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HHS's Role in Reducing Rates of Healthcare-associated infections and Facilitating Quality Improvement Research

Statement of

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Introduction

Good morning Chairman Waxman, Ranking Member Davis and other distinguished Members of the Committee. I am Dr. Don Wright, Principal Deputy Assistant Secretary for Health in the Office of Public Health and Science at the U.S. Department of Health and Human Services (HHS). I am pleased to be here to describe HHS' efforts to reduce the rates of healthcare-associated infections (HAI). There are several agencies within the Department that have taken lead roles in addressing this important public health challenge, including the Centers for Disease Control and Prevention (CDC), the Agency for Healthcare Research and Quality (AHRQ), the Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS). There are many examples of how these agencies have worked collaboratively on this issue. Though there has been significant progress in several areas, HHS recognizes more work and leadership is necessary to enhance patient safety in this regard. HHS recognizes the work of the Government Accountability Office in its recent proposed report to the Committee, *Health-Care-Associated Infections in Hospitals*, which looks at HHS prevention practices and data related to healthcare-associated infections.

Today, I will focus my remarks in four specific areas: 1) activities related to prevention of healthcare-associated infections; 2) activities related to surveillance and monitoring of healthcare-associated infections; 3) payment policy decisions (value-based purchasing) to create incentives to reduce healthcare-associated

infections; and 4) regulatory approaches to facilitate quality improvement research.

Prevention of healthcare-associated infections

CDC, on behalf of HHS, leads and supports a range of infection prevention activities at the national, regional and local levels. CDC's healthcare-associated infection prevention activities include developing evidence-based practice guidelines, assessing institution- and provider-level barriers and best practices for adoption of effective practices, developing and disseminating educational materials and toolkits to assist in translating policy into practice, and identifying and evaluating novel prevention strategies.

CDC produces evidence-based guidelines that serve as the standard of care in U.S. hospitals and guide the clinical practices of physicians, nurses and other providers. An advisory committee to HHS and CDC, the Healthcare Infection Control Practices Advisory Committee (HICPAC), has provided recommendations for the development of evidence-based guidelines for the prevention of healthcare-associated infections, including bloodstream infections, surgical site infections, healthcare-associated pneumonia, urinary tract infections, antimicrobial-resistant infections, and tissue safety issues. Most recently, CDC published guidelines to prevent the emergence of antimicrobial resistance and stop transmission of methicillin-resistant *Staphylococcus Aureus* (MRSA) and other antimicrobial resistant pathogens in healthcare settings, and published an

updated edition of the broader guideline “Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007” that serves as the principal foundation of infection control practices in the United States. Overall, these guidelines represent over a thousand evidence-based recommendations which, while large in number, address the vast complexity of modern medical care. All of the recommendations are prioritized according to the quality of evidence available to support them.

CDC guidelines are translated into practice in several ways, and have served as the basis for national healthcare quality initiatives such as the Institute for Healthcare Improvement’s 100,000 Lives Campaign and the CMS Surgical Care Improvement Project, which bundles together these guidelines to create best practices to reduce healthcare-associated infections. These collaborations help to standardize clinical practice, translate policy into practice, and reduce healthcare-associated infections. In addition, several of these evidence-based recommendations have been incorporated into The Joint Commission standards for accreditation of U.S. hospitals and have been endorsed by the National Quality Forum.

In addition, CDC provides funding to a network of academic centers, called the Prevention Epicenter Program, that work in a collaborative manner to identify novel ways to improve infection control and healthcare quality, assess the effectiveness of existing prevention strategies, including the prevention of MRSA

and other resistant organisms, and pilot new implementation tools to bring CDC guidelines to the bedside. Collaborations with the Epicenters resulted in demonstrating improved detection of surgical site infections, decreased inappropriate use of antimicrobial agents, reduced bloodstream infection rates in intensive care units, and decreased infections caused by MRSA and vancomycin-resistant *enterococci*.

