



# TRENDWATCH

## Clinical Integration – The Key to Real Reform

Regardless of what legislation ultimately passes Congress, many policymakers recognize that systemic changes are needed in how health care is delivered in the United States. Anything less than systemic change may alter the health care system around the edges, but will not achieve the meaningful reform that expands coverage, improves quality and care coordination, rewards effective and efficient care, promotes innovation, and helps control cost. And as the AHA's *Health for Life: Better Health, Better Health Care* initiative has described,<sup>1</sup> achieving greater clinical integration in care delivery is essential to the system change needed to achieve these goals.

Some hospitals already are using a broad range of approaches to integrating more closely with physicians and other health care providers. Clinical integration spans the spectrum from initiatives aimed at achieving greater coordination around a single clinical condition or procedure to fully-integrated hospital systems with closed 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 page 11 for a chart of barriers to clinical integration.] The case studies discussed here demonstrate

the range of clinically-integrated hospital initiatives in existence today and illustrate how arduous and challenging the legal barriers can be. While some of these barriers to clinical integration are surmountable, they can force hospitals and physicians to spend substantial time and expense in implementing solutions.

Clinical integration can improve the quality and efficiency of our health care system; however, current legal barriers frustrate reform efforts. The nation needs laws and regulations that encourage or at least do not impede our progress in improving care and care delivery for patients.

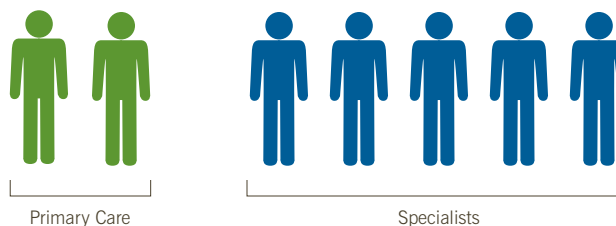
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## The Growing Importance of Clinical Integration

The U.S. health care delivery system is fragmented in several significant ways. First, most office-based physicians continue to practice in solo or small groups.<sup>2</sup> Moreover, to the extent that physicians are moving to larger practices, it is generally to form single specialty practices, and not the multi-specialty groups that are best able to support care coordination.<sup>3</sup> A study of Medicare claims from 2000–2002 found that

### Medicare patients see a multitude of physicians.

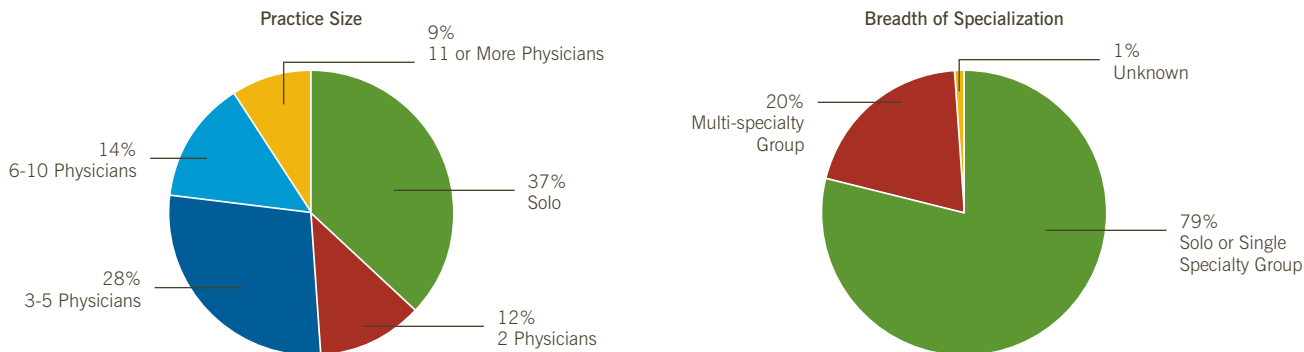
Chart 1: Average Number of Physicians Medicare Beneficiaries Visit Annually



Source: Pham, H, Schrag, D., et al. (2007). Care Patterns in Medicare and Their Implications for Pay for Performance. *The New England Journal of Medicine*, 356; 1130-1139.

Office-based physicians continue to practice in solo or small groups.

