49 NJR 6(2)
June 19, 2017
Filed May 30, 2017

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

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

Authorized By: Cathleen D. Bennett, Commissioner, Department of Health (with the approval of the Health Care Administration Board).

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

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2017-106.

Submit written comments by August 18, 2017, electronically to: http://www.nj.gov/health/legal/ecomments.shtml, or by regular mail postmarked by August 18, 2017, to:

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The agency proposal follows:

Summary

N.J.S.A. 26:2H-1 et seq., the Health Care Facilities Planning Act (Act), declares "the public policy of the State [to be] that hospital and related health care services of the highest quality, of demonstrated need, efficiently provided and properly utilized at a reasonable cost are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the State, the State Department of Health [(Department)] shall have the central responsibility for the development and administration of the State's policy with respect to health planning, hospital and related health care services and health care facility cost containment programs, and all public and private institutions, … serving principally as … facilities for the prevention, diagnosis, or treatment of human disease, pain, injury, deformity or physical condition, shall be subject to" the Act.

N.J.S.A. 26:2H-5 directs the Commissioner of the Department, with the approval of the Health Care Administration Board to "adopt and amend rules … to effectuate the provisions and purposes of [the Act], including but not limited to: … standards and procedures relating to the licensing of health care facilities and the institution of certain additional health care services."

N.J.S.A. 26:2H-12.36 requires hospitals to implement an infection prevention program that incorporates best practices and effective strategies and infection prevention and control policies. N.J.S.A. 26:2H-12.41 requires general hospitals to submit quarterly reports of infection rates to the Department.

Pursuant to this authority, the Department proposes a new rule within the Infection Control subchapter of the Hospital Licensing Standards at N.J.A.C. 8:43G-14.9, which would require hospitals to establish, implement, and periodically update, evidence-based protocols (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.

Medical understanding of the diagnosis, path, and treatment of sepsis is continually evolving. The enhanced availability of evidence from various electronic data sources (such as electronic health records, insurance claims databases, and disease registries) have increased opportunities for study of the epidemiology of sepsis, resulting in emerging insights into the clinical criteria for sepsis diagnosis, the disease pathology, and best practices and protocols for treatment. Shankar-Hari, M., Phillips, G.S., et al., "Developing a New Definition and Assessing New Clinical Criteria for Septic Shock for the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3)," JAMA, 315(8): 775-787, at 776 (February 23, 2016), doi: 10.1001/jama.2016.0289, available at http://jamanetwork.com/journals/jama/fullarticle/2492876. For example, the international Sepsis Definitions Task Force, comprising members of the Society of Critical Care Medicine and the European Society of Intensive Care Medicine, issued international consensus definitions of sepsis in 1991, revised them in 2001, and, in February 2016, articulated a third revised definition. Singer, M., Deutschman, C. S., et al., "The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3)," JAMA 315(8): 801-810 (February 23, 2016), doi: 10.1001/jama.2016.0287, available

at http://jamanetwork.com/journals/jama/fullarticle/2492881 (hereinafter referred to as the “Sepsis-3 definition”).

Given the evolving state of the medical knowledge of sepsis, rather than mandating a particular protocol to which hospitals must adhere, the Department proposes to recommend that hospitals base their sepsis protocols on national and international best practices for identification and treatment.

Proposed new subsection (a) requires hospitals to establish, implement, and periodically update, evidence-based protocols for the early identification and treatment of patients with sepsis and septic shock.

Proposed new subsection (b) establishes the topics that a hospital’s sepsis protocols are to address, at a minimum.

Proposed new subsection (c) identifies the clinical staff a hospital would have to train in its sepsis protocols.

Proposed new subsection (d) establishes the dates by which a hospital is to train existing and new clinical staff in the sepsis protocols, following the effective date of the proposed new rules, and requires a hospital to retrain staff annually thereafter. This would ensure that hospitals apprise clinical staff of required periodic protocol updates and would refresh staff sensitivity to the need for early identification and treatment of sepsis.

