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Infectious Diseases Society of America

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**Submitted electronically: OHQ@hhs.gov**

Department of Health and Human Services  
Office of Healthcare Quality  
200 Independence Ave, SW., Room 711G  
Washington, DC 20201

## **SUBJ: Draft National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination**

Dear Sir or Madam,

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to review and provide comments on the draft Department of Health and Human Services (HHS) National Action Plan to Prevent Healthcare-associated Infections (HAIs): Roadmap to Elimination ("Action Plan"). In October of 2010, we provided input on the draft Action Plan, and we are pleased to see the progress made, as indicated in the latest draft.

IDSA represents nearly 10,000 infectious diseases physicians and scientists devoted to patient care, prevention, public health, education, and research in the area of infectious diseases (ID). The Society's members focus on the epidemiology, diagnosis, investigation, prevention and treatment of infectious diseases in the United States and abroad. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, surgical infections, those with cancer or transplants who have life-threatening infections caused by unusual or drug-resistant microorganisms, people living with HIV and AIDS, and new and emerging infections, such as severe acute respiratory syndrome (SARS) and H1N1 influenza. We view the Action Plan as providing guidance for our efforts throughout the health care system and serving as a foundation of support for our work in preventing and treating infectious diseases. Indeed, as the Action Plan's title indicates, the document should be viewed as a "roadmap" with its ultimate destination being "elimination" of HAIs, which we accept as the imperative goal.

## **We offer the following general comments related to the draft Action Plan:**

- The Action Plan misses a key opportunity to adequately address and effectively advocate for antimicrobial stewardship. HHS

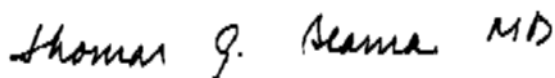
should provide clear guidance that “translates strategy into action” in a compelling manner in support of more specific federal regulatory and research initiatives promoting antimicrobial stewardship.

- The “horizontal integration” of antimicrobial stewardship across our healthcare system should be a goal of the Action Plan.
- The expansion of the Action Plan beyond acute care hospitals to other facilities should be done in a manner that ensures harmonization of data collection and promotes clarity with transparency.
- Agreement on conditions that are considered to be reasonably preventable and consensus on definitions are essential to achieving prevention in HAIs.
- In general, we believe goals for vaccination rates (influenza and hepatitis B) and screening rates (hepatitis C) should be higher and set according to a more aggressive timeline.

**Our additional specific comments related to the Action Plan are attached for your consideration.**

IDSA appreciates the opportunity to provide expert input into the development of the Action Plan. We commend HHS for its efforts to eliminate HAIs. Please contact IDSA staff members Andres Rodriguez ([arodriguez@idsociety.org](mailto:arodriguez@idsociety.org), 703-299-5146) or Irene Stephens ([istephens@idsociety.org](mailto:istephens@idsociety.org), 703-299-0015), should you have any questions or comments.

Sincerely,

A handwritten signature in black ink that reads "Thomas G. Slama MD". The signature is written in a cursive style and is positioned to the left of a vertical line.

Thomas G. Slama, M.D.  
President

Enclosure: IDSA’s Specific Comments on the Action Plan

**IDSA's Specific Comments on the Draft Department of Health and Human Services (HHS) National Action Plan to Prevent Healthcare-associated Infections (HAIs) ("Action Plan")**

**1. The Action Plan fails to adequately address and effectively advocate for antimicrobial stewardship.**

The Action Plan mentions, as one of its “Ten Themes for Translating Strategy to Action,” the importance of implementing and improving antimicrobial stewardship (AS), but falls short of providing more guidance and emphasis related to regulations and financial incentives that are needed. Furthermore, antimicrobial stewardship is recognized as an “Identified Gap in Knowledge and Practice” for many of the conditions listed in the Action Plan and, therefore, warrants more focused research as an infection control intervention. We suggest that in order to truly “translate strategy into action” and achieve meaningful progress, more vigorous administrative and research initiatives, promoting antimicrobial stewardship, are needed.

As stated in the Action Plan, the Medicare Condition of Participation (CoP) specific to infection control is aimed at addressing the reduction of HAIs by providing a structural framework of required organizational roles and hospital policies that guide health systems with the formation of infection control programs. We also recognize that the Centers for Medicare and Medicaid Services’ (CMS) surveys (i.e. Hospital Infection Control Surveyor Tool) and interpretative guidelines serve as “a vehicle for a more specific discussion of best practices in infection control for hospitals.” As explained in the Action Plan, these tools capture data on deficient practices and have revealed that infection control issues are consistently cited in the top 12 areas of deficiency.

