



**American Hospital
Association**

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December 22, 2011

Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

RE: CMS-9070-P; Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Proposed Rule (Vol. 76, No. 205), October 24, 2011

Dear Ms. Tavenner:

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 comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule to amend several Medicare and Medicaid rules to promote program efficiency and transparency, and reduce administrative burden. The notice's preamble identifies the proposed revisions as implementing several elements of the Department of Health and Human Services' (HHS) preliminary plan for review of regulations in accordance with Executive Order 13563, "Improving Regulation and Regulatory Review," issued on January 18 by President Barack Obama.

The AHA strongly supports efforts to reduce regulatory burden and update regulations, and we especially appreciate and support CMS's recent proposal regarding the hospital conditions of participation. We also appreciate the additional changes reflected in this proposed rule, such as replacing the term "mentally retarded" with "intellectually disabled." However, we are disappointed that, while the notice indicates other changes are under consideration, there is no indication of which rules are being reviewed. There also was no response or reaction by the Secretary of Health and Human Services (HHS) to the AHA's recommendations and comments on the preliminary plan published earlier this year. Most of the rules for which we recommended changes fall under CMS's jurisdiction. In addition to our earlier recommendations, we believe two of the proposed revisions related to relaxing standards for ambulatory surgical centers (ASCs) are ill-advised and should be reconsidered. Our specific concerns are outlined below.



COMMENTS ON SPECIFIC PROPOSED REVISIONS

With respect to the current notice, we are concerned about two recommendations related to ASCs.

ASC EMERGENCY EQUIPMENT

The AHA recommends that the proposed revisions to Sections 416.44(c)(1) through (c)(9) and 416.44(c) regarding emergency equipment be dropped. Those revisions would eliminate the list of emergency equipment that an ASC must have on hand to protect the safety of its patients. Instead, an ASC's governing body and medical staff would be required to adopt policies regarding what equipment would be appropriate for the facility's patient population and make those items available. The discussion notes that this would avoid requiring ASCs to purchase and maintain unnecessary equipment. However, the current list of equipment relates to the basic mechanisms used to address complications from the use of general anesthesia – none of which we believe is unnecessary in a facility that performs surgery under general anesthesia. In fact, it is the same list of equipment required for hospital surgery (both outpatient and inpatient) in Sec. 482.51(b)(3) that remains unchanged in the proposed revisions of the hospital conditions of participation. Given the significant expansion in the scope and complexity of surgical procedures now allowed by Medicare in ASCs, we believe the current requirement is a necessary patient safety protection.

ASC INFECTION CONTROL PROGRAM

The AHA recommends that CMS continue to require ASCs to report infection control problems to the appropriate authorities. The proposed revision appears to eliminate the federal requirement for such reporting. The notice indicates that there are two largely duplicative areas of ASC regulations that address infection control. CMS has proposed that the older of the two sections (42 CFR 416.44(a)(3)) be deleted in favor of the newer provisions in Sec. 416.51. However, the section to be deleted is the only one of the two that requires ASCs to report infection control problems to the appropriate authorities. We believe the removal of reporting requirements is ill-advised. The Centers for Disease Control and Prevention (CDC) recently completed studies identifying exceptionally high rates of infection in ASCs. The results were published last year in the *Journal of the American Medical Association (Infection Control Practices in Ambulatory Surgical Centers, Vol. 303 No. 22, June 9, 2010 JAMA. 2010; 303(22):2273-2279)*. Eliminating the reporting requirement in Sec. 416.44(a)(3) rather than adding it to Sec. 416.51 would limit the ability to determine progress in reducing this problem in ASCs.