Proposed new subsection (e) requires hospitals to establish, maintain, and make available upon Department request, records identifying the clinical staff to whom, and the dates on which, hospitals provide training in the sepsis protocols. This would facilitate Department compliance oversight.

Proposed new subsection (f) identifies entities that issue guidelines and suggest best practices for the development and implementation of sepsis protocols and reflects the Department's suggestion that hospitals consider basing their sepsis protocols on these entities' guidelines, as amended and supplemented. These entities are the Surviving Sepsis Campaign, the Hospital Improvement Innovation Network of the Health Research and Educational Trust, and the National Quality Forum.

Because the Department provides a 60-day comment period for this notice of proposal, this notice is excepted from the rulemaking calendar requirement at N.J.A.C. 1:30-3.3(a)5.

Social Impact

The Sepsis-3 definition suggests a lay definition of sepsis as "a life-threatening condition that arises when the body's response to an infection injures its own tissues and organs[,]" Sepsis-3 definition, *supra* at 805, 807, and a clinical definition of sepsis as "life-threatening organ dysfunction caused by a dysregulated host response to infection." *id.* at 804-805.

The Sepsis Alliance identifies the following as among the "human costs" of sepsis:

"[1.] Sepsis affects over 26 million people worldwide each year and is the largest killer of children – more than 5 million each year.

[2.] More than 1.6 million people in the [United States] are diagnosed with sepsis each year – one every 20 seconds and the incidence is rising [by eight percent] every year.

[3.] 258,000 people die from sepsis every year in the [United States] – one every 2 minutes; more than from prostate cancer, breast cancer and AIDS combined.

[4.] More than 42,000 children develop severe sepsis each year and 4,400 of these children die, more than from pediatric cancers.

[5.] Sepsis causes at least 75,000 maternal deaths every year worldwide and is driving increases in pregnancy-related deaths in the [United States].

[6.] Every day, 38 sepsis patients require amputations.

[7.] Sepsis survivors have a shortened life expectancy, are more likely to suffer from an impaired quality of life, and are 42 [percent] more likely to commit suicide." "Sepsis Fact Sheet," (citations omitted), (2016) Sepsis Alliance, San Diego, CA, available at http://www.sepsis.org/downloads/2016_sepsis_facts_media.pdf.

A 2014 study identified a global mortality rate of over 35 percent among people hospitalized with sepsis. Vincent, J. L., Marshall, J. C., et al., "Assessment of the Worldwide Burden of Critical Illness: The Intensive Care Over Nations (ICON) Audit," Lancet Respir Med, 2(5):380–386 (2014), doi: 10.1016/S2213-2600(14)70061-X, (Epub 2014 April 14), available at https://www.ncbi.nlm.nih.gov/pubmed/24740011. Depending on geography and severity, mortality rates in developed nations can reach up to 30 percent for sepsis, 50 percent for severe sepsis, and 80 percent for septic shock. Jawad I., Lukšić, I., and Rafnsson, S. B., "Assessing Available Information on the Burden of Sepsis: Global Estimates of Incidence, Prevalence and Mortality," J Glob Health, (June 2012) 2(1): 010404, doi: 10.7189/jogh.02.010404, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3484761.

In 2015, with 1,957 deaths, sepsis was the seventh leading cause of death among New Jersey residents, representing an increase from 2014, when it was the eighth leading cause of death in New Jersey, with 1,764 deaths. Centers for Disease Control and Prevention, National Center for Health Statistics, "Multiple Cause of Death 1999-2015," CDC WONDER Online Database, released December, 2016, accessed at http://wonder.cdc.gov/mcd-icd10.html on May 15, 2017. The Center for Health Statistics (CHS) of the Department reports that the New Jersey age-adjusted death rate due to sepsis is 1.5 times that of the nation, making sepsis the only leading cause of death for which New Jersey's rate is higher than that of the United States. CHS, "Health Indicator Report of Deaths Due to Septicemia (Sepsis)," New Jersey Department of Health, Trenton, NJ (February 21, 2017), available at https://www26.state.nj.us/doh-shad/indicator/view/SepticemiaDeath.Trend.html.