CMS is using the Preventable Hospital-acquired Condition provision (HAC) and Hospital Pay-for-Reporting initiative to promote increased quality and efficiency of care. Under these programs, CMS has specified 10 categories of conditions, three of which pertain to infection control, (catheter-associated urinary tract infection [CAUTI], vascular catheter-associated infection, and surgical site infections). Furthermore, as stated in the Action Plan, “stakeholders have suggested that water-borne pathogens be considered, that surgical site infection (SSI) category be expanded, and that ventilator-associated pneumonia (VAP) and *S. aureus* septicemia be reconsidered.” As well, infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile* may be considered as candidates for the HAC payment provision in future rulemaking.

MRSA, *C. diff*, and healthcare personnel influenza immunizations will be required to be reported in FY2015 via the National Healthcare Safety Network (NHSN) under the CMS Pay-for-Reporting initiative. Furthermore, it is anticipated that CMS will propose adding three NHSN measures to Hospital IQR, (VAP, post-procedure pneumonia, and multi-drug resistant organisms [MDROs]).

IDSA has submitted comments on the Medicare CoP calling for infection control and prevention programs to be physician-led or supervised and to specifically include mention of antimicrobial stewardship as an integral program component.<sup>1</sup> In CMS' response to our comments provided in the CoP final rule, the agency indicated that they would consider these suggestions in future rulemaking.<sup>2</sup> In a similar manner, we include in this response to the draft Action Plan our call for action to establish CoP for antimicrobial stewardship programs. IDSA applauds CMS for adding questions regarding antimicrobial stewardship programs as part of the Hospital Infection Control Survey Tool. IDSA hopes that the survey results will provide information on best practices and patient safety to allow for a robust discussion on steps to move forward toward making antibiotic stewardship programs either as a CoP or, at a minimum, a patient safety standard. Given the specific conditions that are currently included and anticipated to be included in the HAC and Pay-for-Reporting Initiatives, we believe more should be done, with more urgency, to establish minimum requirements for antimicrobial stewardship programs and infection control staffing. We assert that reducing HAIs and clinically unnecessary or inappropriate antimicrobial use are major imperatives; **antimicrobial stewardship is the major systematic response.**

## **2. The horizontal integration of antimicrobial stewardship should be pursued across the healthcare system.**

Viewing the Action Plan as it has been in place for acute care hospitals and as it will be extended to ambulatory surgical centers (ASCs), end stage renal disease (ESRD) facilities, and long-term care hospitals (LTCHs), we recognize the need for, "horizontal integration" to the implementation of antimicrobial stewardship across the continuum of care to include, but not limited to, acute care, long-term care, ambulatory surgical and dialysis centers.

Many hospitals and other healthcare organizations have developed effective antimicrobial stewardship programs to mitigate the emergence and propagation of MDROs. IDSA has vigorously supported the development and expansion of these programs, co-sponsoring recently published clinical practice guidelines<sup>3</sup> and a policy statement calling for regulatory mechanisms that would require all health care organizations to implement antimicrobial stewardship programs.<sup>4</sup> IDSA stands ready to collaborate with CMS and

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<sup>1</sup> IDSA Comments on CMS' Conditions of Participation for Medicare Program available at [http://www.idsociety.org/uploadedFiles/IDSA/Policy\\_and\\_Advocacy/Current\\_Topics\\_and\\_Issues/Access\\_to\\_Quality\\_Healthcare/Comments/COP%20Proposed%20Rule\\_Final.pdf](http://www.idsociety.org/uploadedFiles/IDSA/Policy_and_Advocacy/Current_Topics_and_Issues/Access_to_Quality_Healthcare/Comments/COP%20Proposed%20Rule_Final.pdf)

<sup>2</sup> Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation Available at <http://www.gpo.gov/fdsys/pkg/FR-2012-05-16/pdf/2012-11548.pdf>

<sup>3</sup> Dellit et al. Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship. *Clinical Infectious Diseases*. 2007. 44(2): 159-177.

