



American Hospital
Association

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June 1, 2012

The Honorable Darrell Issa
Chairman
Committee on Oversight and
Government Reform
U.S. House of Representatives
2157 Rayburn House Office Building
Washington, DC 20515

The Honorable Jim Jordan
Chairman
Subcommittee on Regulator Affairs, Stimulus
Oversight and Government Spending
U.S. House of Representatives
2157 Rayburn House Office Building
Washington, DC 20515

Re: Committee on Oversight and Government Reform request for information on existing and proposed regulations that negatively impact America's hospitals, May 16, 2012

Dear Chairman Issa and Chairman Jordan:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to provide information on opportunities to reduce administrative burdens on America's hospitals. We appreciate the Committee's efforts to streamline and eliminate unnecessary, costly, and burdensome government regulations.

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 *Patient Protection and Affordable Care Act of 2010 (ACA)*, the Department of Health and Human Services (HHS), similarly, must update its regulations and regulatory process. Many Medicare regulations were developed decades ago within the context of cost-based reimbursement, which depended on the discrete silos for each type of provider.

Even absent changes in the ACA, hospitals and health systems are working with physicians, health plans, and employers on private sector delivery and payment reform to better coordinate care for patients. Now that these public and private reforms are pushing providers to break down those silos so that care is more coordinated and patient transitions from one type of care or provider to another are more seamless, HHS must break down the regulatory silos that prevent providers from achieving that objective. While some progress has been made in Medicare, CMS has lagged behind private sector efforts.



Furthermore, we are concerned about the increasingly haphazard way that regulatory policies are being issued, especially with respect to the use of sub-regulatory guidance (including Frequently Asked Questions), the frequently understated compliance costs contained in regulatory analysis, old-fashioned approaches to reporting and recordkeeping, and uncoordinated regulatory policies.

Below we offer a set of principles on the regulation of hospitals. These principles were developed by an AHA task force a decade ago but are equally relevant today. Next, we examine the changes needed to accommodate new directions emanating from the ACA and private reforms, and then discuss standard regulatory issues that need to be simplified, modernized or eliminated. Finally, we close with our observations about the increasingly haphazard manner in which regulatory policies are being issued and the effect that it is having on hospitals' ability to know what the rules are and where to find them.

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 and
 - Ensure fair functioning of the market for competing providers.
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 and
 - 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 and
 - Overwhelming administrative functions and information systems.

IMPLEMENTING HEALTH REFORM

We recognize that 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, we fear that some of the regulatory approaches to implementation are occurring without needed changes in related existing regulations. Specific areas we believe 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 financial 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 consisting entirely of employed physicians.

These efforts have been complicated, or even stymied, by various legal barriers to clinical integration. (See Attachment A.) 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, we had hoped that the Centers for Medicare & Medicaid Services (CMS) and the other agencies involved in monitoring these legal and regulatory barriers would finally clear the path to greater clinical integration. However, we were sorely disappointed by the proposals' failure to do so. We urge you to spur the agencies to revisit the issues and truly support clinical integration.

Specifically, the AHA advocates the following changes:

