American Hospital Association

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

Dear Chairman Issa:

On behalf of the 5,000 members of the American Hospital Association (AHA), I am writing to thank you for the opportunity to identify existing and proposed regulations that have negatively impacted the hospital field. Regulatory relief is of great importance to our members and one of our major legislative priorities this year. We appreciate your invitation to share our views and concerns.

Hospitals are major employers and economic engines in communities across the country. In 2009, hospitals employed more than 5.3 million people, making hospitals the second-largest source of private-sector jobs. The goods and services hospitals purchase from other businesses create additional economic value. With these ripple effects included, hospitals support nearly one in nine U.S. jobs and more than $2 trillion of economic activity. During the recent recession, hospitals remained a source of employment growth. In addition, between now and 2018, the Bureau of Labor Statistics projects that about 26 percent of all new jobs created in the U.S. economy will be in the health care and social assistance sector. This industry—which includes public and private hospitals, nursing and residential care facilities, and individual and family services—is expected to grow by 24 percent, or 4 million new jobs.

At the same time, hospitals are highly regulated at the federal level and, at times, those regulations place impediments in our members' paths as they continue to provide both jobs and health care to their communities. Below we suggest a number of areas where regulatory change could help our members achieve the dual objectives of better care for patients and job creation.

CLINICAL INTEGRATION

Clinical integration is needed to facilitate the coordination of patient care across conditions, providers, settings and time in order to achieve care that is safe, timely, effective, efficient, equitable and patient-focused. At its heart, clinical integration is teamwork: hospitals, doctors, nurses and other caregivers working together to make sure patients get the right care, at the right time, in the right place. Hospitals are trying to spur this kind of teamwork, but regulatory barriers stand in the way. The barriers to clinical integration range from confusing antitrust policies to outdated rules governing relationships between hospitals, doctors and other caregivers. Even Internal Revenue Service (IRS) rules can be a barrier because they are applied by an agency largely removed from health care delivery and how it is evolving.

There are solutions. They range from creating user-friendly antitrust guidelines and safe harbors, to providing clear congressional direction on existing rules that promote instead of hinder clinical integration efforts. We have identified specific barriers and provided suggested solutions to the Administration:

Antitrust Laws. Recently, the antitrust agencies have become more receptive to clinical integration. However, instead of simply issuing guidelines to help caregivers better understand how the laws are applied, the Federal Trade Commission (FTC) has issued lengthy staff opinion letters that are expressly limited to the facts contained in the opinion letter and that warn that the "Commission is not bound by the staff opinion and reserves the right to rescind it at a later time." The result is that caregivers can neither readily understand, nor completely rely on, those opinion letters. The solution is to issue user-friendly, officially backed guidance that clearly explains to caregivers what issues they must resolve to embark on a clinical integration program without violating antitrust laws.

The Ethics in Patient Referrals Act (The Stark Law). The Stark Law was originally enacted to bar a doctor from referring patients to a facility in which the doctor had a financial interest. However, the tight web of regulations and other prohibitions that have grown up around the law can now ban arrangements designed to encourage hospitals and doctors to team up to improve patient care in a clinical integration program. The law should be returned to its original focus by removing compensation arrangements from the definition of "financial relationships" that are subject to the Stark Law. These same compensation arrangements would still be regulated, but by other federal laws already on the books, such as anti-kickback and Civil Money Penalty laws, that are better equipped to do so.

The Civil Money Penalty Law (CMP). This law prohibits hospitals from rewarding physicians for reducing or withholding services to Medicare or Medicaid patients. The Department of Health and Human Services' (HHS) Office of inspector General (OIG), however, has taken the CMP law a step further, claiming that the law prohibits *any* incentive that affects a physician's delivery of care. The result: a clinical integration program that, for example, rewards a doctor for following an evidence-based timetable for the administration of beneficial drugs could be in violation of the law. The CMP law should be amended to make clear it applies only to the reduction or withholding of *medically necessary* services.

The Anti-Kickback Law. The law's main purpose is to protect patients and federal health programs from fraud and abuse. Today, the law has been stretched to cover any financial relationship between hospitals and doctors. Congress, recognizing that the anti-kickback statute sometimes thwarts good medical practices, periodically has created "safe harbors" to protect those practices. However, there is no safe harbor for clinical integration programs that reward physicians for improving quality. Congress should create a safe harbor to allow all types of hospitals to participate in clinical integration programs, establish core requirements to ensure the program's protection from anti-kickback charges, and allow flexibility in meeting those requirements so that the programs can achieve their health care goals.

