American Hospital Association®

Regulatory Relief Agenda

Background

Every time a nurse, physician or other caregiver treats a patient, a host of regulations and statutes govern their actions, especially if the patient is a Medicare or Medicaid beneficiary. More than 30 agencies oversee some aspect of the health care delivery process at the federal level alone. No one questions the need for regulations to ensure safe patient care. However, excessive regulations and reporting, outdated laws, a lack of coordination across federal and/or state agencies and a lack of clear federal guidance can combine to inhibit the innovation and cooperation essential to improving and transforming health care delivery. These practices often drain the time and funding that could more effectively be focused on patient care.

In addition, as health care providers respond to the delivery system reforms contained in the Affordable Care Act (ACA), the Department of Health and Human Services (HHS), must update its regulations and regulatory process. Many Medicare regulations were developed for cost-based reimbursement, which depends on discrete silos for each type of provider. However, public policy and market forces are driving providers to break down those silos to provide more coordinated care so patients can transition seamlessly from one type of care or provider to another. To foster that transition, HHS needs to adjust or rewrite regulations to reflect this new way of delivering care. Furthermore, timing and methods used to set regulatory policies are making it difficult for health care providers to stay abreast of the growing volume and complexity of regulatory requirements.

AHA View

The AHA is concerned about the mounting regulatory burden faced by America's hospitals and its impact on patients and communities. We have identified several areas and/or regulations that impede hospitals' ability to provide care to their communities and to improve care delivery. Below are some of the key policies needing reform:

- Remove barriers to clinical integration;
- Update Medicare Conditions of Participation;
- Rein in Recovery Audit Contractors;
- Amend the False Claims Act;
- Extend federal requirements for adoption of electronic health records (EHRs);
- Streamline and coordinate quality measures reported to payers;
- Simplify administrative requirements of payers, and
- Reform the medical liability system.

The AHA also is concerned about the increasing use of sub-regulatory guidance, such as agency-issued Frequently Asked Questions (FAQs), to articulate new or revised policy in ways that do not provide for constructive public input and are often difficult to identify or track.

Clinical Integration. Clinical integration is needed to facilitate the coordination of patient care across conditions, providers, settings and time to achieve better health and health care at lower costs. At its heart, clinical integration is teamwork: hospitals, doctors, nurses and other caregivers working together to make sure patients get the right care, at the right time, in the right place. Over the years, many hospitals have made tremendous strides in improving coordination across the care continuum, but they first had to overcome the legal barriers that stand in the way. Barriers to clinical integration range from confusing antitrust policies to outdated rules governing relationships between hospitals, doctors and other caregivers. Even Internal Revenue Service (IRS) rules can be a barrier.

There are solutions. They range from creating user-friendly antitrust guidelines and safe harbors, to providing clear congressional direction on existing rules that promote, instead of hinder, clinical integration efforts. The AHA has identified eight specific barriers and provided solutions to the administration. While there has been some limited progress in the context of implementing the Accountable Care Organization (ACO) provisions of the ACA, more needs to be done. For an in-depth analysis, see the AHA March *TrendWatch*, "The Value of Provider Integration."

Updating the Medicare Conditions of Participation (CoPs). The CoPs are the comprehensive set of standards that are used to determine whether a health care provider should be certified to participate in the Medicare program. As such, it is important that the CoPs stay abreast of evolving standards of care and approaches to health care delivery that are capable of meeting changing public and payer expectations. In 2012, the Centers for Medicare and Medicaid Services (CMS) proposed the first comprehensive update of the CoPs since the 1980s. We expect the agency to release three additional regulations related to the CoPs in the first half of 2014.

Governance. CMS is expected to release a final rule that could affect the governance structures of some hospitals. The AHA was supportive of many of the proposed changes in the governance rule, such as CMS's intention to rescind a requirement that hospitals must have a member of the medical staff on the governing board and replace it with periodic consultation between the board and a medical staff member. We are very concerned, however, about CMS's proposal to prohibit 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. This proposal runs counter to efforts to encourage greater integration of health care providers to promote improvements in care, greater efficiency, and more standardization of practice in accordance with current science.