Sepsis is treatable if addressed as a medical emergency. Early identification and prompt treatment of sepsis is critical to survival. Recent studies and quality improvement initiatives demonstrate that the single most important factor in reducing mortality and morbidity from sepsis is early detection with timely administration of treatment. "The World Sepsis Day Fact Sheet," Global Sepsis Alliance, Jena, Germany (2017), available at http://world-sepsis-day.org; Martin-Loeches, I., Levy, M. M., Artigas, A., "Management of Severe Sepsis: Advances, Challenges, and Current Status," Drug Design, Development and Therapy (April 9, 2015) 2015(9): 2079-2088, at 2081, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4403600/pdf/dddt-9-2079.pdf and at https://doi.org/10.2147/DDDT.S78757. A 2006 study found that sepsis survival rates decrease by 7.6 percent for each hour of delay in commencement of

treatment. Kumar, A., Roberts, D., et al., "Duration of Hypotension Before Initiation of Effective Antimicrobial Therapy is the Critical Determinant of Survival in Human Septic Shock," Critical Care Med. (June 2006) 34(6): 1589-1596. A more recent retrospective cohort study of 35,000 patients who were hospitalized through the emergency department "found that each hour of delay in antibiotic administration in patients with sepsis who present to the [emergency department] was associated with a [nine percent] increase in the odds of hospital mortality." Fielding-Singh, V., Greene, J. D., et al., "The Timing of Early Antibiotics and Hospital Mortality in Sepsis," Am J Respir Crit Care Med, 193: A2741 New York, NY (May 2016) (American Thoracic Society 2016 International Conference Abstract), available at http://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2016.193.1_MeetingAbstracts.A2741; see also Liu, V. X., Fielding-Singh, V., et al., "The Timing of Early Antibiotics and Hospital Mortality in Sepsis," Am J Respir Crit Care Med, (March 27, 2017) (Epub ahead of print as doi: 10.1164/rccm.201609-1848OC), available at http://www.atsjournals.org/doi/abs/10.1164/rccm.201609-1848OC.

Thus, patients who are diagnosed and treated in the first hour following presentation with sepsis (referred to as the "Golden Hour") have a survival rate of greater than 80 percent, whereas after the sixth hour, patients have only a 30 percent survival rate. "Saving Lives: Treating Sepsis in the Golden Hour," Global Sepsis Alliance, Jena, Germany (2017), available at www.world-sepsis-day.org (citing Kumar, *supra*).

Even when people survive sepsis, following their recovery, some patients have long-term physical and psychological effects, which can include insomnia, nightmares,

vivid hallucinations, panic attacks, disabling muscle and joint pains, decreased cognitive functioning, loss of self-esteem and self-belief, post-traumatic stress disorder, organ dysfunctions, such as kidney failure and respiratory problems, and amputations. "Life After Sepsis" (Fact Sheet), Centers for Disease Control and Prevention, HHS, Atlanta, GA, available at https://www.cdc.gov/sepsis/pdfs/life-after-sepsis-fact-sheet.pdf; Angus, D. C., "The Lingering Consequences of Sepsis: A Hidden Public Health Disaster?" JAMA 304(16): 1833-34 (October 27, 2010), doi: 10.1001/jama.2010.1546, available at http://jamanetwork.com/journals/jama/article-abstract/186775; "Post-Sepsis Syndrome — PSS," Sepsis Alliance (accessed April 19, 2017), available at http://www.sepsis.org/life-after-sepsis/post-sepsis-syndrome.