The IRS Code. The majority of the nation's hospitals, as not-for-profit organizations, are exempt from federal income taxes. To maintain that not-for-profit status, these hospitals must abide by certain restrictions in the Internal Revenue Code, including one that addresses the payments they provide to physicians, nearly all of whom are not tax-exempt. The rules in question prevent a tax-exempt institution's assets from being used to benefit any private individual, including physicians.

The IRS should issue an Advisory Information Letter or a Revenue Ruling with guidance on payments from a tax-exempt hospital to physicians in clinical integration programs, ensuring that the payments do not violate private-benefit and inurement rules.

RECOVERY AUDIT CONTRACTORS

Recovery Audit Contractors (RACs) were authorized as a Medicare demonstration program under the *Medicare Modernization Act of 2003*, and made permanent by *Tax Relief and Health Care Act of 2006*. They are charged with identifying improper Medicare fee-for-service payments – both overpayments and underpayments. RACs are paid on a contingency fee basis, receiving a percentage of the improper payments they identify and collect. RACs were extended to the Medicaid program through 2010's *Patient Protection and Affordable Care Act*. The Medicare RAC demonstration program suffered from improper oversight by the Centers for Medicare & Medicaid Services (CMS) and resulted in overzealous claim denials. The fundamental flaws in the design and operation of the Medicare RAC demonstration program led to provider appeals, 64 percent of which were decided in the favor of the provider ("CMS Update to the RAC Demonstration Report," June 2010). While CMS listened to provider concerns and made several important changes in the permanent RAC program, the permanent program's rollout was nevertheless beset by problems and delays. Most importantly, more than 50 percent of hospitals report a significant increase in administrative burden due to the RAC program, including employing additional compliance staff and consultants. Hospitals strive for payment accuracy and are committed to working with CMS to ensure the validity of Medicaid payments; in fact, providers already work with multiple CMS contractors to identify inappropriate payments.

ABUSE OF THE FALSE CLAIMS ACT

The Department of Justice and certain Assistant United States Attorneys are abusing their authority by initiating False Claims Act (FCA) investigations of hospitals upon the discovery of evidence of a mistake or overutilization. These government officials have seized upon data analysis that flags billing errors and/or over-utilization and converted it into a presumption of FCA liability. FCA cases pose great risk to hospitals in terms of monetary and administrative sanctions. The threat of FCA liability leads hospitals to incur massive expenses related to retaining specialized counsel and outside forensic accountants and, in the event an overpayment is discovered, to negotiate a formal FCA settlement where a simple cost report adjustment is all that is really necessary.

MEDICARE AND MEDICAID ELECTRONIC HEALTH RECORD INCENTIVES AND CERTIFICATION

Use of electronic health records (EHRs) can improve care quality, efficiency and coordination. Hospitals have been leaders in health information technology (IT) development and use. But the high cost of acquiring and maintaining these systems has been the key barrier for broader hospital adoption. *The American Recovery and Reinvestment Act of 2009* authorized incentive programs under Medicare and Medicaid that will pay bonuses to "meaningful users" of certified EHRs beginning in fiscal year (FY) 2011, then phase-in penalties for those failing to meet "meaningful use" beginning in FY 2015. To be eligible for the incentives, hospitals must use EHRs that have been certified through a new federal process established by the Office of the National Coordinator for Health Information Technology (ONC). When Congress and the President passed this landmark program, 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 ONC are overly complex and confusing, leaving many hospitals concerned about their ability to meet the programs' demands. However, in a new AHA survey conducted over the past week, 53 percent of hospitals cite lack of clarity in regulatory requirements as a barrier to achieving meaningful use in a timely manner, while 52 percent cite 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 IT is really acquired, used and implemented are needed for this program to fully succeed and for hospitals to be able to meet the national goals of an e-enabled health care system.

CLINICAL LABORATORY SIGNATURE ON REQUISITION

CMS recently set a new requirement that a physician or qualified non-physician practitioner must sign requisitions for clinical diagnostic laboratory tests paid through the Clinical Lab Fee Schedule in order for the test to be payable. This policy change is unnecessary, redundant with common practice, and contrary to the agreement struck in the Clinical Laboratory Negotiated Rulemaking. It will result in delays in hospital laboratory testing resulting from labs having to track down the ordering physicians' signature that will be harmful to beneficiaries, and would unfairly hold hospital laboratories financially accountable for non-compliance that is outside of

their control. In finalizing this policy, CMS has not presented an adequate rationale to merit such an onerous system change.

Thank you for the opportunity to share our concerns about the mounting regulatory burden faced by America's hospitals. It is our belief that this burden can be addressed considerably through a critical examination of the current rules and regulations and a common-sense approach to removing barriers to improving patient care.

Sincerely,

Rich Umbdenstock
President and CEO