- *Antitrust.* Antitrust laws hinder caregivers' ability to readily understand how they can work together to improve quality and efficiency. The AHA has advocated that the antitrust agencies – the Department of Justice's Antitrust Division and the Federal Trade Commission – issue user-friendly guidance that clearly explains what issues must be resolved to ensure that clinical integration programs comply with antitrust law.
- *Patient Referral (Stark) Law.* The Stark Law has grown beyond its original intent: to prevent physicians from referring their patients to a medical facility in which they have an ownership interest. Its strict requirements mandate that compensation be set in advance and paid on the basis of hours worked. Consequently, payments tied to quality and care improvement could violate the law. One effective solution: remove compensation arrangements from the definition of "financial relationships" under the law and instead rely on other laws already in place for needed oversight.
- *Civil Monetary Penalty (CMP) Law.* The CMP law is a vestige of concerns in the 1980s that Medicare patients might not receive the same level of services as other patients after the inpatient hospital prospective payment system was implemented. In today's environment, the CMP is impeding clinical integration programs. While health reform is about encouraging the use of best practices and clinical protocols, providers using incentives to reward physicians for following best practices and protocols can be penalized under current enforcement of the CMP law. This law must be updated to apply only to the reduction or withholding of *medically necessary* services.
- *Anti-kickback.* Anti-kickback laws originally sought to protect patients and federal health programs from fraud and abuse by making it a felony to knowingly and willfully pay anything of value to influence the referral of federal health program business. Today's expanded interpretation includes any financial relationship between hospitals and doctors – this clearly affects clinical integration. The AHA is working for broader "safe harbor" language and core requirements that provide reasonable flexibility to hospitals and physicians.
- *Internal Revenue Service (IRS) Rules.* The IRS rules prevent a tax-exempt institution's assets from being used to benefit any private individual, including physicians. This pertains to clinical integration arrangements between not-for-profit hospitals and private physicians. As other regulatory barriers are addressed, the IRS will need to issue an Advisory Information Letter or a Revenue Ruling recognizing that clinical integration programs that reward private physicians for improving quality and efficiency do not violate IRS regulations.
- *Other Barriers.* Other regulations under the Medicare and Medicaid programs may need to be revised or even eliminated to provide an appropriate environment for hospital and physician collaboration.

For example, existing limitations on the use and disclosure of patient information imposed by the current HIPAA privacy rule pose barriers for the creation and successful operation of any clinically integrated care setting, including an ACO. Clinically

integrated settings must focus on and be accountable for all patients. Achieving the meaningful quality and efficiency improvements expected from clinically integrated settings requires that all providers in the care system participate in conducting robust care pattern and population-based analyses of patient information without requiring that individual patients have a direct relationship with each of the organizations and providers that technically “use” and have access to the information as part of those analyses. Current HIPAA rules generally limit sharing patient information to providers with whom patients have a direct relationship, unless complex procedures are followed such as obtaining the patient’s permission. These HIPAA obligations unnecessarily prevent or inhibit such analytical activities within clinically integrated settings, because not all of the providers in the system will have direct relationships with each patient. The AHA believes an appropriate level of protection for the security, integrity and accessibility of patient information exchanged in clinically integrated settings already is ensured by the standards and obligations imposed by the HIPAA security rule.

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. 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, fewer than 20 percent of hospitals had met the meaningful use criteria and received a Medicare incentive payment.

Simplified regulations that recognize how health information technology (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 believes that changes to Stage 2 should be guided by the actual implementation experience of Stage 1.

In contrast, the proposed 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 has proposed to mandate 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 proposes to greatly expand 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 in Stage 2 and defer adding new measures until quality reporting systems that generate valid measures are available.

In addition, CMS has proposed an unfair process to implement penalties. By law, penalties begin in FY 2015; however, CMS proposes to 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 has proposed for Stage 2 to revamp some of its complex, confusing and costly certification rules. In particular, ONC proposes to change 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 AHA has asked ONC to initiate this change in FY 2013 – one year earlier than proposed.

The best path to widespread adoption of EHRs is to have meaningful use Stage 2 requirements that are feasible and sensible and represent a true incremental change from Stage 1. 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.

STANDARD REGULATORY ISSUES

In addition to the changes needed to accommodate new directions emanating from the ACA, there are a variety of outdated regulations that need to be simplified, modernized or eliminated. The following are several notable examples.

Conditions of Participation—Interpretive Guidance and Surveying

Recently the Centers for Medicare & Medicaid Services (CMS) published a final rule revising the existing Medicare and Medicaid Conditions of Participation (CoPs) for hospitals and critical access hospitals (CAHs). CMS adopted over 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, and Congressional review of these issues is needed. 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.

Program Integrity Audits

Hospitals strive for payment accuracy and are committed to working with 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. In addition, CMS must take additional steps to accomplish the goal of the payment integrity programs – reducing improper payments. CMS should be required to allow hospitals to re-bill inpatient denials as outpatient claims to ensure accurate payment to hospitals. Without the ability to re-bill these legitimate and appropriate medical services that Medicare beneficiaries received, Medicare is underpaying hospitals and overpaying the RACs that receive a percentage of the recouped Medicare payments. Additionally, CMS should reinvest a portion of improper payment recoveries into payment system fixes and provider education.

