliance, which will then be publicly reported by CMS on the Hospital Compare website. The sepsis data required by CMS is extensive ... and ... further evaluation of this publicly available data, including an evaluation of whether the Department can utilize this existing data to assist in any transparency and

education efforts, is required before any further reporting requirements are imposed on hospitals.” (5)

22. COMMENT: A commenter makes the following “suggestions to make [proposed new N.J.A.C. 8:43G-14.9] stronger and therefore more likely to improve sepsis survival[:.]”

The commenter suggests that the Department should revise proposed new N.J.A.C. 8:43G-14.9 “to indicate that the Department of Health will annually collect and report compliance to sepsis protocols using a common measurement to allow comparison between individual hospitals. As ... proposed, each hospital may set its own sepsis protocols. If all hospitals use their own versions with varying definitions and goals for timing treatment, it will be unclear whether hospitals are keeping up with the most recent science for evidence-based treatment. Additionally, if different definitions and exclusions are used by hospitals, it will be impossible to measure a uniform set of compliance and data will be meaningless in identifying high performers and outliers. The [Department] should collect and report compliance to sepsis protocols using a common measurement, such as the CMS Severe Sepsis and Septic Shock: Management Bundle protocols.”

The commenter suggests that the Department should revise proposed new N.J.A.C. 8:43G-14.9 to require “hospitals to report sepsis mortality rates on a regular basis to the Department,” and the rule should state and require that “the Department will publicly release sepsis mortality data, as defined by the Department ..., by brick and mortar [hospitals]. This public data will be updated at least annually, reflecting the previous 12 months’ rates, and will indicate the rate of change from the previous year.

Although the internal reporting of bundle protocol compliance (process measure) and sepsis mortality rates collected by [the] NJHA's Collaborative may be helpful for hospitals, it is not helpful for consumers who want to know the safety in their local hospital, or for plans and purchasers who have a financial interest in promoting the safest care and avoiding the expense of caring for highly compromised sepsis survivors. The [commenter] recommends outcome reporting for sepsis survival rates [because evidence indicates that] transparency of outcomes drives improvement in care. This concept is already in place in New York State where hospitals are required to submit data annually to permit [that state's Department of Health] to develop risk-adjusted sepsis mortality rates."

The commenter suggests that the Department should revise proposed new N.J.A.C. 8:43G-14.9 to "require hospitals to report sepsis mortality rates to their Patient and Family Advisory Councils. The model conducted by [a certain entity] could be implemented in New Jersey: [the entity] convened [its] eleven patient advisory councils to review their sepsis data and problem solve with the quality and infection control staff and to launch a community partnership effort based on transparency to raise awareness of sepsis." (8)

RESPONSE TO COMMENTS 21 AND 22: Hospitals routinely submit sepsis-related datasets to CMS. The Center for Health Statistics of the Department analyzes data from CMS and the National Center for Health Statistics of the Centers for Disease Control and Prevention of the United States Department of Health and Human Services, in combination with data from other sources, such as vital records (birth and death certificates), to issue State-level indicator reports on sepsis and other leading causes of

death. See NJ Sepsis Report, described above in response to another comment, and the other NJSHAD System indicator reports for leading causes of death in New Jersey at www.nj.gov/health/shad.

Following the adoption of the proposed new rule, hospitals would implement protocols and training curricula based upon evidence-based clinical guidelines, which are subject to continual updating as the science of identifying and treating sepsis evolves. As these protocols are likely to vary until a scientific and medical consensus emerges as to best practices for sepsis identification, prevention, and treatment, it would be premature for the Department to establish mandatory hospital reporting datasets that would be in addition to the existing datasets that hospitals report to CMS, and the existing data that the Department retrieves from vital records and other sources.

The Department plans to engage in ongoing evaluation of the effectiveness of the proposed new rule over time in reducing sepsis morbidity and mortality rates in hospitals, with a view toward, among other matters: (1) the appropriateness of requiring hospitals to report data to the Department relating to sepsis prevention and treatment quality measures, in addition to the data they report to CMS, depending on if and when the medical and scientific communities achieve consensus as to universally accepted sepsis prevention and treatment quality measures; and/or (2) including sepsis morbidity and mortality data as a quality indicator within the Department's annual Hospital Performance Report (also colloquially known as the "hospital report card"). See <http://nj.gov/health/healthcarequality/health-care-professionals/hospital-performance-report>.

For the foregoing reasons, the Department will make no change on adoption in response to the comments.

Federal Standards Statement

The Department does not adopt the new rule under the authority of, or to implement, comply with, or participate in any program established under Federal law or a State law that incorporates or refers to any Federal law, standard, or requirement. The Department is adopting the new rule under the authority of N.J.S.A. 26:2H-1 et seq., particularly 26:2H-5 and 12.45. Therefore, a Federal standards analysis is not required.

Full text of the adopted new rule follows (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisks *[thus]*):

SUBCHAPTER 14. INFECTION CONTROL

8:43G-14.9 Sepsis protocols

(a)-(c) (No change from proposal.)

(d) A hospital shall ensure that clinical staff receive training in the sepsis protocols:

1. By ***[(six months from the effective date of this new rule)]* *July 16, 2018,*** with respect to existing clinical staff;

2. With respect to a person who becomes a member of a hospital's clinical staff after ***[(the effective date of this new rule)]* *January 16, 2018***, within six months of the first day on which that person becomes a member of the hospital's clinical staff; and

3. (No change from proposal.)

(e)-(f) (No change from proposal.)