



Improving Quality and Patient Safety

Background

In the past decade, hospitals have gone from working on quality and safety in small group efforts to publicly reporting quality and safety data, and engaging in large national projects as well as local efforts designed to improve care for patients. It began with 10 simple measures of care processes and was intended to grow over time to become a set of measures that provided an important window into the quality of care provided to hospital inpatients. The Centers for Medicare & Medicaid Services (CMS) currently requires the reporting of 54 measures for hospitals as part of the inpatient quality program and 22 as part of the outpatient quality reporting program. In addition, another set of 16 measures, chosen from a list of 29 candidate measures, are to be generated from the hospital's electronic health record (EHR) and reported to CMS by any hospital seeking to be certified as a "meaningful user" of an EHR.

These data are displayed on the *Hospital Compare* website and used by the Department of Health and Human Services (HHS) in many of its payment programs for hospitals. However, these are not the only measures policymakers and payers are asking hospitals to collect and report. States, private payers and a variety of other organizations request data from hospitals and seek to rate and rank hospitals' performance, as well as engage hospitals and their medical staffs in quality improvement efforts. While quality measurement and improvement are vital activities to which hospitals are dedicated, the deluge of activities and measures has become overwhelming.

AHA View

Hospitals began efforts to publicly provide quality information in order to share important and reliable quality information with the communities they serve, identify opportunities to improve care and be able to track their improvements. For some of the publicly reported measures, the improvement in care has been significant, as demonstrated in The Joint Commission's *Annual Report: Improving America's Hospitals*. For other measures, it has been more challenging to identify strategies that would lead to better performance as they do not provide the kind of reliable, compelling data that is needed. In other instances, different measures of the same aspect of care provide competing assessments of a hospital's performance and create confusion for providers and the public.

The sheer volume of measures and disparate ranking and rating efforts has become overwhelming and distracting to quality improvement efforts, with different priorities, different goals and disparate incentives impeding efforts to enhance the coordination of care across the continuum. A strategically designed approach that promotes better health and better patient outcomes by appropriately involving all parts of the health care delivery system is urgently needed.

National Quality Strategy. *The Patient Protection and Affordable Care Act* (ACA) calls for developing a National Quality Strategy. The law directs HHS to create a strategic plan that identifies critically important areas for improvement,

sets goals and selects measures to be used in the federal programs. This plan relies on input from affected stakeholders, including hospitals, patients, purchasers, insurers and public policy experts.

The AHA strongly supports the premise of the National Quality Strategy. Our nation's health care system can be improved by focusing on aspects of care that a broad array of stakeholders believe to be important. Alignment of quality reporting and payment across care settings and programs is critically important to the long-term success and sustainability of health care quality improvement efforts, and to helping patients and the general public find the information that is important, understandable and relevant to their care.

For the National Quality Strategy to be a success, it must align measures in various payment and public reporting programs using a consistent set of principles. At a time when health care resources are under intense scrutiny, the alignment of quality reporting and payment efforts across settings and programs would reduce the data collection burden and the unnecessary duplication of efforts among providers. Alignment also would help balance the allocation of limited resources between data collection and actual efforts to improve performance.

The AHA has actively participated in the efforts to convene affected stakeholders and provide input to HHS on priorities, goals and measures. The National Priorities Partnership advises the HHS secretary on priorities and goals, and the Measure Applications Partnership advises the secretary on the selection of measures for various programs. We continue to urge both bodies to take additional steps to more concretely enhance the alignment of quality measurement reporting and payment efforts.

Linking Payment to Quality. The AHA supports the general concept of linking hospital payment to meeting performance targets on quality measures. **However, we are very concerned that many of the quality measures upon which federal pay-for-performance programs are based do not produce accurate performance results, making them inappropriate to use for public reporting and accountability programs. Moreover, we believe the manner in which some of the payment penalties are calculated lack fairness and equity.** To ensure federal pay-for-performance programs realize their potential, the AHA's efforts are focused on several fronts (refer to AHA issue paper, "Linking Payment to Quality," for more details):

Value-based Purchasing (VBP). Mandated by the ACA, the VBP program pays hospitals for their actual performance on quality measures, rather than just the reporting of those measures, beginning in fiscal year (FY) 2013. The VBP program applies to inpatient prospective payment system (PPS) hospitals, with certain exceptions. It is budget neutral but is estimated to redistribute up to \$963 million among hospitals in FY 2013.