Chart 2: Distribution of Office-based Physicians



Source: Characteristics of office-based physicians and their practices: United States, 2005–2006. *Vital and Health Statistics*. 13:1-34, Apr. 2008. Available at <[http://www.cdc.gov/nchs/data/series/sr\\_13/sr13\\_166.pdf](http://www.cdc.gov/nchs/data/series/sr_13/sr13_166.pdf)>

each year the typical Medicare beneficiary saw a median of two primary care physicians and five specialists, collectively working in four different practice settings.<sup>4</sup> Typical patients with multiple chronic conditions saw as many as three primary care physicians and eight specialists in seven different settings.<sup>5</sup> A study by the Robert Wood Johnson Foundation found that for every 100 Medicare patients treated, each primary care physician would typically have to communicate with 99 physicians in 53 practices to coordinate care.<sup>6</sup>

Second, the common model of hospital-physician relationships, as reflected in the organized medical staff, does not assure the optimal level of care coordination between a hospital and its independent physicians.<sup>7</sup> In this

common model, physicians use hospital facilities and rely on hospital staff to provide their services, but the medical staff is not employed by the hospital. As a result, hospitals and physicians have limited tools they can use to positively influence each other’s practice patterns to achieve optimal patient outcomes, especially since most forms of economic incentives may run afoul of Stark, anti-kickback and the Civil Money Penalty laws that apply to Medicare and Medicaid patients. [See chart of potential barriers to clinical integration.]

Third, care is fragmented because patients receive services in several locations, including freestanding ambulatory sites and post-acute settings or their homes. Some of these settings may be affiliated with a hospital, while others may

compete or offer complementary services. This fragmented care can adversely impact quality and efficiency. Without adequate care coordination, patients are more likely to receive duplicative diagnostic testing, have adverse prescription drug interactions and have conflicting care plans. These scenarios add to the challenges patients face in navigating the health care delivery system at a time when they are most vulnerable. Fragmentation also frustrates attempts by hospitals and physicians to improve the quality and efficiency of care. Physicians in small groups are less likely to be able to afford the information technology to implement electronic health records and similar technologies. They also will have more difficulty in sharing “best practices” and accessing peer data for use as benchmarks.

### What Is Clinical Integration?

Clinicians and policymakers have drafted several definitions of clinical integration. The definitions generally focus on efforts that involve collaboration among different health care providers and sites to ensure higher quality, better coordinated and more efficient services for patients. In the context of antitrust,

the Federal Trade Commission (FTC) and Department of Justice (DOJ) have discussed clinical integration in considering when joint negotiations by health care providers with health plans would be permissible. Traditionally, providers had to demonstrate they were financially integrated (e.g., furnishing

services under capitation) in order to come together and jointly negotiate with health plans. In addition to financial integration, the FTC and DOJ also now take clinical integration (nonfinancial integration) into account in examining whether providers may jointly negotiate with health plans.

## Some Definitions of Clinical Integration

“Clinical integration facilitates the coordination of patient care across conditions, providers, settings, and time in order to achieve care that is safe, timely, effective, efficient, equitable, and patient-focused. To achieve clinical integration our nation’s health care system needs to promote changes in provider culture, redesign payment methods and incentives, and modernize federal laws.”

Health for Life Expert Advisory Group on Clinical Integration

“[Clinical] integration can be evidenced by [a physician] network implementing an active and ongoing program to evaluate and modify practice patterns by the network’s physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality. This program may include: (1) establishing

mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care; (2) selectively choosing network physicians who are likely to further these efficiency objectives; and (3) the significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.”

Department of Justice and Federal Trade Commission, *Statements of Antitrust Enforcement Policy in Health Care*, Statement 8 (1996)

“Clinical integration is the extent to which patient care services are coordinated across people, functions, activities, and sites over time so as to maximize the value of services delivered to patients.”

Stephen M. Shortell, Robin R. Gillies, David A. Anderson, *Remaking Health Care in America*, 2000

“In essence, clinical integration involves providers working together in an interdependent fashion so that they can pool infrastructure and resources, and develop, implement and monitor protocols, “best practices,” and various other organized processes that can enable them to furnish higher quality care in a more efficient manner than they likely could achieve working independently. Such programs can enable primary care physicians and specialists of all kinds to work more closely with each other in a coordinated fashion.”

*Guidelines for Clinical Integration*, a Working Paper Prepared for AHA by Hogan & Hartson, LLP, April 2007

## IT Infrastructure Is Required

A key component to most clinical integration strategies involves greater information sharing across providers. In 2009 Congress authorized \$36 billion to fund an electronic health information infrastructure when it passed the *Health Information Technology for Economy and Clinical Health (HITECH) Act*, as part of

the stimulus package. Among other things, beginning in 2011 HITECH will provide additional funding through Medicare and Medicaid to providers who are “meaningful users” of electronic health records.

