



American Hospital
Association®

The Regulation of Hospitals and Health Systems



Introduction

It is widely accepted and well acknowledged that hospitals, doctors and other health care providers are spending too much of their time and resources on regulatory paperwork and compliance. It also is increasingly clear that, as health care providers respond to the delivery system reforms mandated by the *Affordable Care Act of 2010* (ACA), the Department of Health and Human Services

(HHS), similarly, must update its regulations and regulatory process.

Below is a set of principles on the regulation of hospitals, followed by suggestions for improving specific regulations and government programs, as well as suggested rules for the regulators to ensure agencies do not overstep their authority.

Principles for the Regulation of Hospitals

Regulation is essential to protecting patients and building public trust and confidence in the health care system. But unnecessary, poorly targeted or poorly implemented regulation may be of little benefit to the public, often frustrates health care providers and the patients they serve, and can interfere with appropriate care delivery. Below are suggested guiding principles for evaluating the use and effectiveness of regulation in health care. They are equally applicable to new requirements under development and to the review of existing regulations.

1 The need to regulate behavior and the underlying objective of a regulation must be clear, unambiguous and well documented. For hospitals, regulation should be used to:

- Protect patients from harm.
- Ensure that quality and other care and safety standards are met.
- Inform the public about their care.
- Prevent fraud or abuse.
- Control expenditures under government programs.

2 Regulation should facilitate channels of communication between regulators and providers, and accountability of providers to their patients and communities.

3 Regulation should be cost effective. In other words, it should:

- Be linked to specific objectives and regularly assessed as to whether it achieves its objectives.
- Be based on sound scientific, technical, economic and other relevant information.
- Reflect an understanding of the operations of regulated entities and the consequences of the proposed action.
- Minimize the cost of compliance assessment for both the regulated and regulators.
- Embody the greatest degree of simplicity and understandability possible.
- Be scalable to the size and complexity of each provider regulated.
- Integrate and/or coordinate its requirements with those of other regulations.

4 Regulations should establish a safe haven for innovation and encourage the pursuit of excellence through best practices.

5 Regulations should be applied prospectively and their implementation appropriately staged to avoid:

- Disrupting patient care activities.
- Unnecessary costs.
- Overwhelming administrative functions and information systems.

A variety of outdated regulations need to be simplified, modernized or eliminated. The following are several notable examples.

Program Integrity Audits

Hospitals strive for payment accuracy and are committed to working with the Centers for Medicare & Medicaid Services (CMS) to ensure the accuracy of Medicare and Medicaid payments; however, the flood of new auditing programs, such as the introduction of Recovery Audit Contractors (RACs), has subjected hospitals to duplicative audits, unmanageable medical record requests and inappropriate payment denials. In Medicare alone, hospitals are subject to payment integrity audits by Medicare Administrative Contractors, Zone Integrity Program Contractors and RACs, as well as audits associated with the Comprehensive Error Rate Testing program. In Medicaid, hospitals are audited by Medicaid Integrity Program contractors, RACs and other various state auditing programs, including those conducted by Medicaid managed care organizations.

While the payment accuracy programs are well intentioned, there are too many of them. The programs should be streamlined and duplicative audits should be eliminated to avoid diverting resources away from patient care and adding unnecessary administrative costs. CMS should be required to allow hospitals to re-bill inpatient care as outpatient care to ensure payment to hospitals for services delivered. Without the ability to re-bill these legitimate and appropriate medical services, Medicare is underpaying hospitals and overpaying the RACs that receive a percentage of the recouped Medicare payments. Additionally, CMS should reinvest a portion of any improper payment recoveries into payment system fixes and provider education.

Conditions of Participation (CoPs)—Interpretive Guidance and Surveying

Recently, CMS published a final rule revising the existing Medicare and Medicaid Conditions of Participation (CoPs) for hospitals and critical access hospitals (CAHs). CMS adopted more than 15 changes to the CoPs which, taken together, reflect the most significant CoP modifications in more than 25 years. While further revisions are needed to fully modernize the CoPs, AHA and its members are grateful that CMS removed several outdated requirements and approved new provisions that will allow for more integrated

and streamlined hospital management and oversight.