While the AHA supported the general direction of CMS's July 2011 hospital VBP proposed rule, the AHA expressed serious concerns about the inclusion of hospital-acquired conditions (HAC) in the VBP program when a separate HAC provision in the ACA also will impose financial penalties on a segment of hospitals beginning in FY 2015. We also were concerned that the inclusion of measures for 2014 had not been displayed on the *Hospital Compare*, as required by law.

CMS's final rule did not resolve these issues. The AHA continued to raise objections with representatives from HHS and CMS emphasizing how some of CMS's measures and initiatives conflicted with requirements in the ACA. The AHA was pleased that in the outpatient PPS final rule, published in November 2011, CMS suspended HAC measures for use in FY 2014.

In the FY 2014 regulation, the AHA expects to see CMS propose some additions to the slate of measures used to calculate hospitals' VBP payments over the next several years. It also is possible CMS may propose to retire or suspend some measures that have already been adopted once performance on those measures has reached a level that suggests further improvement is unlikely. **The AHA will continue to work with CMS to ensure that the measures selected for use in hospital VBP are evidence-based, reliable, valid and are important in improving patient outcomes and efficiency.**

Post-acute VBP. The AHA is engaged in CMS's processes to implement quality measures for inpatient rehabilitation facilities and long-term care hospitals, including the implementation of pay-for-reporting programs for both settings, which began in October 2012.

Readmissions. The ACA included a readmissions provision that imposes financial penalties on hospitals for "excess" readmissions when compared to "expected" levels of readmissions. This penalty program began Oct. 1, 2012 (FY 2013), with certain hospitals receiving a penalty of up to 1 percent of their Medicare payment. The payment penalty is based on the 30-day readmission measures for heart attack, heart failure and pneumonia.

The AHA had successfully advocated for a provision in the law stipulating that readmissions that are unrelated to the original reasons for admission or are planned should be excluded from the calculations of the measures. CMS did not address this requirement in the initial implementation of the penalty program. However, the agency did undertake a review of its readmission measures and has developed a substantial list of diagnoses that, when they are the cause for the readmission, will result in the readmission being excluded from the measures. Further work is needed to augment this list, and **the AHA will continue to work with CMS to identify those reasons for readmission that should be excluded.**

In addition, the AHA has adamantly advocated that CMS adjust the readmission measures to reflect socioeconomic differences in the patient populations served by different hospitals. Substantial research has shown that readmissions are the result of many factors; some are within a hospital's control, and some are related to the lack of resources elsewhere in the community, such as adequate numbers of primary care clinicians; access to pharmacies, home health services and rehabilitation services; and access to healthy eating alternatives. There is compelling evidence that safety-net hospitals and others serving large numbers of low-income individuals will have difficulty reducing readmissions due to the lack of certain resources in the communities they serve. This creates an unfair system that puts safety-net hospitals at greater risk for substantial readmission penalties. Thus far, CMS has refused to account for these community-level factors in the readmission measures. The Medicare Payment Advisory Commission intends to further explore the role socioeconomic factors play in readmissions.

The AHA continues to urge CMS to account for planned and unrelated readmissions in the readmissions calculations in a manner that does not increase the reporting burden on hospitals, as well as to account for community-level factors that affect readmissions.

Hospital-acquired Conditions (HACs). The ACA's HAC provision applies a financial penalty to hospitals with high risk-adjusted rates of the HACs identified by CMS for use in the inpatient PPS HACs policy, or any other condition selected by HHS. Beginning in FY 2015, hospitals in the top quartile of national HAC rates will receive a 1 percent reduction in their applicable Medicare payments for all discharges. HHS is required to develop and use a risk-adjustment methodology when calculating the HAC rates. **The AHA strongly opposes this provision, as some hospitals will always experience financial penalties each year, despite overall progress made by the field in reducing the occurrence of these events.** As mentioned above, we oppose CMS's plans to include these same conditions in the VBP program, because both policies together could result in double penalties for certain hospitals.

