Mr. Chairman, I am Melinda Hatton, general counsel and senior vice president of the American Hospital Association (AHA). On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 199,000 employed physicians, the AHA thanks you for the opportunity to provide feedback on the impact of the antitrust laws on our nation’s hospital, and hospitals’ efforts to improve the quality and efficiency of care.

Our concerns about recent trends in antitrust enforcement are twofold: first, we support user-friendly guidance from the antitrust agencies on how antitrust laws and policies will be applied to care coordination, or clinical integration, arrangements among hospitals and other caregivers, and urge those agencies to act quickly to provide such guidance. Second, we urge the Department of Justice’s (DOJ) Antitrust Division to be increasingly vigilant about anticompetitive conduct on the part of entrenched health insurers and commend the division for its recent stepped up enforcement.

The current direction of antitrust enforcement needs to coincide with the accelerating pace of change in the nation’s health care delivery system. These changes were not created by passage of the Patient Protection and Affordable Care Act; rather they were accelerated by it with the promise of support for innovative delivery arrangements such as accountable care organizations (ACOs) and new payment models such as bundled payments, as well as penalties for fragmentation. The success of these delivery system changes depends in no small measure on whether Congress and the Administration are willing to effectively tackle and bring down barriers to needed change, such as those presented by our nation’s antitrust laws and policies.
TACKLING THE FRAGMENTATION OF HEALTH CARE DELIVERY

Everyone agrees that the health care system is complex and fragmented and that neither of these attributes contributes positively to patient care. Today, it is clinical integration among caregivers – in its many forms and varieties – that holds the greatest promise of improving the quality and efficiency of our health care delivery system.

At its heart, clinical integration is teamwork: hospitals, physicians, nurses and other caregivers working together to make sure patients get the right care, at the right time, in the right place.

That is different from the way much of health care is delivered today, where providers tend to work separately, in their own “silos” of expertise. Most office-based physicians continue to practice in solo or small groups.¹ Moreover, to the extent that physicians are moving to larger practices, it is generally to form single specialty practices, and not the multi-specialty groups that are best able to support care coordination.² A study of Medicare claims from 2000-2002 found that each year the typical Medicare beneficiary saw a median of two primary care physicians and five specialists, collectively working in four different practice settings.³ Typical patients with multiple chronic conditions saw as many as three primary care physicians and eight specialists in seven different settings. A study by the Robert Wood Johnson Foundation found that for every 100 Medicare patients treated, each primary care physician would typically have to communicate with 99 physicians in 53 practices to coordinate care.⁴

The prevailing model of hospital-physician relationships reflected in the organized medical staff does not assure the optimal level of care coordination between a hospital and independent physicians. In this model, physicians use hospital facilities and rely on hospital staff to provide their services, but the medical staff is not employed by the hospital. As a result, hospitals and physicians have limited tools they can use to positively influence each other’s practice patterns to achieve optimal patient outcomes, especially since most forms of economic incentives may run afoul of regulatory barriers such as the Stark, anti-kickback and the Civil Money Penalty laws that apply to Medicare and Medicaid patients.

Care is fragmented because patients receive services in several locations, including freestanding ambulatory sites and post-acute settings or their homes. Some of these settings may be affiliated with a hospital, while others may compete or offer complementary services. This fragmented care can adversely impact quality and efficiency. Without adequate care coordination, patients are more likely to receive duplicative diagnostic testing, have adverse prescription drug

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interactions and have conflicting care plans. These scenarios add to the challenges patients face in navigating the health care delivery system at a time when they are most vulnerable.

In addition, fragmentation also frustrates attempts by hospitals and physicians to improve the quality and efficiency of care. Physicians in small groups are less likely to be able to afford the information technology to implement electronic health records and similar technologies. They also will have more difficulty in sharing “best practices” and accessing peer data for use as benchmarks.

The AHA began tackling the problem in 2004 by commissioning a Task Force on Delivery System Fragmentation, which concluded:

Health care is about teamwork and requires the talent and dedication of many – doctors, nurses, technicians and many others. Hospital care is especially dependent on the ability of hospital leaders and physicians to work together to improve the efficiency of patient care and to get patients the right care, at the right time, in the right setting.

