

# Shaping the Future for a Healthier America

## Clinical Integration

### Background

Today's health care system is fragmented and complex making it hard for patients to get the care they need at the right time and in the right setting. Clinical integration holds the promise of greater quality and improved efficiency in delivering patient-centered care. 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.

Hospitals seeking greater clinical integration first need to overcome the legal hurdles presented by the antitrust, Stark, Civil Monetary Penalty and anti-kickback laws and the Internal Revenue Code. [See chart of barriers to clinical integration.]

### AHA View

Delivering care that is more efficient, effective and patient-centered requires a team effort. That effort has been complicated or even stymied by various legal barriers to clinical integration. Over the years, many hospitals have made tremendous strides in improving coordination over the care continuum, while others have struggled; many 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. To that end, the AHA is advocating for 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. This approach was championed late last year by Sen. Herb Kohl (D-Wis.), chairman of the Judiciary Committee's Subcommittee on Antitrust, Competition Policy and Consumer Rights, in a letter to the agencies, and by a group of Democratic freshmen senators.

**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 Law.** The Civil Monetary Law also has strayed from its original intent to prohibit hospitals from rewarding physicians for reducing or withholding necessary services to Medicare or Medicaid patients. Today's interpretation prohibits any incentive that tailors the care delivered to evidence-based quality guidelines or similar patient care plans. 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 willingly 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 caregivers.

**IRS Rules.** Internal Revenue Service (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 doctors. 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 doctors for improving quality and efficiency do not violate IRS regulations.

**Other.** 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.

## Chart of Legal Barriers To Clinical Integration and Proposed Solutions

Law	What is prohibited?	The concern behind the law	Unintended consequences	How to address?
<b>Antitrust (Sherman Act §1)</b>	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.
<b>Ethics in Patient Referral Act (“Stark law”)</b>	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.
<b>Anti-kickback law</b>	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
<b>Civil Monetary Penalty</b>	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
<b>IRS Tax-exempt laws</b>	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
<b>State Corporate Practice of Medicine</b>	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.
<b>State insurance regulation</b>	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
<b>Medical Liability</b>	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