Life Safety Code (LSC). On April 14, CMS released a proposed rule related to the LSC requirements embedded in the CoPs. Currently, the CoPs reference the 2000 version of the LSC, even though it was updated in 2012. The AHA believes that CMS should defer to the requirements of the most up-to-date version of the LSC.

Influenza Vaccinations. CMS could release a final rule that may require hospitals, critical access hospitals (CAHs) and other providers to offer flu shots to all inpatients and outpatients during flu season. The AHA urged CMS not to finalize this requirement. First, it is more difficult for hospitals to verify a patient's contraindications than a primary care provider. Second, such a requirement would be costly for hospitals to operationalize because they would need to add nursing and pharmacy staff.

Recovery Audit Contractors (RACs). Hospitals strive for payment accuracy and are committed to working with CMS to ensure the accuracy of Medicare and Medicaid payments. However, the existence of multiple and overlapping auditing programs, including RACs, has subjected hospitals to duplicative audits, unmanageable medical record requests and inappropriate payment denials. According to AHA's RAC*Trac* survey of 2,400 participating hospitals, there was a 60 percent increase in the number of records requested for RAC audits during 2013. These Medicare claims now collectively represent almost $10 billion in Medicare payments, a 56 percent increase from the claims requested for RAC audits through 2012.

Hospitals are drowning in the deluge of unmanageable medical record requests and inappropriate payment denials. CMS and Congress need to make the audit processes fairer and more transparent. The Medicare Audit Improvement Act (H.R. 1250/S. 1012) would implement transparent and fair audit practices and assist hospitals in mitigating excessive overall audit burden. Introduced by Reps. Sam Graves (R-MO) and Adam Schiff (D-CA) and Sens. Mark Pryor (D-AR) and Roy Blunt (R-MO), this AHA-supported legislation would establish annual limits on documentation requests from RACs and other auditors; impose financial penalties on RACs if they fall out of compliance with program requirements; make RAC performance evaluations publicly available; and allow denied inpatient claims to be billed as outpatient claims without regard for existing timely filing limitations, among other provisions. Refer to the AHA issue paper, "Program Integrity," for more information.

Abuse of the False Claims Act (FCA). The Department of Justice and certain Assistant United States Attorneys have abused their authority by initiating FCA investigations of hospitals upon the discovery of evidence of a mistake or overutilization. They have seized upon data analysis that flags billing errors and converted them into a presumption of FCA liability. FCA cases pose great risk to hospitals in terms of monetary and administrative sanctions. The threat of FCA liability leads hospitals to incur massive expenses related to retaining specialized counsel and outside forensic accountants and, in the event an overpayment is discovered, to negotiate a formal FCA settlement where a simple cost report adjustment is all that is necessary. The Fairness in Health Care Claims, Guidance and Investigations Act, H.R. 2931, would ensure that unintentional billing disputes are not pursued and penalized as fraud. Introduced by Reps. Howard Coble

(R-NC) and David Scott (D-GA), this AHA-supported bill would amend the FCA by requiring that federal agencies review their own rules and regulations to determine whether a billing dispute should be pursued as fraud before launching an investigation, and assuring that unintentional billing disputes are not penalized as harshly as fraud.

Medicare and Medicaid EHR Incentives and Certification. In fiscal year (FY) 2014, all hospitals and physicians must upgrade to the 2014 Edition Certified EHR and meet higher performance requirements for meaningful use under Medicare and Medicaid. Hospitals paid under the inpatient prospective payment system will not only miss out on incentives if they cannot meet these requirements, but also will be subject to significant subsequent payment penalties under Medicare. The new requirements are highly proscriptive, and do not always match sensible workflows. They also make the performance of the provider dependent on the actions of others, including other providers and patients, and assume a level of health information exchange infrastructure that does not yet exist. Given the complexities of the program, and the delays in delivery of certified EHRs from vendors, the AHA has advocated extending the 2014 timelines and providing greater flexibility in the meaningful use criteria. Refer to the AHA issue paper, "Health Information Technology," for an in-depth analysis.