<sup>4</sup> IDSA, SHEA, PIDS. Policy Statement on Antimicrobial Stewardship by the Society for Healthcare Epidemiology of America (SHEA), the Infectious Diseases Society of America (IDSA), and the Pediatric Infectious Diseases Society (PIDS). *Infection Control and Hospital Epidemiology*. March 15, 2012. 33(4):322-327.

other stakeholders on the development of these requirements, based on a review of the data collected via the surveyor tool and updated guidelines.

**3. The expansion of the Action Plan beyond acute care hospitals to other facilities should be done in a manner that ensures harmonization of data collection and promotes clarity with transparency.**

In general, we believe the implementation of the Action Plan should address efforts to harmonize data collection between CMS, the Centers for Disease Control and Prevention (CDC), and state health departments. These efforts should recognize the current finite resources that exist when proposing data collection. Funding was made available through the American Recovery and Reinvestment Act of 2009 (ARRA) to enhance state capacity to reduce HAIs as well as enhance state health departments to inspect ambulatory surgical centers, but this funding has expired. Through harmonization, a common governance model can apply at both the national and state-level. Furthermore, in this age of increased transparency for health care consumers, harmonized data collection can simplify the public reporting of performance measures for facilities across the health care system, whether at the state or national level.

We note that the Action Plan calls for the collection of data (new and worsening pressure ulcers, CAUTI, central line-associated bloodstream infections [CLASBI]) beginning in October 2012, from in-patient rehabilitation facilities (IRFs) and LTCHs. As well, it is proposed that ESRD facilities report various measures related to bloodstream infections and hepatitis B and pneumococcal vaccination rates. These data are proposed to be collected either by NHSN or via claims database, which may prove to be challenging. Some of these facilities do not currently report data through these means or will have to do so manually, thereby posing additional administrative burden in complying with these regulations.

We agree that transparency in our health care system is an important component to achieving high quality care. As measures are developed for HAIs, they may be added to the Hospital Compare website to increase awareness and educate consumers and this could be expanded to achieve greater transparency by developing a “Cross-setting Compare” site that reports cross-setting quality measures for acquired infections regardless of site of origin. We can appreciate this ambitious endeavor to provide a cross-setting perspective. It aligns with our interest in applying a “horizontal integration” of antimicrobial stewardship across sites-of-service as an effective enhancement to infection control and prevention efforts. As public reporting evolves at the state and national level, it is our hope that harmonization of data collection will allow for a simplified presentation for consumers. Finally, education and staffing alone will not be optimized and sustained without implementing a culture of safety, one of the ten themes for translating strategy into action.

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#### **4. Agreement on conditions that are considered to be reasonably preventable and consensus on definitions are essential to achieving prevention in HAIs.**

As stated in the Action Plan, “the ability to select additional conditions will depend on the development of evidence-based guidelines and published literature supporting the conclusion that the conditions can be considered reasonably preventable when the guidelines are followed.” While IDSA supports the Action Plan’s goal to eliminate HAIs, and, in fact, co-authored a Call to Action” white paper with CDC and others in support of this goal.<sup>5</sup> However, IDSA recognizes that, at this time, not all hospital-acquired conditions are 100% preventable, even when evidence-based guidelines are followed. Thus, until this goal is reachable, efforts to measure infectious conditions that are not widely accepted as “reasonably preventable” will lead to poor data collection, unrealistic benchmarks, and other unintended consequences. As an example, we cite the proposed actions related to prevention of HAIs in ESRD facilities, which call for bloodstream infections to be assessed by vascular-access type. We are concerned about this proposal due to a lack of consensus of an adequate definition of Vascular Access Infection (VAI). Furthermore, this issue will lead to challenges in data collection and a poor methodology for establishing a known benchmark to define improvement in clinical outcomes. We strongly favor a task force of all stakeholders to develop a consensus statement with the goal of establishing a better definition of VAI, prior to its inclusion in the Action Plan.

Similarly, with ASCs, agreement is needed on what measures should be the focus of effectively preventing HAIs in this setting. Close collaboration with CDC/NHSN and CMS is needed to facilitate the collection of data in a way that is mindful of what is reasonably preventable in this “short stay” environment. We agree that there is no “one size fits all” solution. HAI surveillance and reporting procedures should be developed to allow for flexible application to the specific type of ASC, but provide for some standardization of infection control and prevention procedures (to include antimicrobial stewardship) across this class of facility. IDSA welcomes the opportunity to collaborate with other stakeholders in the development of guidance and ASC-specific measures. We support expanded research into SSI and HAI surveillance for ASCs.

