October 11, 2010

Department of Health and Human Services
Office of Healthcare Quality
200 Independence Ave, S.W., Room 719B
Washington, D.C. 20201

Attention: Draft Tier 2 Modules

Dear Sir or Madam:

The Society for Healthcare Epidemiology of America (SHEA), the Infectious Diseases Society of America (IDSA) and the Pediatric Infectious Diseases Society (PIDS) are pleased to have the opportunity to review and provide comments on the draft HHS Action Plan to Prevent Healthcare-Associated Infections Tier 2 modules including Ambulatory Surgical Centers (ASCs), End-stage Renal Disease (ESRD) Facilities, and Influenza Vaccination of Healthcare Personnel.

As described in Tier 2 of the Action Plan, prevention of HAIs in the ASC and ESRD settings is an important topic that deserves additional attention. SHEA, IDSA and PIDS are supportive of the general goals and recommendations of the Action Plan and look forward to working with HHS and other stakeholders in implementing the recommendations, as well as participating in the conduct of research that HHS has appropriately identified as necessary in order to validate, improve, and refocus infection prevention strategies in these settings. Our specific comments related to the ASC and ESRD modules follow in the attached document.

We also commend HHS for including the topic of influenza vaccination of healthcare personnel (HCP) as part of the Tier 2 Action Plan. SHEA, IDSA and PIDS believe that influenza vaccination of HCP is the professional and ethical responsibility of all facilities where health care is delivered to prevent the spread of influenza to patients and other HCP.

We would encourage HHS to carefully consider the following key points related to the influenza vaccination of healthcare personnel module:
1. SHEA, IDSA and PIDS strongly support the goal of increased vaccination coverage and support the multi-faceted efforts outlined by HHS required to achieve an expectation that all HCP will be vaccinated routinely on an annual basis – based, naturally, on the availability of the current season’s vaccine. We are further pleased HHS recognizes that flu vaccination of HCP must occur beyond the acute care setting where most attention has been focused in the past if we are going to dramatically improve HCP vaccination rates. However, we believe that more detail is needed in the Action Plan related to outreach to other healthcare delivery (non-acute) settings where HCP provide care if the overall total HCP rate is to improve. SHEA, IDSA and PIDS recommend that you consider a separate goal for acute care settings that takes into consideration the higher baseline of immunization and incorporates more rapid achievement of the goal.

2. As acknowledged in the Action Plan, much work remains to be done on standardizing definitions of HCP as well as healthcare settings, and the plan notes that the science behind effective measurement of influenza vaccination rates is just beginning to be tested by the National Quality Forum. SHEA, IDSA and PIDS recommend that examination of all states’ activities, including model language for federal and state statutes, should only be initiated after the baseline activities are accomplished successfully and fully evaluated. Given the wide scope of settings where healthcare is provided, for accurate measurement, it will be important to clearly define the settings to be able to capture denominator and other relevant data. Until these issues are addressed and agreed upon by all stakeholders through a transparent process, SHEA, IDSA, and PIDS believe HHS should not focus initially on developing federal and state statutory language regarding influenza vaccination rates.

3. The Action Plan summarizes the current literature on immunization efforts, successes, and challenges to date. However, because the foundation for much of the knowledge gained is from acute care settings, SHEA, IDSA and PIDS believe that the Action Plan must give additional attention to the unique barriers that may be present in other care settings (e.g. beliefs and behaviors related to immunization, cost, access, education of staff, and employer support).

4. There must be an emphasis placed on early vaccine delivery to all acute and non-acute care sites if HCP are to be protected before they pose a risk of transmission to patients, residents, and clients. Rapid distribution of vaccine to healthcare delivery sites has posed a major challenge in the past. HHS focuses on the importance of early vaccination of HCP to protect those under their care. To meet the department’s goal to achieve maximum vaccination, SHEA, IDSA and PIDS recommend that the Action Plan include an explicit statement of the importance of communication between the HHS Influenza Working Group charged with executing this plan and the federal agencies charged with the distribution of vaccine to healthcare delivery sites.
Attached please find additional comments related to each of the Tier 2 modules for your consideration. SHEA, IDSA and PIDS appreciate the opportunity to provide expert input into the continued development of the Action Plan.