However, the final rule contained two provisions that came as a surprise to hospitals and other interested stakeholders. First, CMS added a new requirement mandating that every hospital and hospital system include a member of the medical staff on its governing board. This provision was never mentioned in the proposed rule, and we believe CMS violated the *Administrative Procedure Act* by adopting it in the final rule. If AHA and its members had been given adequate notice that this change was under consideration, we would have provided comments explaining to CMS that the provision is not feasible for some hospitals. The new requirement may not work where hospital boards are elected, where hospitals are precluded by law from adding a medical staff member as a trustee, and where conflicts of interest could potentially arise because medical staff members either serve as employees of the hospital or enjoy privileges at competing hospitals.

Second, in the preamble to the final rule, CMS reversed a previous interpretation of current medical staff regulations and will prohibit multi-hospital systems from operating with a single, unified medical staff. CMS's decision to force health care systems with an integrated medical staff to undo their organizational structures and create independent medical staffs for each of the hospitals in the system misses the opportunity to reinforce the benefits of an integrated care delivery system. Hospital leaders and medical staffs should be allowed to choose an organizational framework that they believe best allows them to deliver the highest quality care possible.

Beneficiary Notices

HHS is increasingly mandating beneficiary notices of program limitations, provider obligations and beneficiary appeal rights. Generally, these notices must be given by providers to every inpatient and outpatient, no matter how often they may come in contact with the provider. Examples include the *Important Message from Medicare*, discharge appeal rights, coverage limitations, privacy notices and so on. These notices – all of which are required to be made “prominent” to the beneficiary despite their growing number – are generally defined as important documents that must be translated for any beneficiary that has limited-English proficiency (LEP) and frequently require written acknowledgement of receipt by the beneficiary.

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For years, the AHA has recommended that these notices be translated into the most frequently spoken 15 to 20 languages other than English, given the increasing diversity of the U.S. population, including seniors. In many cases, providers are not allowed to alter the language of the notice other than to fill in certain blanks related to individual beneficiary situations. Consequently, the most efficient way to address translations is for the federal agency to provide the notices/forms in multiple languages on its website so that

providers can download them. Otherwise, each individual provider must translate each form when needed for an individual patient. An informal commitment was made by CMS last year to begin translating five notices a year into the same 15 languages into which the Social Security Administration has been translating its forms for several years. While we welcomed this commitment, it was not reflected in the plan. We also support the provision of interpreters for Medicare and Medicaid patients with hearing impairments or LEP.

Implementing Health Reform

Implementing the ACA and the meaningful use provisions in the *American Recovery and Reinvestment Act of 2009* (ARRA) is a daunting task with very short timeframes. However, some of the regulatory approaches to implementation are occurring without needed changes in related existing regulations. Specific areas that deserve more attention are discussed below.

Facilitating Clinical Integration

The ACA and private-sector innovation are driving providers to better integrate to serve Medicare beneficiaries and all patients. Regulatory oversight of relationships between hospitals and physicians, likewise, must change to enable the clinical integration that is essential to achieve the ACA's goals. Meaningful health care delivery reform, and the quality and efficiency improvements it promises, is built around the teamwork clinical integration encourages.

Current clinical integration efforts span the spectrum from initiatives aimed at achieving greater coordination around a single clinical condition or procedure to fully integrated hospital systems with closed medical staffs con-

sisting entirely of employed physicians. These efforts have been complicated, or even stymied, by various legal barriers to clinical integration.

Over the years, many hospitals have made tremendous strides in improving coordination across the care continuum, while others have struggled; some hospitals have focused their efforts on privately insured patients to avoid the legal entanglements associated with government reimbursement. Bottom line – to improve care for all patients, the nation needs to ensure that current laws and regulations do not impede our progress in improving care and care delivery for patients.

With the issuance of rules and policies associated with implementation of the accountable care organization (ACO) Medicare Shared Savings Program, it was hoped that CMS and the other agencies involved in monitoring these legal and regulatory barriers would finally clear the path to greater clinical integration. But they did not do so; consequently, the agencies need to revisit these issues to facilitate clinical integration.

