American Hospital Association

Clinical Integration

Background

The Patient Protection and Affordable Care Act (ACA) provides limited opportunities for providers to better integrate care to serve Medicare and Medicaid beneficiaries. To enable the clinical integration that is essential to improve the efficiency and effectiveness of the health care delivery system, regulatory oversight of the financial relationships between hospitals and physicians must change.

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. Over the years, many hospitals have made tremendous strides in improving coordination across the care continuum, while others have been challenged; some hospitals have focused their efforts on privately insured patients to avoid the legal entanglements associated with government reimbursement. Hospitals seeking greater clinical integration first need to overcome the legal hurdles presented by antitrust, patient referral (Stark), civil monetary penalty (CMP) anti-kickback laws, the Internal Revenue Code and many others. [See chart of barriers to clinical integration.]

AHA View

The development of accountable care organizations (ACOs) as part of the Medicare Shared Savings Program marked a historic regulatory effort among several federal agencies to achieve the goal of better coordinated care. In a major win for hospitals, the antitrust agencies abandoned their proposed requirement for mandatory antitrust review before hospitals could even apply for the ACO program, and instead offered limited guidance for all ACOs. Significantly, the waivers from the fraud and abuse laws for ACOs go well beyond the very limited protections proposed by the Centers for Medicare & Medicaid Services and the Department of Health and Human Services' Office of Inspector General.

While three of the four federal agencies made significant strides with respect to ACOs, it is disappointing that none went further to include any clinically integrated arrangements among providers. The AHA will continue to urge agencies to go farther and to remove barriers beyond ACOs so all patients have the benefit of clinically integrated care from organizations providing accountable care.

To that end, the AHA advocates the following changes:

Antitrust. Antitrust guidance is narrowly and technically drafted without any binding effect; as a result, caregivers can neither readily understand the guidance nor completely rely on it. The AHA has advocated that the antitrust agencies – the Department of Justice's Antitrust Division and the Federal Trade Commission – issue more comprehensive, user-friendly guidance that clearly explains what issues must be resolved to ensure that clinical integration programs comply with antitrust law.

Patient Referral (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, to limit practically any financial relationship between hospitals and physicians. The law's 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 Penalty Law. The CMP law is a vestige of concerns raised in the 1980s that Medicare patients might not receive the same level of services as other patients after the inpatient hospital prospective payment system bundled multiple services under a single Diagnosis Related Group, or DRG. In today's environment, the CMP is impeding clinical integration programs. While health reform is about encouraging the use of best practices and clinical protocols, using incentives to reward physicians for following best practices and protocols can be penalized under current enforcement of the CMP law. 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 willfully 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 negatively affects clinical integration. The AHA is working for broader "safe harbor" language and core requirements that provide reasonable flexibility to hospitals and caregivers.

Internal Revenue Service (IRS) Rules. The 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.

CHART OF LEGAL BARRIERS TO CLINICAL INTEGRATION AND PROPOSED SOLUTIONS

Law	What is prohibited?	The concern behind the law	Unintended consequences	How to address?
Antitrust (Sherman Act §1)	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 precompetitive, innovative arrangements because they are uncertain about antitrust consequences	More comprehensive user-friendly guidance from antitrust enforcers to clarify when arrangements will raise serious issues.
Ethics in Patient Referral Act ("Stark Law")	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
Anti-kickback Law	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
Civil Monetary Penalty	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
IRS Tax-exempt Laws	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 clear and user-friendly guidance providing explicit examples of how it would apply the rules to physician payments in clinical integration programs
State Corporate Practice of Medicine	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
State Insurance Regulation	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
Medical Liability	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

This table appears in the AHA *TrendWatch* report "Clinical Integration − The Key to Real Reform."