There have been several successful regional initiatives in which projects were funded by HHS agencies to increase implementation of CDC guidelines to prevent bloodstream infections. CDC collaborated with the Pittsburgh Regional Healthcare Initiative to prevent central line–associated bloodstream infections, among intensive care unit patients in southwestern Pennsylvania, which resulted in a 68% decline in bloodstream infection rates over a four-year period. AHRQ funded the Keystone Initiative in Michigan that resulted in a 70 percent decline of central-line associated bloodstream infections when CDC guidelines were fully implemented.

CDC has provided direct support, through in-kind technical assistance and extramural funds, as well as assistance to external partners involved in healthcare-associated infection prevention initiatives to translate successful pilot projects at the local level into regional and ultimately national implementation programs. These partners include the Veterans Health Administration of the Department of Veterans Affairs, Institute for Healthcare Improvement, state and

regional initiatives, and other multi-center prevention collaboratives. CDC funded and collaborated with the VA Pittsburgh Healthcare System to use CDC recommendations to prevent MRSA infections; these efforts led to greater than 60 percent reductions in MRSA rates. Influenced by their success, other hospitals in southwestern Pennsylvania are now collaborating on a regional MRSA prevention initiative, and the Veterans Health Administration has launched a national MRSA prevention initiative involving every Veterans Affairs Medical Center in the country. The prevention successes demonstrated in southwestern Pennsylvania have also served as the model for other national and regional initiatives, including one in southeastern Pennsylvania; a statewide initiative coordinated by the Maryland Patient Safety Center; a group of hospitals funded by the Robert Wood Johnson Foundation to prevent MRSA infection in participating hospitals in Pennsylvania, Maryland, Montana, and Kentucky; and a national initiative by the Voluntary Hospital Association members.

Additionally, CDC launched a national evidence-based educational Campaign to Prevent Antimicrobial Resistance in Healthcare Settings that targets healthcare providers. The Campaign focuses on preventing antimicrobial resistance in healthcare settings by promoting four strategies targeting various patient populations including: hospitalized adults, dialysis patients, surgical patients, hospitalized children, and long-term care residents.

A second way the Department works to prevent HAI is through the Agency for Healthcare Research and Quality, the lead agency for patient safety. AHRQ is active in mitigating healthcare-associated infections through provider education efforts.

Specifically, AHRQ has focused its attention on the implementation of evidence-based safe practices through its Partners in Patient Safety (PIPS) grants program. One example of such a safe practice implementation project was led by a team of Johns Hopkins University researchers working with all of the Michigan hospitals to implement proven practices to reduce serious infections acquired by patients in intensive care units (ICU's). The dramatic reductions in serious ICU infections prompted replication in hundreds of hospitals across the country and were described as "one of the most important advances in intensive care in a generation."

In 2007, AHRQ invested close to $2 million in reducing HAIs through its program, Accelerating Change and Transformation in Organizations and Networks (ACTION) program, a field-based research mechanism designed to promote innovation in healthcare delivery. In September 2007, AHRQ awarded five task orders to ACTION partners to support infection mitigation activities at 72 hospitals. For 12 months, multi-disciplinary teams as each participating hospital will implement clinician training that uses AHRQ supported evidence-based tools for improving infection safety. The goal of the training is to facilitate changes in

clinical behaviors and habits, care processes, and the safety culture within hospitals. The finding from the HAI Initiative will provide information on the barriers and challenges to improving and sustaining infection safety.

In addition to these activities, there are two notable interagency initiatives that have recently been launched to reduce the rates of healthcare-associated infections.