ADDITIONAL RECOMMENDATIONS REGARDING REGULATORY RELIEF

The current notice seeks additional recommendations on regulations that should be reviewed under this initiative. Attached you will find a copy of our June 30 letter on this topic for consideration. In summary, those recommendations included:

1. Principles that should govern the regulation of hospitals.
2. Specific areas of current regulation that need to be changed in order to accommodate and encourage implementing the directions included in the *Patient Protection and Affordable Care Act of 2010 (ACA)* and the *American Recovery and Reinvestment Act of 2009 (ARRA)*, including:
 - a. Facilitating clinical integration by removing barriers;
 - b. Modifying Medicare and Medicaid electronic health record (EHR) incentives and certification;
 - c. Coordinating and staging implementation of a variety of information technology (IT) requirements; and
 - d. Aligning the quality measures used for various Medicare and Medicaid programs whenever possible to reduce provider reporting burden.
3. Updating and reducing redundancies or burdens in current regulations governing the Medicare and Medicaid programs, including:
 - a. Modernizing the hospital conditions of participation and the companion interpretive guidelines and surveying instructions;
 - b. Streamlining program integrity requirements to reduce duplicative audits, unmanageable medical record requests and inappropriate payment denials;
 - c. Substantially changing the proposed rule on influenza vaccination;
 - d. Modernizing and simplifying CMS's condition code 44 rule to establish a workable and fair rule regarding changes in a patient's status from inpatient to outpatient status based on medical necessity criteria;
 - e. Updating the rules regarding proficiency testing of samples by hospital laboratories that refer certain types of tests to other laboratories; and
 - f. Modernizing and reducing the burden of Medicare required notices to beneficiaries by providing easy access to translations of the notices into multiple languages and simplifying the process to document beneficiary receipt of notices electronically.
4. Establishing rules for the regulators in how rules are developed and issued, including:
 - a. Reducing reliance on sub-regulatory issuances for policy matters;
 - b. Improving the accuracy of regulatory impact analyses;
 - c. Avoiding the retroactive application of new requirements by labeling them as "clarifications;" and

- d. Separating into discrete notices unrelated regulatory issuances when promulgating new requirements so that they are more readily identifiable and communicated to those affected.

We acknowledge that some progress has been made on a few of these recommendations – most notably the proposed overhaul of the hospital conditions of participation and the one-year postponement of Stage 2 of the EHR meaningful use requirements in recognition of the number of different IT requirements being implemented simultaneously. But substantially more needs to be done, and it would be helpful to know CMS's plans with respect to all of these recommendations and those of others who commented this summer.

Thank you for your consideration of our comments. If you have any questions, please feel free to contact me or Don May at (202) 626-2356 or dmay@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President



**American Hospital
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June 30, 2011

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

***Re: HHS-ES-2011-002; Request for Information on HHS Preliminary Plan for
Retrospective Review of Existing Regulations***

Dear Secretary Sebelius:

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 comment on the Department of Health and Human Services' (HHS) preliminary plan for review of regulations in accordance with Executive Order 13563, "Improving Regulation and Regulatory Review," issued on January 18, 2011 by President Barack Obama.

The AHA welcomes this new commitment to a culture of ongoing retrospective review and we offer several suggestions to add to the list of regulations currently being considered.

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 contained in the *Patient Protection and Affordable Care Act of 2010* (ACA), 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. Now that reform is asking 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. 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 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 is driving providers to better integrate to serve Medicare beneficiaries. 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 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 proposed 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. In an AHA survey conducted in January 2011, 53 percent of hospitals cited lack of clarity in regulatory requirements as a barrier to achieving meaningful use in a timely manner, while 52 percent cited complexity as a barrier. These barriers were cited slightly more often than upfront capital costs (52 percent) and ongoing costs (51 percent).

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. In addition, it must be easier for hospitals and physicians to use a combination of vendor products, but still meet the requirement to use certified EHR technology and receive EHR incentive payments.

ONC's certification requirements are an example of regulatory complexity that acts as a barrier for hospitals trying to use certified technology – the opposite of the intended goal – causing hospitals to buy technology that they will not be using. The AHA and six other organizations active in helping physicians and hospitals achieve meaningful use recently sent you a letter that provides specific suggestions on how to ensure the success of the Medicare and Medicaid EHR incentive programs (<http://www.aha.org/aha/letter/2011/110616-let-collaborative-hhs.pdf>).

