

Moving Health Care *Forward*

Five Barriers to Clinical Integration in Hospitals (and what to do about them)

What is Clinical Integration – and Why is it Important?

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. Clinical integration can take many forms. In some, different providers may collaborate to tackle a single condition, like diabetes. In others, the hospital, doctors and other caregivers may function as a single entity, working together to provide seamless care to all patients.

Regardless of its form, clinical integration relies on teamwork. That is different from the way most health care is delivered today, where providers tend to work separately, in their own “silos” of expertise. Physicians typically work alone or in group practices; physical therapists, social workers and home health providers often work on their own as well. And different facilities tend to work separately, such as acute-care hospitals and long-term care facilities.

Clinical integration is important. Meaningful change in the way health care is delivered, and the quality and efficiency improvements that promises, is built around the teamwork clinical integration creates. Accountable Care Organizations, as well as new payment models, rely on clinical integration to create better

patient outcomes by delivering higher quality care, and making the medical system less expensive, more efficient and easier to navigate for patients and providers alike.

Hospitals are trying to spur this kind of teamwork, but regulatory barriers stand in the way. The following pages describe them and the proposals supported by hospitals that can promote teamwork by knocking down these barriers to clinical integration.

What are the Barriers ... What is the Solution?

The barriers to clinical integration range from confusing antitrust policies to outdated rules governing relationships between hospitals, doctors and other caregivers.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. In one instance, simply refocusing a law on its original intent could solve the problem. For the IRS, the solution involves issuing guidance compatible with these other regulatory changes.



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ANTITRUST

What is Antitrust and Why is it a Barrier?

The antitrust laws govern our nation's policies on competition; their purpose is to protect competition and ensure a level playing field for consumers. The U.S. Department of Justice's (DOJ) Antitrust Division and the Federal Trade Commission (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.

Federal antitrust agencies have traditionally been skeptical of clinical integration 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 typically an essential ingredient in its success.

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 staff opinion letters that are expressly limited to the facts contained in the opinion letter and that warn 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.

What's the Solution?

The best 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. DOJ and FTC have issued such user-friendly and officially backed guidance in the past, and, in their 1996 Statements of Antitrust Enforcement Policy in Health Care, promised to do so again when warranted. The *Statements* can be found at <http://www.usdoj.gov/atr/public/guidelines/0000.htm>.

We believe this approach is now warranted, and that Congress should instruct the antitrust agencies to issue guidance that clearly explains how caregivers can navigate the antitrust laws to create clinical integration programs.

In addition to guidance, Congress should extend the antitrust protections available under the National Cooperative Research & Production Act for innovative joint ventures to clinical integration arrangements. Those protections include removing the threat of criminal prosecution, limiting damages and allowing challenged arrangements to recover attorneys fees and costs when they are vindicated in court. Guidance coupled with these protections would help to remove antitrust impediments to clinical integration.



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THE ETHICS IN PATIENT REFERRALS ACT (THE 'STARK' LAW)

What is this Law and Why is it a Barrier?

Usually called the Stark law, it was originally enacted to ban doctors from referring patients to facilities in which the doctor has a financial interest (known as self-referral). However, a 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 Stark law requires that compensation for health care providers be fixed in advance and paid only for hours worked. As a result, payments that are tied to achievements in quality and efficiency instead of hours worked do not meet the law's strict standards.

That means a hospital or clinic that rewards a doctor, and the doctor who earns the reward, for following protocols that guide the clinical integration program, can be found in violation. For example, a doctor who receives a bonus as part of a clinical integration program that helps patients manage their diabetes according to a well-designed medical protocol, risks being in violation of the Stark law.

The law is so strict that, in order to launch demonstration projects supporting clinical integration, the Centers for Medicare & Medicaid Services (CMS) had to waive the law. Without this waiver, a program in which hospitals shared cost savings with non-employed physicians who participated in a well-designed effort to enhance quality and efficiency would not have been possible.