Sincerely,

Neil Fishman

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Comments from the Society for Healthcare Epidemiology of America (SHEA), the Infectious Diseases Society of America (IDSA) and the Pediatric Infectious Diseases Society (PIDS) on the draft HHS Action Plan to Prevent Healthcare-Associated Infections Tier 2 Modules

SHEA, IDSA and PIDS are pleased to have the opportunity to review and provide the following comments on the draft HHS Action Plan to Prevent Healthcare-Associated Infections Tier 2 modules including Ambulatory Surgical Centers (ASCs), End-stage Renal Disease (ESRD) Facilities and Influenza Vaccination of Healthcare Personnel.

**Ambulatory Surgical Centers (ASC) Module**

Overall, this document provides an excellent summary of existing information and knowledge gaps regarding prevention of infectious complications associated with procedures performed in ASCs. It clearly states the challenges these facilities face with implementing prevention measures and surveillance activities appropriate for the patient populations served.

General comment: This document explains clearly the often confusing oversight of ASC.

General comment: Although this document is focused on operative procedures performed in free-standing ASCs, consideration should be made to extending this focus to include ambulatory surgical procedures performed in other settings, specifically including non-inpatient surgery performed in acute care hospitals (i.e., day surgery procedures). Many of the same issues that are raised for ASCs (e.g., limitations of current surveillance methods and definitions) apply equally to these settings. In addition, other infectious complications have occurred in these settings and it would be useful for the document to address them.

**III. Progress Made**

- **Improved Inspection Frequency and Methodology**
  1) First paragraph: While it is stated that there has been an increased emphasis on the process measures necessary to measure compliance and to examine findings and patterns across surveys, has this been actually measured/reported or is it a perceived increased emphasis?

**IV. Remaining needs and prevention opportunities**

- Need to Sustain and Expand Improvements in Oversight and Monitoring
  1) It should be made clear in the document who should provide this expanded oversight and monitoring. Specifically, will it fall to the SSAs and AOs or should it require collaborative efforts between agencies?

- Need to develop meaningful HAI surveillance and reporting procedures
  1) Paragraph 3: “CDC’s National Healthcare Safety Network (NHSN), which is currently used in all 50 states…” is somewhat misleading since it implies that all
acute care hospitals in those states currently submit SSI data into NHSN and that the state health departments have access to this information. While many acute care facilities in all 50 states report HAI data to NHSN, few report selected SSI data. We would urge you to consider clarifying this statement.

2) Paragraph 4: Could a reference or references be added to support the final sentence of this paragraph?

V. Next steps: “Collaborations for shared solutions”

1. Improve and consider expanding process measures
   1. We would urge you to consider rewording the 1st paragraph to clarify that few SCIP measures currently used for inpatient procedures are relevant to procedures performed in ASC. For example, while appropriate hair removal, patient burn or patient fall are important, there is no evidence to support the benefit of antimicrobial prophylaxis for the majority of minor, clean procedures.
   2. Last sentence of the 2nd paragraph: Would recommend expanding “endoscope reprocessing” to “high-level disinfection and sterilization” as an area that would greatly benefit from measures that assess the processes.

4. Disseminate evidence-based guidelines and training for infection prevention and control in ambulatory settings
   1. We would urge you to consider rewording the 1st sentence to “The ASC ICWs and CfCs are in many respects founded on the basic infection prevention and control principles described in the Healthcare Infection Control Practices Advisory Committee (HICPAC)’s hand hygiene, isolation precautions, and disinfection and sterilization guidelines.”
   2. Is a timeline available for the CDC HICPAC document referred to in this section (first paragraph)?