One study of a "large nationally representative cohort" of community-dwelling United States residents older than 50 years who were hospitalized for sepsis (mean age at hospitalization 76.9 years)

> demonstrated for the first time that severe sepsis is independently associated with enduring cognitive and functional limitations[,] a tripling in the odds of moderate to severe cognitive impairment[, and] the acquisition of 1.5 new functional limitations [(in "activities of daily living")] in patients with no, mild, or moderate preexisting functional limitations. These new disabilities were substantially larger than those seen after nonsepsis general hospital admissions. Cognitive and functional declines of the magnitude seen after severe sepsis are associated with significant increases in caregiver

time, nursing home admission, depression, and mortality [citations omitted]. These data argue that the burden of sepsis survivorship is a substantial, underrecognized public health problem with major implications for patients, families, and the health care system [and] allow us to make an estimate of the overall public health burden of sepsis on 'brain health' among older adults in the United States. [The] results suggest that nearly 20,000 new cases per year of moderate to severe cognitive impairment in the elderly may be attributable to sepsis. Thus, an episode of severe sepsis, even when survived, may represent a sentinel event in the lives of patients and their families, resulting in new and often persistent disability, in some cases even resembling dementia [citations omitted]. The level of severe cognitive impairment found in these patients has been associated with an additional 40 hours per week of informal care provided by families [citation omitted], analogous to an additional full-time job…. In marked contrast to Alzheimer disease and some other forms of dementia, onset and acceleration of cognitive impairment due to sepsis is likely partially preventable in many patients. These benefits might be achieved by raising the standard of care for patients who develop sepsis … and by avoiding sepsis altogether [citation omitted].

[Iwashyna, T. J., Ely, E. W., et al., "Long-Term Cognitive Impairment and Functional Disability Among Survivors of Severe Sepsis," JAMA 304(16): 1787-94, at 1788 and 1791-1792 (October 27, 2010), doi: 10.1001/jama.2010.1553, available at http://jamanetwork.com/journals/jama/fullarticle/186769.]

In late 2014, the Institute for Quality and Patient Safety (IQPS) of the New Jersey Hospital Association (NJHA) and the Surviving Sepsis Campaign established the New Jersey 2015 Sepsis Learning—Action Collaborative (Collaborative) with the mission "to spread evidence-based sepsis interventions beyond [hospital intensive care units and emergency departments] to medical-surgical patient populations," and with the goal that by "the end of 2015, all New Jersey hospitals will: 1. Implement sepsis early recognition screening and standardized sepsis treatment protocols[and] 2. Reduce severe sepsis mortality rates in New Jersey by 20 percent." "New Jersey 2015 Sepsis Learning--Action Collaborative Charter," IQPS, NJHA, Princeton, NJ (2014), available at http://www.njha.com/media/316665/Charter-NJHA-Quality-Institute-New-Jersey-2015-Sepsis-Learning-12-2014.pdf. The Collaborative includes hospitals Statewide and involved implementation of best practices and protocols and voluntary data reporting and analysis, based on the Surviving Sepsis Campaign guidelines.

The Collaborative reported in September 2016, that its efforts resulted in participating hospitals realizing, in 2015, "a 10.76 percent decrease in severe sepsis mortality Statewide from the baseline measurements [of 28.71 percent patient mortality

rate in 2014], which translates into nearly 400 lives saved." "New Jersey Sepsis Learning Action Collaborative: First Year Results," Health Research and Educational Trust of New Jersey and IQPS, NJHA, Princeton, NJ (September 13, 2016), available at http://www.njha.com/media/707850/Sepsis-Learning-Action-Results-Sept-16.pdf.

Upon reviewing the Collaborative's first year results, Commissioner of Health Cathleen Bennett noted, "This collaboration among health care providers demonstrates a continued commitment to quality improvement ... A nearly 11 percent reduction in mortality shows substantial progress in just one year." Lilo H. Stainton, "NJ Hospitals Join Forces to Reduce Deaths Caused by Sepsis," NJ Spotlight, Montclair, NJ (September 13, 2016), available at http://www.njspotlight.com/stories/16/09/12/nj-hospitals-join-forces-to-reduce-deaths-caused-by-sepsis.

Based on this past evidence of positive gains in reducing sepsis rates in New Jersey hospitals, the Department anticipates that the proposed new rule requiring hospitals to establish evidence-based protocols for the early identification and treatment of sepsis, and for staff training in the protocols, would result in continued reduction of sepsis morbidity and mortality rates in New Jersey. This, in turn, would reduce the corresponding burden on public health resources and other public and private community social resources that are needed to support the families of deceased patients and the short and long-term care needs of surviving patients and their families.