Specifically, the AHA advocates the following changes:

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Law	What Is Prohibited?	The Concern Behind the Law	Unintended Consequences	How to Address?
Antitrust (Sherman Act §1)	Joint negotiations by providers unless ancillary to financial or clinical integration; agreements that give health care provider market power	Providers will enter into agreements that either are nothing more than price-fixing, or which give them market power so they can raise prices above competitive levels	Deters providers from entering into procompetitive, innovative arrangements because they are uncertain about antitrust consequences	Guidance from antitrust enforcers to clarify when arrangements will raise serious issues and legislation to protect innovation from harsh penalties
Ethics in Patient Referral Act (“Stark Law”)	Referrals of Medicare patients by physicians for certain designated health services to entities with which the physician has a financial relationship (ownership or compensation)	Physicians will have financial incentive to refer patients for unnecessary services or to choose providers based on financial reward and not the patient’s best interest	Arrangements to improve patient care are banned when payments tied to achievements in quality and efficiency vary based on services ordered instead of resting only on hours worked	Congress should remove compensation arrangements from the definition of “financial relationships” subject to the law. They would continue to be regulated by other laws
Anti-kickback Law	Payments to induce Medicare or Medicaid patient referrals or ordering covered goods or services	Physicians will have financial incentive to refer patients for unnecessary services or to choose providers based on financial reward and not the patient’s best interest	Creates uncertainty concerning arrangements where physicians are rewarded for treating patients using evidence-based clinical protocols	Congress should create a safe harbor for clinical integration programs
Civil Monetary Penalty Law	Payments from a hospital that directly or indirectly induce physician to reduce or limit services to Medicare or Medicaid patients	Physicians will have incentive to reduce the provision of necessary medical services	As interpreted by the Office of Inspector General (OIG), the law prohibits any incentive that may result in a reduction in care (including less expensive products)...even if the result is an improvement in the quality of care	The CMP law should be changed to make clear it applies only to the reduction or withholding of medically necessary services
IRS Tax-exempt Laws	Use of charitable assets for the private benefit of any individual or entity	Assets that are intended for the public benefit are used to benefit any private individual (e.g., a physician)	Uncertainty about how IRS will view payments to physicians in a clinical integration program is a significant deterrent to the teamwork needed for clinical integration	IRS should issue guidance providing explicit examples of how it would apply the rules to allow physician payments in clinical integration programs
State Corporate Practice of Medicine	Employment of physicians by corporations	Physician’s professional judgment would be inappropriately constrained by corporate entity	May require cumbersome organizational structures that add unnecessary cost and decrease flexibility to achieve clinical integration	State laws should allow employment in clinical integration programs
State Insurance Regulation	Entities taking on role of insurers without adequate capitalization and regulatory supervision	Ensure adequate capital to meet obligations to insured, including payment to providers, and establish consumer protections	Bundled payment or similar approaches with one payment shared among providers may inappropriately be treated as subject to solvency requirements for insurers	State insurance regulation should clearly distinguish between the risk carried by insurers and the non-insurance risk of a shared or partial risk payment arrangement
Medical Liability	Health care that falls below the standard of care and causes patient harm	Provide compensation to injured patients and deter unsafe practices	Liability concerns result in defensive medicine and can impede adoption of evidence-based clinical protocols	Establish administrative compensation system and protection for physicians and providers following clinical guidelines

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Medicare and Medicaid Electronic Health Record (EHR) Incentives and Certification

When the Medicare and Medicaid EHR Incentive Programs were introduced, hospital leaders were excited about the opportunity to be rewarded for their efforts to adopt health information technology (IT). However, the rules set out to manage this program by CMS and the Office of the National Coordinator for Health Information Technology (ONC) are overly complex and confusing, leaving many hospitals concerned about their ability to meet the programs' demands. For example, CMS has more than 150 "frequently asked questions" about the program, some of which make substantive changes to requirements. In the most recent data from CMS, only about one-third of hospitals had met the meaningful use criteria and received a Medicare incentive payment by the end of 2012.