#### **5. The Action Plan’s goals for influenza vaccination rate for health care personnel (HCP) should be higher. We support the goals for hemodialysis patients related to influenza and hepatitis B vaccinations as well as hepatitis C screening.**

IDSA strongly endorses initiatives to achieve a HCP influenza vaccination rate of 90 percent or greater, in accordance with Healthy People 2020 program goals. On June 14, 2012, the U.S. Senate, through the Senate Appropriations Committee report on the FY 2013 appropriations bill, also articulated its expectation that “CDC work in partnership

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<sup>5</sup> Cardo et al. Moving Toward Elimination of Healthcare-Associated Infections: A Call to Action. Am J Infect Control. 2010 Nov; 38(9):671-5.

with CMS to ensure that all healthcare workers receive the annual influenza vaccination.”<sup>6</sup> With the Senate’s expectation in mind, IDSA does not support the Action Plan’s interim target rate of 70 percent by 2015, as this goal is not sufficiently aggressive. We encourage HHS instead to commit to an accelerated timeline to meet the 90 percent goal by 2015. Ultimately, HHS should set a goal of 100% influenza vaccination rate for all eligible HCP.

As stated in IDSA’s previous comments to HHS on the draft HAI Action Plan Tier 2 modules, IDSA believes HHS should endorse mandatory annual influenza vaccination of HCP as a core patient safety practice. Health care facilities striving to reach a 90 percent target have a greater ability to do so with mandatory influenza vaccination programs in place, even though this rate is less than what is optimally protective for all involved. Based on the experience of healthcare systems such as the Hospital Corporation of America (HCA), implementation of multifaceted mandatory influenza vaccination programs lead to rapid and sustained increases in influenza vaccination rates. HCA has implemented a mandatory patient safety program in 163 hospitals, 112 outpatient centers, and over 400 physician practices in 23 states. The policy required all employees in contact with patients to either receive influenza vaccination or wear a surgical mask in patient care areas. As of 2010, the average vaccination rate increased from 58 percent to 95 percent, a total of over 153,000 persons.<sup>7</sup>

As acknowledged in the Action Plan, the annual morbidity, mortality, and economic impact from influenza is substantial. IDSA believes the Action Plan should be explicit in referencing the many reports of nosocomial transmission and the devastating consequences and costs to patients, families, HCP, and health care facilities under the Background (section II).

Overall, the factors and strategies listed to address HCP vaccination rates in section III are correctly identified, but IDSA would like to suggest the following changes.

Under reasons HCP report for declining influenza vaccination (page 194), we request the following be added as a reason:

“Lack of enforceable federal standards and a culture of professional responsibility for insuring patients and other HCP are protected from influenza transmission by infected HCP.”

Following the paragraph on the HAI Increasing Influenza Vaccination Coverage Among Healthcare Personnel Working Group (page 195), we suggest adding under Working Group tasks:

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<sup>6</sup> U.S. Senate. Committee on Appropriations. *Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, 2013 (to Accompany S. 3295)*. Available at: <http://www.gpo.gov/fdsys/pkg/CRPT-112srpt176/pdf/CRPT-112srpt176.pdf>. Accessed: 6/18/12.

<sup>7</sup> Septimus EJ et al. A Multifaceted Mandatory Patient Safety Program and Seasonal Influenza Vaccination of Health Care Workers in Community Hospitals. *JAMA*. 2011; 305(10):999-1000.

“Widely disseminate the ethical considerations and imperative for HCP influenza vaccination as a critical part of a program to protect patients from influenza transmission by infected HCP.”

IDSA, several medical organizations, and public health groups endorse mandatory HCP influenza vaccination, and encourage health care facilities to embrace a culture of compliance to achieve immunization coverage goals.

IDSA supports the hepatitis B vaccination goal of 90 percent that the Action Plan has set forth. This is in alignment with the Healthy People 2020 goal. With respect to hepatitis C screening of hemodialysis patients, we suggest that the target should be higher (90 percent) due to higher prevalence and transmission in this vulnerable population. This more aggressive goal would parallel broader screening efforts called for in recent CDC recommended Hepatitis C screening guidelines.<sup>8</sup>

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<sup>8</sup> Centers for Disease Control and Prevention. *Proposed Recommendations for the Identification of HCV Chronic Infection Among Persons Born during 1945 through 1965*. Available at: <http://www.cdc.gov/hepatitis/HCV/BirthCohortTesting.htm>. Accessed: 6/25/12.