Economic Impact

In May 2016, 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:

1. The most expensive condition treated in hospitals in the United States, accounting for over $23.7 billion, or 6.2 percent, of the aggregate annual costs for all hospitalizations;

2. The second most common reason for hospitalization nationally, accounting for 3.6 percent of all hospital stays, or approximately 1.3 million stays;

3. The most expensive condition billed to Medicare, accounting for over $14.5 billion, or 8.2 percent, of national Medicare expenditures (representing 838,000 hospital stays);

4. The second most expensive condition billed to Medicaid, accounting for over $3.3 billion, or 5.3 percent, of national Medicaid expenditures (representing 143,000 hospital stays);

5. The fourth most expensive condition billed to private insurance, accounting for over $4 billion, or 3.7 percent, of national private health insurance expenditures (representing 218,000 hospital stays); and

6. The most expensive condition occurring among uninsured individuals, accounting for over $1 billion, or 5.7 percent, of costs incurred nationally by uninsured individuals (representing 62,000 hospital stays). Torio, C. M., Moore, B. J., "National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2013. Healthcare Cost and Utilization Project Statistical Brief #204 (May 2016)," AHRQ, HHS, Rockville, MD, available at https://www.hcup-us.ahrq.gov/reports/statbriefs/sb204-Most-Expensive-Hospital-Conditions.jsp.

A 2017 study of 2013 data from the Centers for Medicare and Medicaid Services (CMS) National Readmissions Database found: sepsis was "a leading cause of

unplanned 30-day hospital readmissions and associated costs"; that "the mean length of stay for unplanned readmissions following sepsis hospitalizations was longer than readmissions for" other diagnoses; and that the "estimated mean cost per readmission was highest for sepsis compared with" other diagnoses (over $10,000). Mayr, F. B., Talisa, V. B., et al., "Proportion and Cost of Unplanned 30-Day Readmissions After Sepsis Compared With Other Medical Conditions," JAMA 317(5): 530-31 (February 7, 2017), doi: 10.1001/jama.2016.20468, available at http://jamanetwork.com/journals/jama/article-abstract/2598785.

The above studies describe costs associated with hospitalizations for sepsis. They do not describe the costs that patients' families incur following patient deaths from sepsis, which include at least funeral expenses and loss of deceased patients' income. As described in the Social Impact above, patients who survive sepsis suffer resulting long-term physical and psychological effects, such as amputations, organ failures, respiratory problems, chronic pain, cognitive impairments, symptoms akin to post-traumatic stress disorder, and loss of abilities to perform activities of daily living. These impairments cause survivor absenteeism from employment, with attendant income losses to themselves and their families, and burden government unemployment, disability, and welfare compensation systems.

The population of New Jersey is aging. The median age increased from 39 in 2010 to 39.6 in 2015, and the number of people over 65 increased by over 150,000 in that same period. "Annual Estimates of the Resident Population for Selected Age Groups by Sex for the United States, States, Counties and Puerto Rico Commonwealth and Municipios: April 1, 2010 to July 1, 2015," United States Census Bureau, Population

Division (June 2016). The cognitive impairments and functional disabilities that are independently associated with surviving sepsis, particularly among older populations, as demonstrated by Iwashyna, *supra*, likely impose significant financial demands on the State's economic resources to provide medical care, including physical, psychological, and cognitive rehabilitation, and long-term care services, to sepsis survivors. They impose financial demands on sepsis survivors' families, such as loss of income if a family member discontinues paid employment to care for a disabled survivor. To the extent sepsis can be avoided or its impact minimized, sepsis unnecessarily compounds the economic burden on the available resources to care for the State's growing aging population, and correspondingly reduces the resources available to serve persons of all ages who are disabled for reasons other than sepsis.

