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Clinical Integration: Linchpin of Real Reform

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I. INTRODUCTION

During the year-long debate over health care reform, removing barriers to clinical integration received far less attention than it should have. It was preempted by debate over more voluble issues like single payer options, individual mandates, and filling donut holes. Now that attention has turned to making health reform—officially, the Patient Protection and Affordable Care Act of 2010—work for patients and caregivers, the issue is getting the attention it deserves.

Clinical integration is another way of talking about teamwork: hospitals, doctors, nurses, and other caregivers working together to provide the right care at the right time in the right setting. While the notion of working together seems unremarkable, our current health care system is built on a system of nearly unbridgeable silos, where hospitals, doctors, nursing homes, social workers, physical therapists, and other caregivers work and bill separately. So, instead of a continuum of care best suited to a patient's needs, each silo looks to do the best it can with the particular segment of care it controls.

The new law takes aim at these silos through a "a robust set of delivery system reforms aimed at incentivizing physicians, hospitals and other providers to modernize the delivery of health care by pursuing collaborative models and different cooperative arrangements to promote high quality, patient-centered care." The reforms they refer to are wide-ranging and include a Medicaid global payment system demonstration, an accountable care organization program, medical "homes" for Medicaid patients with chronic conditions, and a Center for Medicare and Medicaid Innovation charged with finding and testing innovative payment and service delivery models.

In a recent *Washington Post* editorial, the new Centers for Medicare & Medicaid Services chief, Don Berwick, reinforced the collaborative nature of health care reform: "[It] will help us pay for quality outcomes, not volume, with innovative tools such as bundled payments, incentives for hospitals that prevent readmissions, and accountable care organizations in which health-care providers who work in teams deliver better care with lower costs."

But bridging silos is no easy task. It requires both a cultural shift among caregivers too used to working independently, and coordinated efforts by at least five different federal agencies to overhaul a legal and regulatory system predicated on maintaining silos and punishing deviation.

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² Letter to U.S. Government Accountability Office from Senators Baucus, T. Udall, Warner, Bennett, M. Udall, Burris, Gillibrand, Kirk, Hagan and Franken, December 23, 2009.

II. LEGAL & REGULATORY BARRIERS

Two separate federal agencies oversee the nation's antitrust laws: the Department of Justice's Antitrust Division ("DOJ") and the Federal Trade Commission ("FTC"). Antitrust law, which is intended to protect competition for the benefit of consumers, tends to be complicated because it looks to court decisions and fact patterns rather than an established regulatory regime to determine whether an arrangement is legal. "Guidance" for caregivers on whether a clinically integrated arrangement passes antitrust muster is currently available in the form of dense staff opinion letters. Those letters don't bind the agency itself, typically cost caregivers about \$100,000 in legal fees, and take about a year to obtain. To date, the agencies—FTC in particular—have resisted calls from a bipartisan group of 30 senators to issue user-friendly guidance on clinical integration that is understandable for caregivers and that the agencies will stand behind.

The Department of Health and Human Services ("HHS") oversees both the barrier-creating "Stark" and Civil Monetary Penalty ("CMP") law. Regulations issued under Stark—officially the Ethics in Patient Referrals Act—require that compensation for medical services be fixed in advance, and paid only for hours worked—an outdated payment system for a piecework model. That means payments tied to improving care quality and efficiency, the hallmarks of clinical integration, do not meet Stark's strict standards.

CMP law is the vestige of outdated concerns that Medicare patients might not receive the same care as private patients. The Department of Health and Human Services ("HHS") interprets CMP to prohibit any incentive that might affect a physician's delivery of care. That means that rewarding doctors for providing the right care at the right time—evidence-based medicine for example—runs afoul of this law.

HHS shares jurisdiction with DOJ over a fourth barrier-creating law originally intended to protect federal programs from fraud and abuse—the anti-kickback law. Over the years, this well-intended law has been stretched to cover virtually *any* financial relationship between a hospital and doctor. Practically, that means a clinical integration arrangement that rewards a doctor for following evidence-based medicine could violate the law. While it is possible to get a protective opinion from HHS, such opinions are limited strictly to the facts stated and the person requesting it, leaving other caregivers wanting to do the same or nearly the same thing in legal limbo.

The Internal Revenue Service is home to yet another regulatory barrier dealing with restrictions on nonprofit organizations using assets to benefit private individuals. About 60 percent of U.S. hospitals are not for profit, but nearly all physicians operate privately for profit. That means that when a hospital rewards a physician or other caregiver for following evidence-based medicine as part of a clinical integration arrangement, the hospital could jeopardize its tax-exempt status.

None of these barriers are insurmountable; but, they are serious. Guessing wrong can subject caregivers to stiff fines, debarment from federal programs, criminal prosecution, and/or the loss of their tax-exempt status. No caregiver should have to risk so much to follow a path so clearly blazed by health care reform.

III. BEYOND BARRIERS

There are tangible benefits to consumers and providers of breaking down barriers to clinical integration. A recent *TrendWatch* on clinical integration published by the American

Hospital Association, Clinical Integration—The Key to Real Reform, February 2010, contained many examples of the benefits of clinical integration:

- Continuum Health Partners in New York City was able to achieve savings of approximately \$900 per case in the course of a Medicare gainsharing demonstration project, where doctors shared rewards for improving the efficiency of care delivery and lowering its cost. It is worth noting that this project began without any Medicare or Medicaid patients because of the lack of a waiver for the Stark, anti-kickback, and CMP laws.
- Minneapolis' Fairview Health Services has created a set of "care packages" each covering a set of defined clinical best practices for a condition, such as diabetes. Providers are paid based on a single fee covering the entire package of services.
- Advocate Physician Partners in metropolitan Chicago is implementing 37 key clinical initiatives that address clinical outcomes, efficiency, medical, and technological infrastructure, patient safety, and patient satisfaction. Participating physicians receive feedback on these initiatives via "report cards" that are the basis of performance-driven financial incentives. Advocate has achieved significant clinical and efficiency results.

There are other examples of the benefits of clinical integration, but still not as many as there should be, or will be, until legal and regulatory barriers are lowered.

For the full benefits of clinical integration to be realized, and the goals of health care reform to be achieved, the administration and Congress must tackle the barriers to clinical integration with the seriousness of purpose the issue deserves.