Drug Availability and Safety. Hospitals and health systems remain deeply concerned about chronic drug shortages. There were 299 active drug shortages in the last quarter of 2012, the highest quarterly number to date. Nearly half of these shortages involve generic sterile injectable drugs, including critical hospital drugs such as succinylcholine, propofol, emergency syringes, preservative free morphine and electrolytes. Drug shortages continue in 2013 and make delivering patient care more difficult and dangerous by causing delays in treatment and forcing the use of alternative drugs that are less familiar to the provider. Shortages also are costly to hospitals and health systems in terms of staff time and other resources to manage the shortages and the increased cost of buying alternative drugs "off contract."

The AHA has been working closely with the Food and Drug Administration (FDA) and Congress to better understand and seek solutions for this critical public health crisis. After strong advocacy by the AHA and a coalition of health care stakeholders, Congress passed the *Food and Drug Administration Safety and Innovation Act of 2012* (FDASIA), which included provisions to help alleviate critical drug shortages. The law:

- broadens and strengthens requirements for manufacturers to notify FDA in advance of discontinuance or interruptions in drug production;
- requires FDA to consider the impact on supply of drugs prior to taking enforcement actions against manufacturers;
- permits expedited drug application reviews and site inspections to help mitigate or prevent shortages;
- requires coordination between the FDA and the Drug Enforcement Administration for shortages involving controlled substances;
- relaxes FDA requirements for hospitals that repackage shortage drugs for use within their own health system; and
- requires FDA to establish a task force to develop and implement a strategic plan for enhancing the response to drug shortages and to submit an annual report to Congress on drug shortages and the agency's related actions.

While the enactment of FDASIA was a significant achievement, additional efforts are underway. The AHA is engaged in an ongoing dialogue with FDA officials on the impact of shortages on hospitals and health systems and monitoring FDA's implementation of drug shortage provisions of FDASIA. We also continue to work with House and Senate committees, the Government Accountability Office and other national stakeholder organizations to explore causes and solutions for drug shortages.

Pharmacy Sterile Compounding. Linked to drug shortages is the issue of inadequate federal and state oversight of pharmacy sterile compounding activities. As noted, some of the drugs in shortage are sterile injectible drugs critical for patient care in hospitals. While many hospitals have historically compounded drugs internally or contracted with outside compounding pharmacies, the chronic shortages of sterile injectible drugs has increased hospitals' dependence on sterile compounding to meet patient needs. This increasing demand from hospitals and other providers has led some compounding pharmacies to expand to large-scale manufacturing.

Poor compounding practices and a lack of adequate oversight of compounding resulted in the tragic infections in 2012 from contaminated products made by the New England Compounding Center (NECC). Tens of thousands of patients were

exposed to nine contaminated lots of drugs compounded by NECC. As of December 2012, a total of 620 infections, which included 39 deaths, had been reported in 19 states.

The AHA is working to improve the safety of compounded medications and to preserve the ability of hospitals and health systems to compound drugs for their own patients. Throughout the NECC crisis, the AHA was in communication with FDA and the Centers for Disease Control and Prevention in order to keep hospital and health systems informed about the emerging crisis and its implications for patient care. In February, the AHA co-hosted with the Association of Health-System Pharmacists and the Pew Charitable Trust a Pharmacy Sterile Compounding Summit. The summit brought together national experts and stakeholders to examine the current processes and gaps in legislative and regulatory oversight with the goal of recommending solutions to improve patient safety. The AHA will continue to work with its members and national partners to develop a consensus around what steps are necessary to fill the gaps in oversight for compounding pharmacies and to pursue the enactment of legislative, regulatory and/or standards-based solutions to protect patients and ensure continued access to compounded medications.

Conditions of Participation (CoP). In February, CMS proposed changes to the Medicare CoPs for the second time since 1985. These changes are intended to reduce the burden on hospitals by eliminating outdated and outmoded requirements. For example, the agency rescinded a CoP provision that was finalized last year to require a member of the governing board of a hospital be a member of the medical staff and rather proposes to require periodic consultation between the governing body and the head of the medical staff. In addition, however, CMS proposed a new requirement that prohibits hospitals in the same health care system from having a unified medical staff serving two or more of its hospitals, if the hospitals have different CMS certification numbers. CMS also is working on revisions to the life safety codes embedded in the CoPs, and a proposed rule delineating those changes is expected later this year.