Under a limited exception to the Stark and anti-kickback laws and guidance from the Internal Revenue

Service (IRS), hospitals are able to assist physicians in developing electronic health records. Additional flexibility would be helpful; the exception does not allow hospitals to share hardware or completely subsidize connectivity and software. Despite these limitations, systems like Sutter Health have successfully expanded use

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*from the field*

“Most physicians are in small practices. No matter what happens in health care reform, that won’t change any time soon. Clinical integration connects the dots and enables these physicians to meet the needs of the community.”

Lee Sacks, M.D., President, Advocate Physician Partners

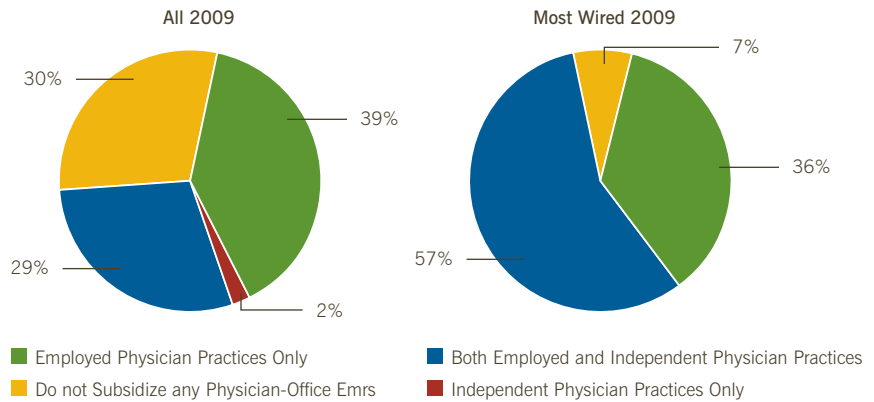
of information technology as a result of the lowered regulatory barrier.

While limited regulatory relief helped increase IT sharing, as Chart 3 demonstrates, there is still a huge opportunity for hospitals and physicians to establish the type of information sharing that will support greater clinical integration.

Other steps that could facilitate information sharing include development of clinical guidelines and other measures to help caregivers assess their effectiveness in delivering appropriate care.

**Hospital subsidies for physician office electronic medical records (EMRs).**

Chart 3: The Percentage of Respondents in Each Benchmark Group that Subsidize Physician-office EMRs



Source: *Hospitals & Health Networks' Most Wired Survey and Benchmarking Study, March 2009*

**Sutter Health – Using Information Technology for Clinical Integration**

Sutter Health has a long-standing commitment to investing in innovation that advances clinical integration across the care continuum. The health system utilizes fully integrated MIDAS software across its 25 acute care facilities to consistently report and measure quality indicators as well as standardize case and utilization management functions. Sutter also designed a fully integrated

electronic health record (EHR) system (from the Epic platform) that facilitates care coordination across care settings and geographic locations. For example, EHR technology is available in Sutter’s retail urgent care clinics – Sutter Express Care – that provides timely information to primary care physicians that their patients were seen and addresses care follow-up that might be needed.

Similarly, Sutter offers remote connectivity to EHR data for community physicians who have referral relationships. Finally, the Sutter-affiliated Palo Alto Medical Foundation is researching the use of online services integrated with the electronic health record to further partner with and empower chronically ill patients to take an active role in managing their health.

**Using Payment Reforms to Promote Integration**

Policymakers increasingly are looking to payment reforms as a means to promote greater clinical integration. The Medicare Payment Advisory Commission’s (MedPAC) 2008 *Report to Congress* recommended replacing the current Medicare fee-for-service system with one that “would pay for care that spans across provider types and time (encompassing multiple patient visits and procedures) and would hold providers accountable for the quality of

care and the resources used to provide it. This new direction would create payment system incentives for providers that reward value and encourage closer provider integration, which would maximize the potential for tools such as pay for performance and resource management to improve quality and efficiency.”<sup>8</sup>

MedPAC suggested three approaches to help achieve these goals –medical homes, bundled payments and “accountable care organizations (ACOs).” These

suggestions are not entirely new; the Centers for Medicare & Medicaid Services (CMS) is conducting several Medicare demonstration projects to test payment and delivery reforms that rely on enhanced clinical integration. It is important to note that these projects have required waiver of various regulatory restrictions that otherwise would have prevented their implementation.