Use of Condition Code 44 (CC-44)

CMS's condition code 44 rule is unworkable and in need of modernization. The AHA recommends that the criteria for the use of CC-44 be simplified to allow hospitals to use it effectively. CC-44 is used in order to change a patient's status from inpatient to outpatient in the event that the admission did not meet CMS's requirements for medical necessity for inpatient care. However, the required criteria for CC-44 render it almost unusable. In order to use CC-44, there must be a review by the hospital's Utilization Review (UR) committee and concurrence by

the physician in charge of the patient's care (who cannot be the same as the UR physician). Further, CC-44 can only be applied after the patient is notified about his/her status change from inpatient to outpatient, prior to the discharge or release of the patient, and before the inpatient claim is submitted to CMS. Many hospitals do not have a UR committee operating 24 hours a day, seven days a week. Generally they operate only during weekdays on a single shift during regular business hours (i.e., 8 a.m. – 5 p.m.). For short-stay patients, use of CC-44 is especially challenging and becoming a growing problem as advances in medical care allow more cases to be treated in an outpatient setting. A consequence of the difficulties in applying CC-44 is that "borderline" patients are often held in outpatient observation for extended periods on weekends and only admitted on the following weekday when the UR committee is operating.

The AHA recommends that the criteria for the use of CC-44 be revised to allow its use after the patient has been discharged so that the hospital may review the admission during normal working hours. Patients who are admitted after UR committee hours on the weekend could be informed in advance that their status as an inpatient could change after their discharge depending on review by the UR committee.

Enforcement of Clinical Laboratory Improvement Amendment (CLIA) Regulations Regarding Proficiency Testing Sample Referrals

The CLIA regulation needs to be updated because the penalty for minor infractions is too severe in the context of current laboratory practices. The AHA recommends that CMS establish a rapid review process and the use of intermediate sanctions under the CLIA regulations for hospital laboratories that refer proficiency testing (PT) samples to another laboratory. CMS imposes overly severe sanctions on hospitals – requiring the revocation of the hospital or a health system's CLIA certificate, even if the referral of the PT samples was not done "intentionally." For instance, some hospitals have had their CLIA certificate revoked merely because the laboratory staff followed its own standard operating procedure and referred a PT sample for a test that it does not normally perform in-house to a reference laboratory. In these instances, there was no intent to circumvent the CLIA regulations and what has occurred is just an unfortunate error that does not put patient safety at risk. If the hospital is part of a health system that has a single CLIA certificate, CMS is required to revoke the certificate for the entire system. Because a hospital cannot function unless it has access to stat laboratory testing, the implications for a revocation of a CLIA certificate reverberate far beyond the laboratory itself. A policy that provides for a rapid review of such cases and an option for CMS to impose intermediate sanctions would be appropriate.

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.

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.

RULES FOR THE REGULATORS

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 work load 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 proposed rule and the 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 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.

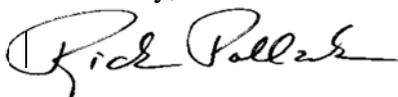
One such example of a sub-regulatory change and application of that change on a retrospective basis is recent CMS activity related to physician supervision of hospital outpatient therapeutic services. In a March 2008 transmittal, CMS made revisions to its Medicare Benefits Policy Manual (Section 20.5.1) 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.

We appreciate your consideration of our recommendations. If you have any questions, please contact me or Linda Fishman, senior vice president of policy, at (202) 626-4628 or lfishman@aha.org.

Sincerely,



Rick Pollack
Executive Vice President

Cc: The Honorable Elijah Cummings, Ranking Member,
Committee on Oversight and Government Reform

The Honorable Denis Kucinich, Ranking Member,
Subcommittee on Regulatory Affairs, Stimulus Oversight and Government Spending

(Attachment A)

Chart of legal barriers to clinical integration and proposed solutions

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. DOJ indicated it will begin a review of guidance in Feb. 2010.
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	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 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

The table above comes from the new *AHA TrendWatch* report "Clinical Integration – The Key to Real Reform." For more information on the report, click on the "Research and Trends" section of www.aha.org.