In FY 2008, AHRQ was awarded $5 million in appropriated funds to implement a new initiative in collaboration with both CDC and CMS to identify gaps in the prevention, diagnosis, and treatment of MRSA-related infections across the health system and to fund research, implementation, measurement, and evaluation practices that mitigate infections. The three agencies completed an analysis of their individual ongoing MRSA efforts nationwide, the needs of specific populations and venues, the availability of resources and the likelihood of success. While some information is known about MRSA, much remains unknown about the epidemiology in selected settings (acute care, community care, and long term care), prevention of colonization and infection, diagnosis in non-hospital settings, and effective treatment for eradication in all settings. The inter-agency group proposed 7 projects that would address identified gaps through multiple, specifically targeted projects rather than investing the entire appropriation in one single project. Funds will be awarded through existing contract mechanisms during FY 08 and the studies are expected to be completed

in 2 – 3 years. Study results will be widely disseminated via AHRQ publications and at professional conferences. In addition, the Agency will develop and disseminate tool kits for a variety of professional and consumer audiences based on the project study findings. CDC plans to use the new knowledge and findings to update multi-drug resistant organism prevention HICPAC recommendations, to modify MRSA clinical management recommendations as appropriate, and to advise prevention implementation campaigns on how best to prevent MRSA infections or hospitalizations. CDC plans to base future surveillance, research, and investigations on the knowledge generated in part from these studies. CMS expects that the MRSA Initiative projects results will enhance the quality of care for Medicare beneficiaries and, in general, public health.

Second, the Office of Public Health and Science in the Office of the Secretary has launched a departmental initiative to increase influenza vaccination amongst healthcare workers. Influenza is a serious disease that accounts for an average of 36,000 excess deaths and over 200,000 hospitalizations annually in the United States. Healthcare workers can acquire influenza from patients or transmit influenza to patients and other staff. Despite the documented benefits of healthcare worker influenza vaccination on patient outcomes and healthcare worker absenteeism, and on reducing influenza infection among staff, vaccination coverage among healthcare workers remains low (i.e., <45 percent), and well below the Healthy People 2010 objective of 60 percent. Healthcare workers are a high priority for expanding influenza vaccine use, as recommended

by the Advisory Committee on Immunization Practices. Accordingly, the Assistant Secretary of Health has launched an interagency taskforce to discuss current activities promoting and/or providing healthcare worker influenza vaccination for the 2008-2009 flu season. The first specific objective of the taskforce is to increase vaccination of HHS healthcare workers. These personnel work predominantly in the Indian Health Service (IHS), National Institutes of Health (NIH), Federal Occupational Health (FOH) and at CDC. The taskforce also hopes to promote vaccination of non-federal healthcare workers who work at federally funded healthcare sites, such as the Health Resources and Services Administration's (HRSA) community health centers and the Office of Population Affairs' (OPA) family planning clinics. The second objective of the taskforce is to increase vaccination of the broader healthcare workforce by partnering with Federal agencies (DoD and VA), health profession associations, advocacy organizations, and private stakeholder organizations to raise awareness of this important issue.

Surveillance and Monitoring

CDC has developed and validated both standardized definitions for tracking healthcare-associated infections and mechanisms for comparing facilities and regions that are now used by most hospitals in the United States and by many hospitals around the world. CDC leads several activities to track and prevent healthcare-associated infections. The National Healthcare Safety Network (NHSN), formerly the National Nosocomial Infection Surveillance (NNIS) System,

is a web-based tool for hospitals and state health departments to measure healthcare-associated infections and is an integral part of many prevention strategies. It is built and maintained using Public Health Information Network (PHIN) components and standards, including security infrastructure for PHIN systems, messaging services, and vocabulary and data exchange standards. NHSN offers many options to hospitals and local health authorities, and provides hospitals with an accurate measure of infections attributable to a patient's hospital stay as well as information which can drive infection prevention efforts at the hospital level. Additional options to be released in 2008 to facilities and states participating in NHSN include the ability to measure MRSA among both inpatients and outpatients to help the facility prioritize staffing and prevention efforts. CDC's surveillance systems, including NHSN, provide the means for building the future infrastructure to capture data from electronic sources in an automated fashion, which in turn could provide accurate, timely measures to direct local prevention efforts and track the effectiveness of prevention programs. Participation in NHSN has increased in the past few years, and the Network is expected to continue to expand in order to accommodate local, state, and federal reporting initiatives for healthcare-associated infections. CDC is currently providing support to more than 1300 hospitals in16 states that are using NHSN to fulfill state reporting requirements.