Simplified regulations that recognize how health IT is actually acquired, used and implemented are needed for these programs to fully succeed and for hospitals to be able to meet the national goals of an e-enabled health care system. In particular, the requirements for meaningful use should be clear, but not over-specified. The AHA recommends an independent evaluation of current experience before moving forward.

In contrast, the final rules for Meaningful Use Stage 2 continue to up the ante on regulatory complexity and set forward regulatory requirements that are beyond the current experience of today's health systems. For example, ONC mandated that all providers use an uncommon vocabulary standard to record patient problems (SNOMED) at the same time that CMS is requiring providers move to ICD-10 for patient diagnoses and procedures. Similarly, CMS greatly expanded the scope of EHR-based quality reporting requirements, despite significant challenges experienced so far in calculating accurate quality data from certified EHRs that are currently on the market. The AHA believes that we should correct the problems with the 15 current EHR-

reported quality measures and defer adding new measures until quality reporting systems that generate valid measures are available.

In addition, CMS finalized an unfair process to implement penalties. By law, penalties begin in fiscal year (FY) 2015; however, CMS will base penalties on whether hospitals met the meaningful use requirements two years earlier, or 15 months earlier for those first attesting to meaningful use. We believe penalties should be assessed based on hospitals' performance in FY 2015.

As requested by the AHA, ONC revamped some of its complex, confusing and costly certification rules. In particular, ONC changed its definition of "certified EHR technology" in a way that requires hospitals and physicians to have EHR technology to support only the objectives they use to achieve their stage of meaningful use. This change will decrease the cost and burden of buying systems and make it easier to combine products from multiple vendors.

The best path to widespread adoption of EHRs is to have meaningful use requirements that are feasible and sensible and represent a true incremental change. We are especially concerned about the impact of the program on small and rural providers, and believe that the EHR incentives programs should close, not widen, the existing digital divide. Data from the AHA's surveys indicate that, while hospitals as a whole saw tremendous increases in adoption of EHRs in 2011, the rate of increase was strongest among large and urban hospitals, and rural hospitals had the lowest level. Stage 2 must also be viewed in light of the many competing demands on hospital and physician IT systems, including the movement to a new coding system for payment (ICD-10), new rules for electronic claims submission and other administrative transactions, the introduction of value-based purchasing, and additional health reform initiatives that will require calculation of quality metrics and other information system changes. HHS must carefully coordinate these programs to avoid unnecessary or duplicative requirements.

When regulatory agencies act, they too are governed by rules regarding how they do so. The basic federal requirements are contained in the *Administrative Procedures Act*, supplemented by subsequent acts of Congress as well as presidential executive orders. These rules are designed to ensure that agencies do not step beyond the authority granted by Congress. Specific provisions also are sometimes written into laws that specify how the statute is to be implemented by the agencies (for example, the required use of a negotiated rulemaking process or a guaranteed phase-in of requirements).

The AHA is concerned about the increasingly haphazard way that regulatory policies are being issued, especially with respect to the use of sub-regulatory guidance (including FAQs), the frequently understated compliance costs contained in regulatory analyses, old-fashioned approaches to reporting and recordkeeping, retroactive application of requirements, lack of coordination and so on. For example:

- *Required Retention of Paper Beneficiary Acknowledgements.* Many of the Medicare beneficiary notice rules discussed above require that beneficiaries sign an acknowledgement of receipt and understanding of the notice. In many cases, CMS requires that those signed acknowledgements be maintained on paper in physical files. With the increasing pace of movement to EHRs for patients, we believe that providers should be allowed to electronically scan into the EHR all beneficiary acknowledgements, thereby eliminating the requirement to maintain physical copies in file cabinets.
- *Use of Sub-regulatory Issuances for Policy Matters.* The Medicare and Medicaid EHR Incentive Programs include large numbers of very 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 ONC has provided more than 20. Although sub-regulatory guidance may be available through town hall meetings, webinars and in various locations on the ONC and CMS websites, the information is sometimes conflicting within and between sites, can be hard to find and may be difficult to

understand. In addition, though FAQs can be very 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.