Table 1. Summary of literature review of surgical site infection surveillance practices conducted in non-acute care settings
   1. Overall, the table is somewhat confusing. When sensitivity and specificity are mentioned, what is the comparator? Additionally, could specific references be added to table elements to clearly define support for the statements?
   2. Row starting with “Claims data algorithm incorporating….”: Under the “Potential Disadvantages” column, would delete “application in a limited, managed care type setting where patients follow up in the same system that they received operative treatment”. Use of claims data for surveillance would NOT be limited to single healthcare systems since claims are generated for care received, regardless of the location of that care. For example, a hospitalization resulting from infectious complications following an ambulatory surgical procedure would result in claims submitted to that patient’s healthcare payer (e.g., CMS, managed care organization or other insurer), regardless of that hospital’s affiliation. Other repositories of claims data (e.g., state HCUP data) could also be utilized for claims-based SSI screening.
   3. Row starting with “Claims data algorithm incorporating….”: Under the “Potential Disadvantages” column, would change “poor sensitivity” to “variable sensitivity of diagnosis codes alone, depending on the procedure type”. Combining diagnosis
codes and pharmacy information had high sensitivity (higher than routine surveillance) for detecting SSIs following many inpatient procedures\textsuperscript{iv} and diagnosis codes alone demonstrated high sensitivity following total hip and total knee procedures.

**End-Stage Renal Disease Facilities Module**

**IV.C.1. Prevention of Intravascular Infections**

**Priority Module 1 – Selection of Vascular Access**
Consider adding this as a second bullet: “Long-term catheters or dialysis port catheter systems should be used in conjunction with a plan for permanent access, such as arteriovenous fistula.” If and when a CVC is placed, a plan for long term access should be developed; ideally this would include placement of a fistula, allowing it time to mature, and then removing the CVC. While the current bullet emphasizes that fistulae or grafts are preferrable to CVCs, the proposed second bullet would underscore the need to convert patients, when possible (NKF KDOQI 2.1.3.2). It also complements the third recommendation in priority module 3: to remove catheters that are non-essential; if a patient has a fistula placed and it matures, the catheter should be removed.

**Priority Module 3 – Recommendations for Appropriate Maintenance of Vascular Catheters**

**Bullet #4:** Use polymyxin B/ bacitracin/ gramicidin (e.g., Polysporin® Triple) or povidone-iodine antiseptic ointment at the hemodialysis catheter exit site after catheter insertion and at the end of each dialysis session. Select an ointment that does not interact with the material of the hemodialysis catheter. HICPAC Category IA; NKF KDOQI

The HICPAC evidence ranking for this intervention is Category IB, not Category IA. [“Use povidone iodine antiseptic ointment or bacitracin/neomycin/polymyxin B ointment at the hemodialysis catheter exit site after catheter insertion and at the end of each dialysis session only if this ointment does not interact with the material of the hemodialysis catheter per manufacturer’s recommendation (108, 144, 206-209). Category IB”] The Category IA designation is assigned to the recommendation against use of antibiotic ointments for non-dialysis catheters. [“Do not use topical antibiotic ointment or creams on insertion sites (except when using dialysis catheters) because of their potential to promote fungal infections and antimicrobial resistance (107,213). Category IA”] Although not specifically studied yet, the now common use of chlorhexidine-based antiseptics and dressings may provide benefit equivalent to or in excess of that provided by antibiotic and antimicrobial ointments.
IV.C.2. Prevention of Bloodborne Pathogen Transmission

Priority Module 1: Recommendations to Prevent Hepatitis B Virus and Hepatitis C Virus Infections

Bullet #3: “For patients who respond to the hepatitis B vaccine series, check surface antibody titers annually and administer a booster dose when indicated. CDC; CMS, ACIP”

It would be helpful to include the current indication for administration of a booster dose (i.e., when serum hepatitis B surface antibody (anti-HBs) levels have declined to less than 10 mIU/mL). This level of specificity would be appropriate given that similar details are provided for other recommendations, such as pneumococcal vaccination.

IV.C.3. Prevention of Influenza and Pneumococcal Disease

Priority Module 1 – Recommendations to Prevent Influenza and Pneumococcal Disease

Bullet #3: Offer 1-dose of pneumococcal polysaccharide vaccine to adult dialysis patients and a one-time booster dose after 5 years have elapsed. ACIP

This recommendation is not entirely consistent with current ACIP recommendations. The recently revised ACIP recommendations for use of the pneumococcal vaccine provide the following statements: “All persons should be vaccinated with PPSV23 at age 65 years. Those who received PPSV23 before age 65 years for any indication should receive another dose of the vaccine at age 65 years or later if at least 5 years have passed since their previous dose. Those who receive PPSV23 at or after age 65 years should receive only a single dose.” “A second dose of PPSV23 is recommended 5 years after the first dose for persons aged 19--64 years with functional or anatomic asplenia and for persons with immunocompromising conditions” which include chronic renal failure. (MMWR 2010;59(34):1102-6). We suggest the following revision to the language of this recommendation:

Offer 1-dose of pneumococcal polysaccharide vaccine to adult dialysis patients and a one-time booster dose, for those vaccinated prior to age 65, after 5 years have elapsed. ACIP

V. Metrics and Evaluation

A general comment about this section is that the frequency with which these metrics are to be calculated has not been specified. Are these intended to be measured monthly, annually, or at some other interval? Also, it may be that the frequency of measurement should vary by metric. For instance, annual assessment of the metrics for CVC use and long-term CVC may be adequate and most useful whereas infection rates may be better assessed on a more frequent (e.g., monthly) basis in order to allow for more timely
recognition of clusters/outbreaks and/or the need for intervention. Further consideration of this is needed.

V. Priority Module 1: Bloodstream and Vascular Infection Rates and Care Processes
B. Outcome Measures

Access-related BSI = Positive blood culture with vascular access or unknown suspected source per 100 patient-months

The NHSN event to which this measure refers is “access-associated bacteremia,” not “access-related bacteremia.” Although this may seem perhaps an inconsequential difference in style, it is important to distinguish between a bloodstream infection that is associated with a vascular access device and one that is truly related to a vascular access device (which is not routinely done in many areas of clinical practice). Thus, the terminology should be consistent with NHSN, which is technically more accurate than the one used in the draft action plan. We suggest changing the name of this outcome metric to “access-associated BSI.” (Of note, the metric “access-associated bacteremia” in the NHSN dialysis event protocol is technically a measure of “access-associated bloodstream infection” since fungemias are also reported. Consistency in terminology will lead to a better understanding and standardization of the methodologies across institutions and organizations. Ideally, this discrepancy in terminology within NHSN will be resolved and there will then be complete agreement between NHSN and HHS Action Plan terminology.) In addition we suggest that you stratify the access-associated BSI by the type of access used—i.e., per 100 CVC patient months, per 100 AVG patient months and per 100 AVF patient months. The type of CVC should also be specified (cuffed, non-cuffed and port).

It also would be helpful to specify the time-interval for non-duplicate BSI isolates with the current guidance from NHSN for non duplicate events being 21 days.

Access-related infection in patients with CVC = Positive blood culture with vascular access or unknown suspected source per 100 CVC patient-months

The definition provided for “access-related infection” actually describes “access-associated bloodstream infection in patients with CVC” which is a subset of patients with access-related infections. Access-associated infection also includes local infection (such as exit site infections). We suggest changing the name of this outcome metric to “access-associated BSI in patients with CVC.” The type of CVC should also be specified (cuffed, non-cuffed and port).

Consideration should also be given to other measures such as

(1) # of intravenous antimicrobial starts per 100 patient months (stratified by access device).

(2) # of hospitalizations per 100 patient months (stratified by access device)
as there is enormous variation in policies and practices of obtaining appropriate blood cultures to document BSI. For the intravenous antimicrobial start a new event occurs after an interval of 21 or more days.

Priority Module 2: Hepatitis B and C

A. Process measures

Hepatitis B vaccine coverage = # of hemodialysis patients who have ever received ≥ 3 doses of hepatitis B vaccine / all hemodialysis patients x 100.

As currently defined, this measure does not account for hemodialysis patients who are immune to hepatitis B virus upon admission to the dialysis facility as a result of previous infection or previous immunization without documentation of seroconversion. A better measure would be to have # of hemodialysis patients who have received ≥ 3 doses of hepatitis B vaccine or have documented immunity to hepatitis B as evidenced by a positive HBsAb/ all hemodialysis patients x 100.

Isolation room use = # of facilities with dedicated isolation room/ # of facilities that treat HBs patients x 100

As currently defined, this does not actually measure isolation room use. It simply measures the presence or availability of an isolation room. The availability of an isolation room does not ensure that it is used appropriately. The actual use of an available isolation room would require direct observation of practice within the facility. Perhaps this measure would be better named “Isolation room availability.”