CDC and other HHS agencies have made concerted efforts to establish greater consistency and compatibility of healthcare-associated infection data collected

across the Department. CDC and CMS are working collaboratively toward a common set of data requirements for monitoring both healthcare-associated infections and adherence to their prevention guidelines. CDC and CMS are also working together on data requirements for measurement of MRSA as part of CMS's Ninth Scope of Work for the Quality Improvement Organization (QIO) program. The likely outcomes of this effort will be wider use of CDC's NHSN by hospitals participating in the QIO program and dual use of NHSN data by CDC and the QIOs. CDC and CMS also are working toward agreement on the surgical procedures that should be monitored as part of public reporting of surgical site infection rates.

Another example of Inter-agency cooperation has been in the area of surgical improvement. Building on the efforts of the National Surgical Quality Improvement Program (NSQIP), implemented by the Veteran's Health Administration, AHRQ funded the implementation of NSQIP in civilian hospitals. Due to the program's success, CMS is using NSQIP as the basis for the Surgical Improvement Project (SCIP) which is being supported as a national implementation effort thorough the QIOs. AHRQ and CDC continue to actively support this CMS- led effort, an example of effective cooperation among various federal agencies building one another's efforts for improving healthcare.

HHS has several different surveillance systems tracking healthcare-associated infections. However, it is important to note that these data collection programs

are designed for very different purposes. For example, the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU), a CMS program, is designed for participating hospitals to report several infection-related measures. These measures are currently publicly reported on CMS' Hospital Compare website to promote value-driven healthcare and quality transparency, and provide information by hospital to the public (in contrast, NHSN provides estimates of national burden from HAI's but does not provide information on individual hospitals). The Medicare Patient Safety Monitoring System (MPSMS) is a surveillance project designed to identify the rates of specific adverse events within the Medicare population using inpatient medical records and administrative data selected as part of the Medicare Hospital Payment Monitoring Program (HPMP). As a result, the MPSMS, a large national randomly selected set of charts serves as its sample (25,533). Additionally, the MPMS data is used by AHRQ for its National Healthcare Quality and Disparity Reports (NHQR/NHDR), particularly for data on HAIs. The MPSMS is the most reliable data on rates for specific HAIs in the Medicare population.

CMS is working to improve the collection of healthcare-associated infection data. CMS is currently evaluating replacing the current coding system, ICD-9-CM, with an updated system, ICD-10. Identifying hospital-acquired conditions requires clear and detailed diagnosis codes. The current coding system, ICD-9-CM,has numerous instances of broad and vague codes which has made it difficult for CMS to identify cases with a hospital-acquired condition. ICD-10 codes are more

precise and capture information using medical terminology used by current medical practitioners. CMS plans to be ICD-10 ready by 2011.

Measurement and data efforts at AHRQ also enhance our capacity to track HAIs at the national, state, and community level. The AHRQ Patient Safety Indicators (PSIs) are a set of indicators based upon readily available hospital inpatient administrative data. The AHRQ PSIs provide information on potential in-hospital complications and adverse events following surgeries, procedures, and childbirth. Select AHRQ PSIs provide the ability to assess hospital acquired infections (e.g. post-op sepsis, selected infections due to medical care and others).

Through AHRQ's partnership with 39 states in the Healthcare Cost and Utilization Project, which includes data on 90 percent of the hospital discharges in the country, AHRQ can track variations in HAI across regions and over time using these PSIs. AHRQ summarizes information from these hospital discharge data, along with NHSN and CMS data in the annual National Healthcare Quality Report and National Healthcare Disparities Report.