- *Using Unrelated Regulatory Issuances to Promulgate New Requirements.* Another mechanism increasingly used by CMS is to tag new requirements onto unrelated regulatory notices already moving through the publication process, rather than issuing them on a standalone basis. For example, the annual payment notices for various providers or payment programs have become “Christmas trees” on which a variety of unrelated provisions are attached. In some cases, the tag-along requirements are not even related to the entities governed by that payment program. For example, a particular proposed provision will be tagged onto the inpatient prospective payment system (PPS) notice, but be finalized in the outpatient PPS notice. We understand that the agencies are under significant time pressures due to the volume of notices and regulations added to their workload as a result of the ACA and previous budget reconciliation bills. However, it has made tracking specific issues very difficult for regulated entities.
- *Understated Regulatory Impact Analyses and Sharing Data Related to Proposals.* Major rules that have limited impact analyses raise significant concerns for hospitals and other health care stakeholders. HHS and its various agencies have a responsibility to be transparent in the impact of their proposals. Far too often, CMS’s analyses underestimate the impact of regulations. For example, the Medicare Shared Savings and EHR incentive program rules overestimate payments to providers, underestimate provider burden and cannot be duplicated by outside experts and stakeholders. CMS should reach out to providers and others for help in understanding financial impacts of their proposals prior to releasing proposed rules. Additionally, the introduction of ACOs, bundling and readmissions policies create the need for new types of patient- and date-identifiable data. These data are critical for stakeholders to model the impacts

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of proposed rules and provide useful feedback to agencies. HHS needs to revise its protocol for developing impact analyses and ensure the availability of data on a timely basis for use by stakeholders to replicate HHS modeling.

- *Retroactive application of new requirements.* Another significant concern for hospitals is CMS “clarifications” that are, in actuality, significant policy changes. Often, because they are merely “clarifications,” they are applied retroactively. Changing the rules retroactively and holding providers to different conditions is among the most problematic of regulatory practices – and it unfortunately occurs far too often.

One such example of a sub-regulatory change and application of that change on a retrospective basis is recent CMS activity related to physician supervision of hospital outpatient therapeutic services. In a March 2008 transmittal, CMS made revisions to its *Medicare Benefits Policy Manual* (Section 20.5.1) that appeared to make changes to longstanding CMS regulatory policy regarding physician supervision of hospital outpatient department services and caused great concern to hospitals around the country. Eventually, with additional input from the AHA and others, some of these manual changes were revoked. These sorts of retroactive policy changes unfairly set providers up for noncompliance, judgments and penalties.

However, subsequently, in the preamble to the calendar year 2009 outpatient PPS proposed and final regulations,

CMS issued a “restatement and clarification” of the physician supervision policy that reiterated and expanded upon physician supervision requirements, incorrectly asserting that since 2001, CMS had a policy in place that required direct supervision by a physician for all outpatient therapeutic services for hospitals, including critical access hospitals (CAHs). At the time, direct supervision meant that a supervising physician had to be physically present in the outpatient department at all times that services were being furnished to Medicare beneficiaries. This interpretation was contrary to language contained in earlier rulemaking and was inconsistent with the vast majority of hospitals’ understanding of CMS outpatient supervision policy.

Instead, based on previous language from CMS, hospitals had long understood that direct supervision by a physician was required only for services furnished in off-campus provider-based departments of the hospital and, that for services furnished in the hospital and on its main campus, supervision was “assumed” to be met. By asserting in the 2008 outpatient PPS rule that the agency’s policy has required since 2001 direct supervision by a physician, CMS exposed hospitals to years of potential retroactive enforcement scrutiny, including potential recoupments and whistleblower actions for services dating back to 2001. In 2010, 2011 and 2012 rulemaking, CMS made a number of significant regulatory improvements to soften the impact of the rule and used its enforcement discretion to delay implementing the supervision policy for certain types of hospitals. Nevertheless, this type of retroactive, sub-regulatory activity harms the relationship between CMS and providers.