While the AHA applauds CMS for recognizing that its COPs are out of date, and while we support many of the proposed changes, **we are concerned that CMS's proposal to prohibit unified medical staffs runs counter to efforts to promote greater integration of health care providers to better care for patients. It also rejects the choices of the self-governing medical staffs and the hospital governing bodies at those facilities that have chosen to unify in order to promote improvement in care, greater efficiency and more standardization of practice in accordance with current science.** The final rule is expected in the spring.

PURSUING EXCELLENCE

Through the AHA's strategic platform to accelerate performance improvement, *Hospitals in Pursuit of Excellence* (HPOE), the AHA provides field-tested practices, tools, education and other resources that support hospital efforts to meet the Institute of Medicine's Six Aims for Improvement – care that is safe, timely, effective, efficient, equitable and patient-centered. HPOE draws upon the resources of the entire association, including the American Organization of Nurse Executives, AHA Solutions, the Center for Healthcare Governance, Health Research & Educational Trust (HRET), Institute for Diversity in Health Management, Physician Leadership Forum and the AHA's nine Personal Membership Groups.

CMS contracted with the AHA and HRET to be a driving force in the agency's Partnership for Patients campaign. Through the Hospital Engagement Network contract, HRET assists hospitals with the adoption of best practices with the goal of reducing inpatient harm by 40 percent and readmissions by 20 percent. HRET provides education and training for the nearly 1,600 hospitals recruited by its 31 state hospital association partners in support of their quality improvement efforts in 10 targeted areas. The ongoing program has seen significant improvements in quality in areas such as infection control, early elective deliveries, falls, ventilator-associated pneumonia and readmissions, and has realized an estimated cost savings of more than \$100 million.

In addition, by using the Comprehensive Unit-based Safety Program (CUSP), which is funded by the Agency for Healthcare Research and Quality (AHRQ) and led by HRET, hospitals have improved care in several ways:

- On the CUSP: Stop CLABSI – More than 1,000 hospitals and 1,800 hospital-unit teams participate in the project to reduce central line-associated bloodstream infections (CLABSI). The effort has reduced infections by 40 percent and is estimated to have saved more than 290 lives, and at a minimum \$97 million in excess costs have been averted to date. HRET expects those figures to continue increasing over time.
- Neonatal Intensive Care Units (NICUs) – CLABSIs also may affect infants. Frontline caregivers in 100 NICUs in nine states relied on the program's prevention practice checklists and better communication to decrease CLABSI rates by 58 percent. During the course of the study, an estimated 131 infections were prevented with more than \$2.2 million in cost savings.
- On the CUSP: Stop CAUTI – Reducing complications associated with catheter-associated urinary tract infections (CAUTI) results in decreased length of stay, patient discomfort, excess health care costs and sometimes mortality. With more than 1,200 hospitals in 29 states, the program continues to successfully expand to a wide variety of hospitals.

In addition to supporting this work, HRET continues to accelerate quality improvement in the health care field by:

- Sharing best practices through www.hpoe.org in the areas of patient safety, flow, wellness, care coordination, health information technology and other topics;
- Providing action guides on a variety of topics, including disparities, population health, variation and payment innovations; and
- Offering fellowship programs in patient safety and health care system reform.

Achieving Equitable Care. The AHA has joined four leading health organizations in *Equity of Care*, a national call to action to eliminate health care disparities and improve quality of care for every patient. The *Equity of Care* initiative focuses on three areas:

- Increasing the collection and use of race, ethnicity and language preference data;
- Increasing cultural competency training; and
- Increasing diversity in governance and leadership.

HRET is supporting the AHA's work, which includes disseminating free resources and sharing best practices on the *Equity of Care* website, www.equityofcare.org. To help hospitals measure and thereby effectively address disparities, HRET developed a Disparities Toolkit that allows hospitals to collect race, ethnicity and primary language data in a uniform way. The toolkit is continually reviewed to reflect ACA requirements and The Joint Commission standards. In addition, the AHA's Center for Healthcare Governance and Institute for Diversity in Health Management developed a trustee training program to help hospitals expand the racial and ethnic diversity of their governing boards.