AHRQ has also been collaborating with CDC and CMS, as well as other agencies, in another effort that involves greater consistency and compatibility of HAI data: the development of common definitions and reporting formats to support implementation of the Patient Safety and Quality Improvement Act of 2005 (PSQIA). This effort, spearheaded by AHRQ, includes CDC, CMS, FDA, NIH, HRSA, and the IHS within the Department and the Departments of Defense

and Veterans Affairs. Proposed regulations for PSQIA were published in February that, when final, will allow implementation of this landmark legislation that creates uniform, national confidentiality and privilege protections for clinicians and entities performing patient safety activities. Secretary Leavitt has asked AHRQ to provide "common formats" as technical assistance to newly designated patient safety organizations (PSOs), so that patient safety data gathered among and across PSOs are comparable and can be aggregated for faster learning. Compatible data reported to HHS will be included in AHRQ's annual National Healthcare Quality Report. Among the common formats being developed are those for HAIs, and, with CDC participating in the effort, AHRQ will ensure that the clinical content of the formats is consistent with that of the CDC's National Healthcare Safety Network. These data formats can be used as measurement tools across the health care community, not solely within the PSO context.

Payment Policy Incentives

A novel approach to reducing healthcare-associated infections through payment policy incentives is commonly referred to as value-based purchasing. Currently, CMS is seeking legislative authority to implement a value-based (VBP) purchasing program for Medicare inpatient hospital payments that ties 5% of hospital payments to the hospital's actual performance. Payments would be based on improving a hospital's quality of care as well achieving absolute levels of quality of care.

The Deficit Reduction Act (DRA) required CMS to select certain conditions for which Medicare will no longer pay an additional amount when that condition is acquired during a hospitalization. The Secretary was asked through the Act to identify at least two conditions that are: (a) high cost or high volume or both; (b) result in the assignment of a case to a Diagnosis Diagnostic Related Group that has a higher payment when present as a secondary diagnosis; and (c) could reasonably have been prevented through the application of evidence-based guidelines. CMS has collaborated closely with CDC on the selection of these conditions, with particular attention to identifying evidence-based guidelines that are consistent with CDC's recommended practices. Thus, this Medicare payment provision is closely tied to CDC's prioritized practices.

In the Inpatient Prospective Payment System FY2008 final rule, of the eight selected conditions for the hospital-acquired provision, three conditions involved nosocomial infections. Specifically, catheter-associated urinary tract infections, vascular catheter-associated infections, and a surgical site infection, mediastinitis after coronary artery bypass graft surgery, were selected. Beginning October 1, 2008, Medicare cannot assign these selected conditions to a higher paying DRG unless they were present on admission. In addition, CMS is seeking public comment on additional hospital-acquired conditions, which will include several healthcare-associated infections. Also this week, CMS announced a proposal to expand the list of conditions.

As a prerequisite for implementing this Medicare payment provision, the DRA also requires hospitals to begin reporting present on admission (POA) indicator data to identify whether the selected conditions are acquired during a hospitalization. Beginning October 1, 2007, hospitals were required to begin submitting information on claims specifying whether diagnoses were present on admission. POA data will be needed to determine whether payments should be made for the selected healthcare-associated infections. CMS' collection of POA data will generate increased information about hospital-acquired conditions, including infections, which can be used by CDC and others to develop and disseminate reliable national estimates of these conditions.

Quality Improvement Research

HHS recognizes that the implementation by healthcare institutions of evidence-based quality improvement protocols can significantly reduce the number of healthcare-associated infections. The Department realizes that quality improvement research needs to continue to improve patient care and safety for all Americans. The key federal regulations that apply to some quality improvement research are the HHS human subject protection regulations at 45 CFR part 46. These regulations include the Basic HHS Policy for the Protection of Human Research Subjects (also known as the Federal Policy for the Protection of Human Subjects), which is codified at subpart A of 45 CFR part 46 and identifies requirements involving institutional review board (IRB) review and

informed consent of subjects and other measures designed to protect the rights and welfare of human subjects in research.