Presciently, the Task Force saw that better alignment among providers was the key to improving patient care and enhancing productivity, and that removing impediments to such alignment created by various federal laws and policies was essential. It called upon a variety of federal agencies, including the Federal Trade Commission (FTC) and DOJ to:

Establish a simpler, consistent set of rules for how hospitals and physicians construct their working relationships. The complexity, inconsistency and sometimes conflicting interpretations of federal laws and regulations affecting hospital-physician arrangements is a significant barrier. Few arrangements can be structured without very significant legal expense.5

THE NEED FOR ANTITRUST GUIDANCE TO SUPPORT CLINICAL INTEGRATION

Because of their complexity and potential consequences, the antitrust laws are among the most significant barriers to clinical integration. Moreover, unlike some other barriers, the antitrust laws are always present because they apply whether patients are covered by federal programs, such as Medicare and Medicaid, or through private insurers.

The purpose of the antitrust laws is to protect competition and ensure a level playing field for patients. DOJ’s Antitrust Division and the FTC share authority to interpret and apply antitrust laws, and there are serious civil and criminal penalties for violating these laws … even if the violation is unintentional.

Historically, the antitrust agencies have been skeptical of clinical integration when they involve multiple providers and/or provider organizations because there typically is no conventional shared financial risk. In other words, no “up front” money is at stake; clinical integration seeks to improve care coordination and quality by encouraging caregivers to work together to meet specific practice guidelines and/or quality standards … and rewards them when these goals are achieved. The ability to negotiate together for the payment that will cover the services offered through the clinical integration program is often an essential ingredient in its success, but the agencies have typically frowned upon these activities.

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 would be applied, the FTC has issued lengthy and dense staff opinion letters that are expressly limited to the facts contained in the opinion letter and warn that the “Commission is not bound by the staff opinion and reserves the right to rescind it at a later time.” The result: caregivers can neither readily understand nor completely rely on those opinion letters, and they remain uncertain about which clinical integration activities will pass muster.

The AHA and a bipartisan group of Senators who sit on the committees of jurisdiction agree that the best solution to tackle antitrust law as a barrier to clinical integration 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. In three separate letters to the antitrust agencies over seven months, lawmakers clearly called for user-friendly antitrust guidance:

Your agencies could make a significant contribution to [clinical] integration efforts by providing guidance on clinical integration similar to that provided on related topics in the Statements on Antitrust Enforcement in Health Care. (Senators Kohl, Leahy, Feinstein, Whitehouse and Specter. November 3, 2009.)

We write to acknowledge and encourage what we hope are renewed efforts by your agencies toward developing and issuing guidance to physicians, hospitals and others in the health care provider community seeking to pursue collaborative care models and different cooperative arrangements to promote high quality, patient-centered care. (Senators Warner, Udall, Bennet, Burris, Kirk, Franken, Udall, Gillibrand and Hagen. December 23, 2009.)

Chief among the challenges to reforming the health care delivery system are federal laws and regulations that discourage collaboration among providers, such as hospitals, doctors, nurses, long-term care providers and others in the health care continuum. Lack of clarity in the antitrust laws and how those laws will be administered by the federal antitrust agencies has contributed to the problem. (Senators Hatch, Cornyn, Roberts, Snowe, Coburn and Graham. June 8, 2010.)

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6 Letters from Senators Kohl, Leahy, Feinstein, Whitehouse and Specter (November 3, 2009); from Senators M. Udall, Warner, Bennet, T. Udall, Burris, Gillibrand, Kirk, Hagan and Franken (December 23, 2009); and from Senators Cornyn, Graham, Coburn, Hatch, Roberts and Snowe (June 8, 2010).
DOJ and FTC have issued user-friendly and officially backed guidance in the past in other areas and, in their 1996 *Statements of Antitrust Enforcement Policy in Health Care*, promised to do so again when warranted. Clearly, there is widespread support for them to do so without delay.

**THE NEED FOR VIGILANT ANTITRUST ENFORCEMENT FOR HEALTH PLANS**

Criticizing the historic lack of a robust and coherent enforcement policy on health insurance plan mergers and anticompetitive conduct in May 2009, the AHA called upon DOJ to re-examine and bolster its enforcement policy as it applies to health plans in *The Case for Reinvigorating Antitrust Enforcement for Health Plan Mergers and Anticompetitive Conduct to Protect Consumers and Providers and Support Meaningful Reform*. Among AHA’s requests were that the Antitrust Division:

- Undertake a comprehensive study of consummated health plan mergers.
- Revisit and revise its analytical framework for reviewing health plan mergers and conduct complaints. The areas of scrutiny should include whether:
  - Proposed mergers by plans with pre-existing market power should be viewed as presumptively unlawful;
  - The ability of merged or dominant health plans to price discriminate against certain hospitals poses particular concerns about likely competitive harm;
  - Merged or dominant health plans can wreak competitive harm in ways other than reducing prices below competitive levels, such as adversely affecting the development or adoption of quality protocols or technology tailored to meet the needs of hospitals and the patients they serve; and
  - Mergers of health plans with service areas that technically do not overlap because of license or other agreements still pose a risk of competitive harm and, therefore, should be challenged.