Coordination and Staging of IT Requirements

Meaningful use is not the only federal initiative that requires changes to hospitals' IT systems. The scope of change currently underway is creating a "perfect storm" of overlapping regulatory requirements that threatens to overwhelm providers. In addition to EHR adoption, hospitals and physicians also are overhauling their IT systems to implement: new administrative transactions standards (5010) and associated business rules by January 2012; a new ICD-10 coding standard by October 1, 2013; and changes to support myriad reporting requirements and information transfers for the current quality reporting program under Medicare, as well as numerous initiatives introduced by the ACA, such as reductions in readmissions, value-based purchasing, ACOs and bundling of payments. Hospitals also are participating in state-level health information exchange initiatives. As implementations for ICD-10 and other projects begin, our members report significant financial, staffing and change management challenges. The full array of policies and their overlapping timelines are depicted in Attachment B. It is essential that these multiple regulatory initiatives be coordinated and staged in a logical progression and at a reasonable pace.

Quality Measures

The number of quality measures on which hospitals must report to CMS is growing rapidly, not only for the inpatient and outpatient quality reporting programs, but for the meaningful use requirements and the voluntary accountable care organization (ACO) program. The quality measures selected for all public reporting purposes should be driven by a common set of national priorities for quality improvement and public reporting. These priorities can be found in the National Quality Strategy and in the work of the National Quality Forum's National Priority Partners, in which CMS and other federal agencies participate. We further urge the agency to always use quality measures endorsed by multi-stakeholder organizations. We believe those entities should be the National Quality Forum (NQF), the Hospital Quality Alliance (HQA), and when it is fully ready to recommend measures, the Measure Application Partnership (MAP).

We urge CMS to align the measures used for various Medicare programs whenever possible to reduce provider reporting burden. A key step toward alignment is the development of a national core measure set, with measures that are applicable across health care settings. CMS should also move to standardize data elements across measures. For example, patient age should always be reported in the same format, such as a two-digit month, two-digit day, and four-digit year.

The HHS regulatory review preliminary plan calls on CMS to determine whether any quality measures may be eliminated or revised. While we appreciate the intent of this effort, we believe it is critical that CMS focus first on understanding which measures are critical to driving the best possible outcomes for patients. Individual measures of process or outcome can be important, but more often than not, quality will be improved through the use of a set of measures that assess performance on the key steps in the care. In the safety work on reducing central line blood stream infections and reducing errors in surgery, it's clear that the best possible results cannot be achieved by a focus on only one or two of the prescribed steps in care. Instead, all must be accomplished all of the time to get to the best results. For many of the other measure sets currently in use, like heart attack, heart failure, or surgical infection prevention, we have no idea whether removing some measures from a set will result in worse outcomes for patients or not. This really must be assessed before CMS simply chooses to eliminate a measure from a set.

Further, studies done by The Joint Commission and others have indicated that eliminating a single measure or two from a set of measures does not substantially affect the burden of data collection for patients with those conditions. To truly minimize reporting burden, the entire measure set must be retired. Thus, we urge CMS to take a thoughtful and well considered approach to deciding what measures should be included in required reporting and used in value based purchasing. This will involve looking carefully at when it is critical that *all* steps in the process be assessed and when single measures can be eliminated from data collection and reporting without adversely affecting patients. We believe that both the value of measurement and the burden of data collection will be better managed when measure sets are the focus of attention, not individual measures. The Joint Commission is already engaged in some thoughtful work with regard to understanding which measures are really driving improved outcomes for patients, a group that The Joint Commission refers to as "accountability measures." CMS should draw on this work to inform its own process of decision-making around measures.

