

## Delivery System Reform Programs

### Background

Hospitals, health systems and payers are adopting delivery system reforms to better align provider incentives to improve care coordination and quality, and reduce costs. These reforms include forming accountable care organizations (ACOs), bundling services into discrete episodes of care, developing new incentives to engage physicians in improving quality and efficiency, and testing payment alternatives for vulnerable populations. Private payers and large employers are working with hospitals and health systems to pursue these models. On the federal level, many of these activities are being coordinated within the Center for Medicare & Medicaid Innovation (CMMI), which was created by the *Patient Protection and Affordable Care Act* (ACA). The CMMI, with access to \$1 billion annually from 2011-2020, is intended to serve as a vehicle for transforming the delivery and payment of health care services.

### AHA View

Our fragmented health care system is rapidly transforming to a delivery system where care is more integrated, providers are at more financial risk, and all elements of the system are more accountable to the public. The AHA is working to ensure that changes to health care delivery are implemented responsibly and improve care for patients and communities. The AHA urges the Centers for Medicare & Medicaid Services (CMS) to establish a reliable evaluation system to assess the impact of all delivery system reform programs and report to Congress on the approaches that warrant broader consideration. These programs should not be automatically implemented by law or regulation. A variety of projects with proper evaluation can determine what best serves patients' needs. The AHA's efforts around delivery system reform programs focus on the following:

**Accountable Care Organizations.** When CMS initially released its proposed rule governing the creation of ACOs under the Medicare Shared Savings Program, the hospital field was very concerned that the agency had created a program that was neither financially attractive nor operationally viable. At the AHA's urging, CMS made extensive revisions in the final regulation to improve the program. Most significantly, the final rule allows all participants to share in first-dollar savings and eliminates down-side risk for ACOs participating in one option of the program. The AHA also advocated that changes in the ACO program also apply to the CMMI's Pioneer ACO program. The Pioneer program allows providers to become Medicare ACOs that also have ACO arrangements with one or more private payers. Currently, there are more than 250 ACOs participating in the Medicare Shared Savings Program, representing a mix of hospital and physician-led organizations and covering 4 million lives. The CMMI also has given the green light to 32 Pioneer projects.

In conjunction with the rule, the Department of Justice (DOJ) and the Federal Trade Commission (FTC) issued a final Statement of Antitrust Enforcement Regarding Accountable Care Organizations, abandoning their proposed mandatory antitrust review before hospitals could even apply for the ACO program and

replacing it with guidance applicable to all ACOs. The guidance said the agencies will “vigilantly” monitor complaints about anti-competitive behavior and all ACOs’ competitive conduct will be evaluated under the “rule of reason,” which takes pro-competitive benefits into account. In addition, CMS and the Department of Health and Human Services (HHS) Office of Inspector General issued an interim final rule with comment period that created five waivers that go beyond the limited protections offered in the proposed rule to provide protection from fraud and abuse laws for hospitals and other providers considering participation in an ACO. While these protections are a good first step, the AHA continues to urge broader federal regulatory reforms to help providers continue the movement toward clinical integration approaches to care delivery (see Clinical Integration section below).

**Bundled Payments.** Bundled payment, where providers are reimbursed a set fee for an episode of care, has the potential to create consistent, efficient high-quality care. Under the ACA, HHS must establish a five-year, voluntary pilot bundling program beginning in 2013 to test different models of bundling to determine what works before broad adoption. The program is to include 10 conditions representing a mix of chronic, acute, surgical and medical conditions. In preparation for the pilot, more than 400 hospitals and health systems have participated in CMMI’s Bundled Payments for Care Improvement initiative. Participants selected one of four different bundling models that range from inpatient-only services, to post-acute only services, to services that span the full care continuum. These organizations will have a six-month risk-free period before making a final decision to continue participation under a risk-based contract or withdraw from the pilot.