Those found in violation of the law face severe consequences. In addition to civil penalties, providers can be barred from serving Medicare, Medicaid and other federal program patients for years, effectively shutting down the hospital and ending the doctors' careers.

What's the Solution?

The best solution is to return the Stark law to its original focus of regulating self-referral to physician-owned entities. This could be done 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.



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THE CIVIL MONETARY PENALTY LAW

What is the Law and Why is it a Barrier?

The Civil Monetary Penalty (CMP) law prohibits hospitals from rewarding physicians for reducing or withholding services to Medicare or Medicaid patients. The prohibition was established in the 1980s in response to concerns that Medicare patients served under the new prospective payment system for hospitals might not receive the same level of services as other patients.

The Department of Health and Human Services' 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.

Those found in violation face severe consequences. Penalties range from \$2,000 per patient affected to \$50,000 for other types of violations. In addition to civil penalties, providers can be barred from serving Medicare, Medicaid and other federal program patients for years, effectively shutting down the hospital and ending the doctors' careers.

An illustration of how CMPs, and the OIG's interpretation of them, impede clinical integration comes from a recent court decision. Finding that the Centers for Medicare & Medicaid Services lacked the authority to waive the CMP, the court forced CMS to terminate a demonstration project that had been designed specifically to improve the efficiency of surgical services.

What's the Solution?

The CMP law should be amended to make clear it applies only to the reduction or withholding of *medically necessary* services.



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THE ANTI-KICKBACK LAW

What is the Law and Why is it a Barrier?

The anti-kickback law's main purpose is to protect patients and federal health programs from fraud and abuse. The law states that anyone who knowingly and willfully receives or pays anything of value to influence the referral of federal health program business, including Medicare and Medicaid, can be held accountable for a felony. Today, the law has been stretched to cover any financial relationship between hospitals and doctors.

If, as part of a clinical integration program, a hospital rewards a doctor for following evidence-based clinical protocols, the reward could be construed as violating the anti-kickback law. That is because, technically, such a reward could influence a doctor's order for treatment or services. The law carries both civil and criminal penalties and can result in both the hospital and the doctor being barred from Medicare, Medicaid and other federal programs ... effectively shutting down the hospital and ending the doctor's career.

The Department of Health and Human Services' Office of Inspector General can protect good medical practices by issuing an advisory opinion. However, advisory opinions are strictly limited to

the facts in the letter delivering the opinion, and to the person making the official request for that opinion. They do not protect other clinical integration programs that want to engage in the *very same activity*.

And Congress, recognizing that the anti-kickback statute sometimes thwarts good medical practices, has periodically created "safe harbors" to protect those practices. However, there is no safe harbor for clinical integration programs that reward physicians for improving quality.

What's the Solution?

Congress should create a safe harbor for clinical integration programs. The safe harbor should allow all types of hospitals to participate, establish core requirements to ensure the program's protection from anti-kickback charges, and allow flexibility in meeting those requirements so the programs can achieve their health care goals.



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THE IRS

How is the IRS a Barrier to Clinical Integration?

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 difficulty arises because not every payment from a tax-exempt hospital to a tax-paying doctor violates the tax code and IRS rules. But, until the IRS issues guidance on the subject, tax-exempt hospitals have no assurance about how the IRS will rule in a particular situation, including on payments as part of a clinical integration program. Since the IRS has the power to revoke a hospital's tax exemption or impose large penalties, known as intermediate sanctions, uncertainty about how the IRS will rule can be a significant deterrent to clinical integration.

For example: To facilitate the flow of critical patient information – one of the past two administrations' highest priorities – the Department of Health and Human Services (HHS) changed its rules to allow hospitals to share software and Internet connectivity services with doctors. However, it took months of discussion before the IRS provided concrete assurance to tax-exempt hospitals that providing financial assistance to help doctors purchase software and connectivity services, which was clearly allowed under HHS rules, would not violate IRS rules.

What's the Solution?

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. A Revenue Ruling would have greater impact, because it would provide explicit examples of how the IRS would apply its rules to specific clinical integration arrangements.