Quality Measures. Both public quality reporting and value-based purchasing programs improve hospital quality and patient safety. To date, however, federal quality reporting and payment programs have proliferated without strong alignment to specific, measurable national improvement objectives and goals for quality improvement. As a result, the sheer volume of measures and disparate ranking and rating efforts has become overwhelming and distracting to providers and the public. Quality improvement efforts with different priorities, goals and incentives impede efforts to enhance coordination across the care continuum. The challenge of meeting multiple, and often non-aligned, quality measurement and reporting requirements poses a significant burden to hospitals and other providers in collecting data. Unaligned, disparate requirements confuse the public and other users of the data as they attempt to assess how well the health care system as a whole, or their community providers, are doing. And, most importantly, non-alignment becomes an impediment for improvement efforts in trying to determine which practices and processes are most likely to lead to the best outcomes for patients.

To improve the alignment of federal quality reporting and value-based purchasing programs, the AHA urges CMS to establish a limited number (e.g., three to five) of clear, meaningful national goals for quality improvement with specific and measurable objectives that could be used for all of the agency's programs. These goals would be the same across payment programs; the decision to use particular measures in a particular program would be driven by a consistent set of principles. The national goals for quality improvement also should be applied to CMS's

related regulatory activities around quality, such as CoPs and conditions of coverage. To learn more, refer the AHA's "Quality Reporting and Pay-for-Performance Programs" issue paper.

Administrative Simplification. Simplifying and standardizing administrative requirements across all payers is a critical component of AHA's regulatory agenda because it can reduce administrative costs for all stakeholders – providers and health plans alike. Originally adopted as a part of the Health Insurance Portability and Accountability Act (HIPAA), administrative simplification required standardized electronic transactions between health plans and providers. HIPAA's scope reaches the majority of health plans with limited exceptions for government programs.

The AHA-supported administrative simplification provisions of the ACA call for the adoption of operating rules for each HIPAA transaction standard to improve its efficiency and effectiveness. The operating rules are intended to reduce variation in how individual health plans and clearinghouses actually implement the HIPAA transaction standards by adopting standardized best practices. The rules also seek to establish performance expectations on the electronic response to an inquiry to ensure a satisfactory response time. Refer to the AHA issue paper, "Administrative Simplification," for more details.

Medical Liability Reform. The increased costs that result from our flawed medical liability system not only hinder access to affordable health care, but also raise health care premiums and costs for everyone. The AHA supports a more sensible liability system that promotes use of evidence-based standards, reduces frivolous lawsuits, and produces prompt and fair compensation for injured patients. Specifically, the AHA seeks to:

- Model federal proposals on proven state models of reform;
- Cap non-economic damages;
- Allow the courts to limit lawyers' contingency fees;
- Make each party liable only for the amount of damages directly proportional to its responsibility;
- Enact a reasonable statute of limitations after the date of the manifestation or discovery of an injury; and
- Establish "safe harbor" protections for providers who follow evidence-based clinical practice guidelines.

To learn more, refer to the AHA's "Medical Liability Reform" issue paper.

Use of Sub-regulatory Issuances for Policy Matters. Increasingly, federal agencies are developing policy through the issuance of sub-regulatory guidance. The Medicare and Medicaid EHR Incentive Programs include a large number of

specific requirements promulgated through regulation and sub-regulatory guidance. Health care providers and the vendors that serve them are often challenged to fully understand and stay abreast of regulatory requirements for certification and meaningful use requirements. For example, CMS has published more than 150 FAQs, while the Office of the National Coordinator for Health IT has issued more than 20. The use of sub-regulatory issuances has been substantially magnified during the implementation of the new health insurance marketplaces. Although sub-regulatory guidance may be available through town hall meetings, webinars and in various locations on the HHS, CMS and departments of Labor and Treasury websites, the information sometimes conflicts within and between sites, can be hard to find and may be difficult to understand. In addition, though FAQs can be helpful in providing clarification on issues not addressed in sufficient detail in regulation, in practice some FAQs have resulted in uncertainty. The FAQs also are established on an ad hoc basis, and are not tied to any routine schedule or process of updates, which makes it challenging for providers to stay abreast of changes. Hospitals need predictability and certainty in order to navigate the transforming health care delivery landscape. The AHA urges government agencies to refrain from the use of FAQs and instead allow for appropriate public notice and comment.