Although expression of this statistic as a percentage may be useful when discussing ESRD facilities as a group, it is not particularly useful for individual facilities where it becomes a dichotomous variable (i.e., yes or no).

Medication room use = # of facilities with separate clean medication preparation room / all facilities x 100

As currently defined, this does not actually measure medication room use. It simply measures the presence or availability of a medication room. The availability of a medication room does not ensure that it is used appropriately. The actual use of an available medication room would require direct observation of practice within the facility. Perhaps this measure would be better named “Medication room availability.”

Although expression of this statistic as a percentage may be useful when discussing ESRD facilities as a group, it is not particularly useful for individual facilities where it becomes dichotomous variable (i.e., yes or no).
**Staff hepatitis B vaccine coverage** = \# of hemodialysis healthcare personnel who have received $\geq 3$ doses of hepatitis B vaccine / all hemodialysis healthcare personnel x 100

SHEA, IDSA and PIDS agree that hepatitis B vaccination for healthcare personnel is an important component of the worker safety program for personnel in end stage renal disease facilities, as it is for personnel in other healthcare facilities. However, it is not quite clear how staff hepatitis B vaccine coverage is directly related to the goals of this action plan to prevent healthcare-associated infections (HAI) in these facilities. In Part II Background, it specifically states that HAIs are infections that occur “to a patient in a health care facility.” Infections that occur in personnel at such facilities would not meet this definition. Since healthcare worker-to-patient transmission is not a common mode of acquisition of hepatitis B in end stage renal disease facilities (and is not mentioned as a concern in section III D), the primary reason for healthcare worker vaccination is healthcare worker safety. Although we support and encourage hepatitis B vaccination among healthcare personnel, it may be misleading to include staff hepatitis B vaccine coverage as a process measure for prevention of hepatitis B and C infection in ESRD patients. If used as a measure, we suggest modification to include documentation of immunity in the numerator. i.e., \# of staff with documented immunity to hepatitis B as evidenced by a positive HBsAb or received $\geq 3$ x doses of hepatitis B vaccine.

**VI. Incentives and Challenges**

**B. Challenges**

In the Challenges section, the Action Plan identifies several important and significant challenges to infection prevention and reporting in ESRD facilities. SHEA, IDSA and PIDS appreciate HHS acknowledging these challenges, which include a frequent lack of financial and personnel support for IC activities, definitional differences among a variety of process and outcomes metrics that are used by a variety of public health and regulatory agencies, and complicated reporting requirements that involve reporting of different metrics for the same process or outcome to different agencies. We support HHS in acting to resolve these unnecessarily complicated and time-consuming data collection and reporting processes.

**VII. Information Systems and Technology.**

SHEA, IDSA and PIDS support the proposed integration of systems across CMS and CDC to monitor HAI among dialysis patients. We also support inclusion of dialysis providers in the HITECH initiative to improve data sharing between dialysis centers and acute care facilities. Consideration should also be given to exploring the potential use of immunization information systems as a method of collecting vaccine coverage data among staff and patients for the above outlined metrics.
IX. Summary of Recommendations

There are many excellent recommendations provided in this section, but it is unclear who HHS expects to implement these recommendations on a practical level to achieve these important goals. SHEA, IDSA and PIDS encourage HHS to take a major role in operationalizing and monitoring this plan.

Recommendation #2: Infection Type

Recommend that efforts largely be placed on vascular-access related, hepatitis B and hepatitis C infection at this time because of higher prevalence and/or incidence rates of these infections in HD, their potential for significant morbidity and mortality in the ESRD population as well as demonstrated improvability in infection rates with proper adherence to infection control processes and in the case of HBV, use of vaccination.

As written, this statement may be interpreted to mean that efforts should be placed on hepatitis B and hepatitis C infections that are vascular-access related. Is this truly what was intended or were there two topics of emphasis vascular access-related infections (e.g., bloodstream infection) and viral hepatitis infection (hepatitis B and C)? The content of the document support placing efforts on the two distinct problems.