Unlike other sectors of the health care field, such as hospitals and physicians, we pointed out that health plan mergers and other anticompetitive conduct had received comparatively little scrutiny:

> In the past eight years, the Antitrust Division has requested only relatively minor divestitures and other relief in two health plan mergers. In addition, the Antitrust Division has offered no explanation for failing to respond to provider requests for more robust enforcement in the last two major health plan mergers.

While enforcement has been stepped up recently, it is noteworthy that since AHA’s May 2009 letter, DOJ has challenged only one health insurance transaction, involving a small provider-owned HMO, while other larger transactions have been cleared.

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Contrasting with that lack of scrutiny was the fact that during the same time period, the FTC launched a major retrospective of the hospital field that was intended to lead to more successful challenges to hospital mergers, apparently in an attempt to overcome losing virtually all of its challenges to those mergers in the federal courts. Following that retrospective, the FTC challenged one long-consummatated hospital merger via an internal agency hearing and blocked another outright. The FTC also has aggressively applied antitrust law to arrangements between physicians and between physicians and hospitals, all to “protect” patients from any increase in market power resulting from such arrangements. Where was the comparable focus on health plan mergers and market power?

Today, some would turn the lack of antitrust enforcement against health plans on its head, contending instead that hospitals – the object of so much antitrust scrutiny – have somehow acquired the power to dictate terms to health plans. To examine these claims, the AHA recently commissioned two well-known and respected antitrust economists from Compass Lexecon to evaluate two publications that have been widely cited as support for this mistaken notion: a 2010 Health Affairs article about California health care providers and the 2010 report by the Massachusetts Attorney General on health care costs.

In short, the economists from Compass Lexecon concluded, after rigorous analysis, that neither publication contains any credible support for such claims. While the two publications have different but serious flaws, they share one that is particularly glaring: they confuse patient preference for providers with highly differentiated services or specialized service with market power.

A hospital can become highly desired simply by providing excellent care. Indeed strong consumer preferences for specific hospitals and their services provide an incentive for hospitals to improve services, enhance quality or expand output of services in greater demand, and to expect an appropriate return on the investment required to provide these services.

Hospitals, in particular, are held accountable for the care they provide to their communities; for example, quality and patient satisfaction are routinely measured and publicly reported. Hospitals also have been subject to intense scrutiny by the federal antitrust agencies. Conversely, insurers, which wield enormous – largely unchecked – market power in most markets, have not faced nearly as much public antitrust scrutiny and oversight.

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Most importantly, however, patients get real benefits when caregivers work together to provide more coordinated, more efficient and higher quality care. That is the path we are on and the one that holds the greatest promise for fixing a fragmented delivery system. The antitrust laws can make a real contribution to progress if the agencies enforcing them are willing to exercise the same type of leadership and foresight that led to the issuance of the *Statements on Antitrust Enforcement in Health Care*. User-friendly guidance for clinical integration and more vigilance in the health insurer sector are important steps, not just for hospitals, but for the future health and vitality of the nation’s health care delivery system and the patients it serves.