The proposed new rule requiring hospitals to establish protocols for early recognition and treatment of sepsis, and to train staff in those protocols, could reduce the economic burden of sepsis, described above, by preventing or reducing deaths and minimizing short and long-term survivor debilitation. Health care facilities would incur costs associated with establishing protocols, identifying persons to receive training, and recording and retaining records of training. The Department anticipates that most hospitals will use existing administrative staff and facility resources to accomplish these tasks, and those hospitals that participated in the Collaborative likely already have performed some of these tasks and incurred these costs. If protocol establishment and training continue to help hospitals reduce sepsis rates, hospitals may realize cost savings associated with eliminating prolonged patient hospitalizations and risk management liability losses. They may also realize greater Federal reimbursements

and incentive payments if they reduce unplanned readmissions to treat undetected sepsis cases and demonstrate adherence to CMS-designated quality measures relating to sepsis.

Federal Standards Statement

The Department does not propose 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 proposing 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.

Jobs Impact

The Department does not expect that the proposed new rule would result in the creation or loss of jobs in the State.

Agriculture Industry Impact

The proposed new rule would not have an impact on the agriculture industry of the State.

Regulatory Flexibility Statement

The proposed new rule would impose requirements that are applicable only to hospitals that the Department licenses, which are not small businesses within the meaning of the New Jersey Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. Therefore, a regulatory flexibility analysis is not required.

Housing Affordability Impact Analysis

The proposed new rule would have an insignificant impact on the affordability of housing in New Jersey and there is an extreme unlikelihood that it would evoke a change in the average costs associated with housing because the proposed new rule would impose requirements concerning the establishment of sepsis protocols and related staff training that are applicable only to hospitals that the Department licenses and would have no impact on housing costs.

Smart Growth Development Impact Analysis

The proposed new rule would have an insignificant impact on smart growth development and there is an extreme unlikelihood that it would evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan in New Jersey. The proposed new rule would impose requirements concerning the establishment of sepsis protocols and related staff training that are applicable only to hospitals that the Department licenses and would have no impact on development or housing.

Full text of the proposed new rule follows (additions indicated in boldface **thus**; deletion indicated in brackets [thus]):

SUBCHAPTER 14. INFECTION CONTROL

8:43G-14.9 [(Reserved)] **Sepsis protocols**

(a) A hospital shall establish, implement, and periodically update, evidence-based protocols for the early identification and treatment of patients with sepsis and septic shock (sepsis protocols).

(b) The sepsis protocols shall address, at a minimum:

1. Screening patients for, and early recognition in patients of, healthcare-acquired and community-acquired sepsis and septic shock;

2. Identification of patients for whom treatment, using the sepsis protocols, is appropriate, and for whom treatment would be inappropriate based on patient-specific clinical and/or bioethical considerations, and documentation of these patient identification activities;

3. Treatment guidelines;

4. Components that are population-specific as clinically indicated in accordance with evidence-based best practices, such as perinatal, neonatal, pediatric, and adult variations that may exist in the identification and treatment of sepsis, with corresponding development and use of clinical staff training materials and practice tools that distinctly identify these population-specific variations; and

5. Training of clinical staff in the sepsis protocols and providing updated training upon substantive revision thereof.

(c) Clinical staff who are to receive training include:

1. Clinical practitioners;

2. Registered professional nurses;

3. Licensed practical nurses; and

4. Other licensed health care professionals.

(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) 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), within six months of the first day on which that person becomes a member of the hospital's clinical staff; and

3. With respect to all clinical staff, annually thereafter following initial training.

(e) A hospital shall establish, maintain, and make available upon request to the Department, a record that identifies:

1. The name and position of each member of the hospital's clinical staff who is to receive training pursuant to (d) above; and

2. The date on which each clinical staff member receives training pursuant to (d) above.

(f) The Department suggests that hospitals consider basing their sepsis protocols on guidelines issued by the following entities, as amended and supplemented:

1. The Surviving Sepsis Campaign, available at http://www.survivingsepsis.org;

2. The Hospital Improvement Innovation Network of the Health Research and Educational Trust, available at http://www.hret-hiin.org; and

3. The National Quality Forum, available at http://www.qualityforum.org.