Recommendation #3: Immunization

Immunize all patients against hepatitis B, screen ESRD patients for HBsAg positivity annually and encourage immunization with the HBV vaccine for those susceptible to HBV (CDC, ACIP);

Technically, only susceptible patients should be immunized against hepatitis B. Would suggest the following change:

“Immunize all susceptible patients against hepatitis B, screen susceptible ESRD patients for HBsAg positivity annually and encourage immunization with the HBV vaccine for those susceptible to HBV (CDC, ACIP).

Influenza Vaccination of Healthcare Personnel Module

The introduction and background of the document make a strong case for HCP influenza vaccination as a core patient and worker safety practice. The document summarizes the evidence related to factors that contribute to current vaccination rates—factors that will likely continue to play a role as long as influenza vaccination remains an optional strategy for all facilities where health care is delivered. The document correctly identifies
the need for adoption of a standardized definition of HCP and the need to reduce variation in measurement practices.

SHEA, IDSA, and PIDS strongly endorse the need to make a commitment to achieving a high (90% or greater) rate of HCP vaccination, but believe that the proposed pace of improvement (70% by 2015) is too slow. We have additional concerns that the proposed focus of the inaugural project might contribute to further delays in reaching acceptable HCP influenza vaccination rates. While Goal A states “there are many successful strategies for implementing influenza vaccination programs for HCP,” we believe that evidence is mounting to support the fact that when success is defined as having 90% or greater vaccination rates, only programs that make HCP influenza vaccination mandatory achieve that success. IDSA and SHEA, consisting of leaders in the fields of infectious diseases and healthcare epidemiology, have convened workgroups to review the evidence, and have decidedly endorsed the need for mandatory HCP influenza vaccination. We are part of a growing group of prestigious professional groups that have endorsed mandatory HCP influenza vaccination, including PIDS, the Association for Professionals in Infection Control and Epidemiology (APIC), the National Patient Safety Foundation (NPSF), the American Academy of Pediatrics (AAP), the National Foundation for Infectious Diseases (NFID), and the U.S. Department of Defense.

Based on the experience of healthcare systems such as Virginia Mason Medical Center (VMMC), BJC Healthcare, and the Hospital Corporation of America (HCA), implementation of multifaceted mandatory influenza vaccination programs lead to rapid and sustained increases in influenza vaccination rates. VMMC, for instance, implemented a mandatory policy in 2005 and has not only achieved, but sustained, a 98% vaccination rate. BJC Healthcare implemented a mandatory program in 2008, and has reached a 98.4% immunization rate of over 26,000 HCP. In 2009, HCA implemented a mandatory patient safety program in 163 hospitals, 112 outpatient centers, and over 300 physician practices. The policy required all employees in contact with patients to either receive influenza vaccination or wear a surgical mask in patient care areas. After implementation of the policy, the average vaccination rate increased from 62% to 96%, a total of over 140,000 persons.

IDSA, SHEA, and PIDS urge HHS to endorse mandatory annual influenza vaccination of HCP, as a core patient safety practice. We encourage HHS to establish an ultimate goal of 100% influenza vaccination rate for all eligible HCP, and to commit to a more rapid timeline for meeting the 90% target, which we believe is readily achievable through mandatory influenza vaccination programs. We believe that the inaugural project should focus on the quick creation of model policies for states and other jurisdictions to use in establishing influenza vaccination of HCP as a condition of employment, and the development of toolkits designed to assist facilities where health care is delivered implement mandatory influenza vaccination programs. Key pieces of such toolkits will include establishing a standard definition of HCP and a process for measurement and reporting of HCP vaccination.
The Joint Commission should strengthen its accreditation requirements related to facilities’ HCP vaccination program by expanding the influenza vaccine standard to all accredited settings, require public reporting of vaccination rates, and set a benchmark necessary for accreditation. IDSA, SHEA, and PIDS also encourage the National Quality Forum (NQF) to permanently endorse HCP influenza rates as a measure to be reported publically.

In summary, the best preventive measure against influenza is the use of a safe and effective influenza vaccine. IDSA, SHEA, and PIDS strongly believe that HHS must endorse a policy that requires all HCP without a valid medical contraindication receive an annual influenza vaccination. Not only is annual influenza vaccination a core patient and HCP safety practice, it is also an ethical and professional responsibility of HCP to prevent the spread of influenza to patients and others.

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