Recent media accounts have raised questions about whether the regulations apply to quality improvement activities. The HHS regulations for the protection of human subjects in research do not apply to most quality improvement efforts, but they do apply to some of them. Institutions need to correctly identify which quality improvement activities do not fall under the regulations and which ones do fall under those regulations, so that the appropriate protections for human subjects can be put into place. To determine whether these HHS regulations apply to a particular quality improvement activity, the following questions should be addressed in order: (1) does the activity involve *research* as defined in the regulations[1] (45 CFR 46.102(d)); (2) does the research activity involve *human subjects* as defined in the regulations[2] (45 CFR 46.102(f)); (3) does the human subjects research qualify for any of the six *exemptions* described in the

[1] **"*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."** (45 CFR 46.102(d))

[2] **"*Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains**
(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information.
***Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects."** (45 CFR 46.102(f))

regulations[3] (45 CFR 46.101(b)); and (4) is the non-exempt human subjects research conducted or supported by HHS or otherwise covered by an applicable Federalwide Assurance approved by HHS' Office for Human Research Protections (OHRP). Some quality improvement activities fall outside of the regulations at each of these four decision points. Domestic institutions may voluntarily extend their Federalwide Assurance to cover all human subjects research conducted by the institution, regardless of the source of support for the research. These regulations only apply to quality improvement activities

[3] **"Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:**
(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture." (45 CFR 46.101(b))

involving non-exempt human subjects research that are conducted or supported by HHS, and to non-exempt human subjects research conducted by an institution that has chosen on its Federalwide Assurance to extend the applicability of the regulations to all its non-exempt human subjects research. These are the same criteria that are used to determine whether other public health-related practices, such as public health surveillance or evaluation activities, require the regulatory protections appropriate to human subjects in research.

The regulations provide substantial flexibility in a number of ways related to how those quality improvement activities that are covered by the HHS human subjects protection regulations can satisfy the regulatory requirements. That flexibility includes various alternatives for cooperative arrangements for IRB review, the use of expedited review procedures, and the option to waive informed consent. This flexibility allows institutions to adjust the degree of oversight to the level of risk in the planned activity.

First, under the regulatory provisions for cooperative arrangements for IRB review, the HHS regulations allow one IRB to review and approve research that will be conducted at multiple institutions. An institution such as a community hospital participating in a research activity has the option to rely upon IRB review from another institution by designating that IRB on its Federalwide Assurance, submitting a revised assurance to OHRP with this designation, and having an IRB Authorization Agreement with the other institution. In this way, multiple institutions can share the review conducted by one IRB.

Second, if the human subjects research activity involves no more than minimal risk (defined in the regulations) and fits one of the categories of research eligible for expedited review provided under the regulations, the IRB chairperson or another member designated by the IRB chairperson may conduct the review. This allows the institution to go forward with the review of minimal risk activities instead of having to wait until the next meeting of the convened IRB to review the research plan.

Third, the HHS regulations allow an IRB to waive the requirements for obtaining informed consent of the subjects of the research under certain conditions. An IRB can agree to requests to waive informed consent in the following circumstances: (a) the risk to the subjects is minimal; (b) subjects' rights and welfare will not be adversely affected by the waiver; (c) conducting the research without the waiver is not practicable; and (d) if appropriate, subjects are provided with additional pertinent information after their participation. This provision provides the flexibility to determine whether or not informed consent should be obtained.

Conclusion

The reduction of healthcare-associated infections to enhance patient safety and reduce unnecessary costs is a top priority for HHS. Through prevention activities, surveillance and data monitoring initiatives, value-based purchasing,

and guidelines to facilitate quality improvement research, the Department is tackling this public health challenge in many different ways. There are many examples of inter-agency collaboration in this area throughout the Department. HHS looks forward to working with all stakeholders – public and private – in meeting its shared responsibility to reduce healthcare-associated infections.

Thank you for the opportunity to testify today; I am happy to take any questions you may have.