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

We applaud HHS for including revision of the hospital Conditions of Participation (CoP) on its list of regulations that need to be reviewed. CMS has made limited revisions to individual sections of the CoPs, but there has not been a full review of hospital CoPs in over 25 years. The delivery of health care has evolved extensively since the 1980s and a full revision of the hospital CoPs is long overdue. Though including the hospital CoPs on the list of regulations that must be reviewed is an important first step, additional changes are warranted. The CoPs have corresponding interpretive guidelines (IGs) and surveyor instructions by which CMS directs those who will be conducting the surveys of hospitals on what to look for to determine compliance with a CoP. We urge HHS to include both

parts of this process in its regulatory review. The CoPs are currently crafted by CMS and are improved through a public comment process. The IGs are published in a sub-regulatory fashion that does not involve public comment, and as a result, many of the implementation issues and questions that might have been raised by the public are not surfaced until after the guidance has been issued to surveyors and they run into challenges in implementing it. For example, some guidance is not compatible with the requirements of various state laws and regulations. We believe the IGs would benefit immensely from review by experts in the field prior to issuance and encourage CMS to think about how it might use technical expert panels or similar opportunities to provide such feedback that would eliminate the need for re-work of the guidance once it has been issued.

We also recommend that HHS rethink the central role that CMS currently has in the survey process. The CMS survey process is duplicative with the survey and accreditation process that over 80 percent of hospitals undertake through The Joint Commission. Other hospitals use smaller survey organizations that have been deemed by CMS or rely on state employees that are working under contract to CMS. Uniquely, The Joint Commission has a robust process for updating its standards to keep them current with advances in medical practice, the science of quality improvement, and with emerging insights into safety and quality. Additionally, The Joint Commission conducts rigorous training of its surveyors, and provides on-going technical support to ensure consistent and appropriate application of the standards across surveyors. In contrast, surveyors working under the direction of the states and CMS have applied varying interpretations of the CoPs in ways that result in an uneven review of hospital care across the country. The work of The Joint Commission could provide a strong foundation for CMS in re-thinking its own CoPs, interpretive guidance, and survey procedures.

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 reinvest a portion of improper payment recoveries into payment system fixes and provider education.

CMS Proposed Rule on Influenza Vaccination

On May 4, CMS issued a proposed rule that would revise the Medicare and Medicaid Conditions of Participation (CoPs) to require hospitals and certain other facilities to offer all inpatients and outpatients an annual influenza vaccination during influenza season. While the AHA agrees that increasing the number of individuals who receive the annual influenza vaccination is a key factor in reducing the morbidity and mortality rates from influenza, doing so in a hospital-based setting in the manner that CMS has proposed would be overly complex to implement and is far from the most cost effective way to accomplish CMS's goal.

We believe that it is inappropriate to use the Medicare CoPs for these purposes. According to CMS, the CoPs are "minimum standards for patient health and safety, and CoPs focus on creating a foundation to ensure quality and safe care for beneficiaries throughout a given facility." In other words, the CoPs are supposed to articulate the processes and structures hospitals should have in place to ensure safe and effective delivery of the services they have chosen to provide; they are not supposed to introduce requirements for expanded services.

We also are concerned that CMS's proposal is essentially an unfunded mandate for hospitals in the midst of a difficult economic climate and that CMS has vastly underestimated the cost and burden posed by this rule in its impact analysis. The AHA urges CMS to address national influenza vaccination goals through a different mechanism.

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 Samples Referral

The CLIA rule needs to be updated because the penalty for minor infractions is too severe in the context of current laboratory technology and test referral 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 “knowingly and 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 they do 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, which is mentioned as a candidate for review on page 4 of Appendix B in HHS' proposed plan.

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, the EHR incentive program rules, and the proposed CoP requiring hospitals to offer every patient the seasonal influenza vaccine, 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

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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. 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 and 2011 rulemaking, CMS made a number of significant regulatory changes to soften the impact of the rule and used its enforcement discretion to delay implementing the supervision policy for certain types of hospitals. This type of retroactive, sub-regulatory activity harms the relationship between CMS and providers and raises serious questions about CMS’s ability to partner in caring for the nation’s seniors.

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,

/s/

Rick Pollack
Executive Vice President

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.

ATTACHMENT B

Overlapping Timelines of ICD-10, Meaningful Use of EHRs, and Health Reform Initiatives