**CONCLUSION**

Mr. Chairman and distinguished members of the committee, thank you for the opportunity to discuss these issues with you today. America’s hospitals look forward to working with you and the Administration to improve the quality and efficiency of care for all patients in every community. It is our belief that clinical integration is one proven strategy for achieving these aims, and that health care providers’ efforts to improve care delivery should not be complicated by unnecessary barriers.
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<th>Law</th>
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<tr>
<td><strong>Anti-trust (Sherman Act §1)</strong></td>
<td>Joint negotiations by providers unless ancillary to financial or clinical integration; agreements that give health care provider market power</td>
<td>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</td>
<td>Delays providers from entering into procompetitive, innovative arrangements because they are uncertain about antitrust consequences</td>
<td>Guidance from antitrust enforcers to clarify when arrangements will raise serious issues. DOJ indicated it will begin a review of guidance in Feb. 2019.</td>
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<td><strong>Ethics in Patient Referral Act (“Stark Law”)</strong></td>
<td>Referrals of Medicare patients by physicians for certain designated health services to entities with which the physician has a financial relationship (ownership or compensation)</td>
<td>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</td>
<td>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</td>
<td>Congress should remove compensation arrangements from the definition of “financial relationships” subject to the law. They would continue to be regulated by other laws.</td>
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<tr>
<td><strong>Anti-kickback Law</strong></td>
<td>Payments to induce Medicare or Medicaid patient referrals or ordering covered goods or services</td>
<td>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</td>
<td>Creates uncertainty concerning arrangements where physicians are rewarded for treating patients using evidence-based clinical protocols</td>
<td>Congress should create a safe harbor for clinical integration programs</td>
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<td><strong>Civil Monetary Penalty</strong></td>
<td>Payments from a hospital that directly or indirectly induce physician to reduce or limit services to Medicare or Medicaid patients</td>
<td>Physicians will have incentive to reduce the provision of necessary medical services</td>
<td>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</td>
<td>The CMP law should be changed to make clear it applies only to the reduction or withholding of medically necessary services</td>
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<td><strong>IRS Tax-exempt Laws</strong></td>
<td>Use of charitable assets for the private benefit of any individual or entity</td>
<td>Assets that are intended for the public benefit are used to benefit any private individual (e.g., a physician)</td>
<td>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</td>
<td>IRS should issue guidance providing explicit examples of how it would apply the rules to physician payments for clinical integration programs</td>
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<tr>
<td><strong>State Corporate Practice of Medicine</strong></td>
<td>Employment of physicians by corporations</td>
<td>Physician’s professional judgment would be inappropriately constrained by corporate entity</td>
<td>May require cumbersome organizational structures that add unnecessary cost and decrease flexibility to achieve clinical integration</td>
<td>State laws should allow employment in clinical integration programs</td>
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<td><strong>State Insurance Regulation</strong></td>
<td>Entities taking on role of insurers without adequate capitalization and regulatory supervision</td>
<td>Ensure adequate capital to meet obligations to insured, including payment to providers, and establish consumer protections</td>
<td>Bundled payment or similar approaches w/ one payment shared among providers may inappropriately be treated as subject to solvency requirements for insurers</td>
<td>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</td>
</tr>
<tr>
<td><strong>Medical Liability</strong></td>
<td>Health care that falls below the standard of care and causes patient harm</td>
<td>Provide compensation to injured patients and deter unsafe practices</td>
<td>Liability concerns result in defensive medicine and can impede adoption of evidence-based clinical protocols</td>
<td>Establish administrative compensation system and protection for physicians and providers following clinical guidelines</td>
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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.
Compendium of AHA Resources on Clinical Integration

Task Force on Delivery System Fragmentation Report, Nov. 2005:
www.aha.org/aha/content/2007/pdf/modernizinggainshare.pdf

Health for Life: Most Efficient, Affordable Care, Dec. 2007:
http://www.aha.org/aha/content/2007/pdf/071204_H4L_Efficient_Affordable.pdf

Ideas for Change: Beginning the Discussion, Mar. 2008:
http://www.aha.org/aha/content/2008/pdf/08-03-PolicyIdeasforChange.pdf

AHA Statement on the Importance of Clinical Integration to the Nation’s Hospitals and their Patients, “Clinical Integration in Health Care: A Check-Up,” May 29, 2008:


Trendwatch: Clinical Integration – The Key to Real Reform, Feb. 2010:

Getting More from Health Reform – Five Barriers to Clinical Integration in Hospitals (and what to do about them), Mar. 2010:
http://www.aha.org/aha/content/2010/pdf/5barrierstoclininteg.pdf

Accountable Care Organizations: AHA Research Synthesis Report, June 2010:

A Critique of Recent Publications on Provider Market Power, Oct. 4, 2010:
http://www.aha.org/aha/content/2010/pdf/100410-critique-report.pdf


Guidance for Clinical Integration (Updated) Working Paper, Sept. 2010:
http://www.aha.org/aha/content/2010/pdf/070417clinicalintegration.pdf

AHA Letter to Jonathan Blum, Deputy CMS Administrator Regarding Structuring Accountable Care Organization, Nov. 17, 2010:
Attachment C

Antitrust Letters from U.S. Senators