The AHA conducted extensive data analysis to help hospitals better understand the intricacies of a bundled payment system and to develop policy recommendations to CMS on the national bundled payment pilot. (Refer to the AHA Issue Brief, “Moving Towards Bundled Payment” for more information.) Chief among the issues addressed include:

- Identifying which episodes are well-suited to payment bundling based on their prevalence and expense to the Medicare program, the level of variation in program payment, and the availability of evidence-based care guidelines;
- Developing the case for risk-adjustment for factors that cause substantial variation in episode payments, such as beneficiary demographic and clinical characteristics, and facility characteristics;
- Understanding care pathways including how readmissions and patient placement at discharge affect episode costs.

**State Integration Activities.** The ACA created the Medicare-Medicaid Coordination Office within CMS to improve the quality and efficiency of caring

for dual-eligible beneficiaries. These beneficiaries are low-income seniors and younger persons with disabilities who are enrolled in both Medicare and Medicaid. This population accounts for a disproportionate amount of health care spending in comparison to non-dually eligible Medicare or Medicaid beneficiaries. The Coordination Office's Financial Alignment Initiative allows states to design and implement demonstration programs to better coordinate care for dual-eligible beneficiaries; 26 states have submitted proposals to CMS. All proposed programs are required to incorporate Medicare and Medicaid primary care, acute care, behavioral health and long-term supports and services through either a capitated or a managed-fee-for-service model. As of March 2013, five states (California, Illinois, Massachusetts, Ohio and Washington) have been accepted to participate, while other states' applications are under review by CMS.

**Medical Homes.** Medical homes offer a new and promising approach to providing comprehensive primary care to patients in a highly coordinated manner. While not a new concept, medical homes received enhanced attention during the health care reform debate. A provision in the ACA provides grants for capitated payments to primary care providers that organize into interdisciplinary health teams.

Medicare Medical Homes. The CMMI's Comprehensive Primary Care initiative is a multi-payer initiative that offers bonus payments to primary care doctors who better coordinate care for their patients. Primary care practices that choose to participate in this initiative are given resources to better coordinate primary care for their Medicare patients. Currently, there are seven participating sites across the country, representing more than 2,300 providers caring for about 315,000 Medicare beneficiaries.

Medicaid Medical Homes. The ACA states that Medicaid beneficiaries are potentially eligible for medical home services if they have two chronic conditions, or have one chronic condition and are at a high level of risk of a second, or have been diagnosed with a mental health condition. States receive a 90 percent federal match rate for medical home services during the first two years a state medical home plan is in effect; states also may receive federal Medicaid matching funds for expenditures up to \$500,000 for medical home development activities. Eight states (Idaho, Iowa, Missouri, New York, North Carolina, Ohio, Oregon and Rhode Island) have received federal approval as of March 2013. The majority of states are reimbursing medical homes at a per member per month capitated rate and have encouraged the utilization of health information technology to facilitate care coordination.

**Clinical Integration.** Meaningful health care reform, and the quality and efficiency improvements it promises, is built around the teamwork clinical integration encourages. 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) and anti-kickback laws as well as the Internal Revenue Code and many others.

The development of ACOs as part of the Medicare Shared Savings Program marked an historic regulatory effort among several federal agencies to achieve the goal of better coordinated care, as discussed above. While some of the federal agencies (e.g., DOJ-FTC antitrust guidance) made significant strides with respect to ACOs, it is disappointing that none went further to include any clinically integrated arrangements among providers. In fact, in a recent H&HN Daily e-newsletter, a former DOJ acting assistant attorney general in the antitrust division, Sharis Arnold Pozen, called on the FTC and DOJ to issue additional guidance. Pozen urges the agencies to expand antitrust safety zones, clarify bounds of strict per se unlawfulness and evaluate the methodology for defining market share. The AHA continues to urge the agencies to go further and to remove barriers beyond ACOs so all patients have the benefit of clinically integrated care from organizations providing accountable care. The chart on page 5 outlines the various barriers to clinical integration that are the focus of AHA advocacy.

## 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 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.
<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 clear and user-friendly 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

This table appears in the AHA *TrendWatch* report “Clinical Integration – The Key to Real Reform.”