Interest in payment reforms to promote greater clinical integration has

increased over the past year, and is seen by many as integral to “bending the cost curve” to ensure meaningful and long-term health care reform.<sup>9</sup> In late December 2009, a group of freshmen senators sought to advance clinical integration by exploring ways to lower regulatory barriers. In a letter to the heads of DOJ’s Antitrust Division and the FTC, the senators asked the agencies to issue “clear and accessible guidelines on forming collaborative care models.”<sup>10</sup> In a separate letter, Sen. Max Baucus (D-MT) joined the senators in asking the Government Accountability Office to study and report on federal and state laws “that may impede or discourage” collaborative relationships among caregivers,

including Stark and anti-kickback laws.<sup>11</sup>

National health care reform proposals have called for demonstrations involving new patient care models, all of which involve greater clinical integration. For example, lawmakers have proposed a three-year pilot program on ACOs.

States are embarking on a similar path. Massachusetts’ Special Commission on the Health Care Payment System recently recommended that global payments with adjustments to reward accessible and high quality care become the predominant form of payment to providers. Such care would be provided through ACOs “composed of hospitals, physicians, and/or other clinician and non-clinician providers working as a team to manage both

the provision and coordination of care for the full range of services that patients are expected to need.”<sup>12</sup>

A demonstration project at Continuum Health Partners (CHP) in New York City offers another example of the type of cost and quality improvements that can be achieved by aligning hospitals and physicians through appropriate financial incentives. Preliminary results of CHP’s initial gainsharing program involving commercial patients (implemented before the Medicare demonstration was approved) indicated that participating physicians were able to achieve cost-savings of \$900 per admission, twice as much as physicians who did not participate in the program.

### Continuum’s Medicare Gainsharing Demonstration Project

Medicare currently is conducting several demonstration projects designed to test whether gainsharing – whereby a hospital shares some of the cost savings from increased efficiency with its physicians – can align incentives between hospitals and physicians to lead to improved quality and efficiency. One of these is being undertaken at two hospitals of Continuum Health Partners, Inc. (CHP), a six-hospital health care system in New York City. (Medical staff at these two demonstration hospitals includes both employed and independent physicians.)

#### ALIGNING INCENTIVES

A starting point in the CHP demonstration was the realization that not

only is there a tremendous variation in resource use among providers in different parts of the country – which has been widely-recognized – but that even within a single hospital there can be a wide variation in costs for treating the same severity-adjusted cases. Thus, CHP estimated that the cost variations for inpatient care for commercial patients of all its physicians eligible for a pay-for-performance program in 2007 was \$100 million. This was the difference between the amount spent on patients treated by physicians at the 25th percentile and those at the 75th percentile. This suggested the opportunity for very significant savings that, if shared, could be used to substantially align the

incentives of CHP and its physicians.

CHP’s program provides an incentive of up to 25% of the third-party payment to the “responsible physician” for each inpatient, to be determined based on improvement (compared to performance the prior year) and relative performance (compared to a “best practice norm” derived from peer providers in the CHP system). Among other things, to be eligible for incentive payments, physicians must meet or exceed certain quality thresholds, such as Medicare Core Measures, readmission rates, unplanned return to the operating room and timely completion of medical records. All data used for the program is both case-mix and severity-of-illness adjusted.

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*from the field*

“Crucial to clinical integration is giving physicians a real involvement in decision-making at the hospital. Physicians must be able to work with hospital administration to identify a shared set of goals for the enterprise – what do they want to accomplish together – and then they can together develop tactics to achieve those goals.”

Nick Wolter, M.D., CEO, Billings Clinic

**TACKLING REGULATORY HURDLES**

The program began in 2006 with only commercial patients because of restrictions under the civil monetary penalties, anti-kickback and Stark laws that would apply to Medicare and Medicaid patients. CMS granted a waiver to these restrictions starting in October 2008 as part of the Medicare Hospital Gainsharing Demonstration Project under Section 5007 of the *Deficit Reduction Act of 2005*. Congress explicitly granted CMS the authority to make such waivers after a federal court had ruled that a similar demonstration project initiated several years earlier could not proceed without a waiver of the gainsharing prohibition. (*Robert Wood Johnson University Hospital, Inc.*

*v. Thompson*, 2004 U.S. Dist. LEXIS 6893 (D.N.J. 2004))

Administrators involved with the program believe that it has great potential for savings, and that it could be replicated at other facilities nationwide. They caution that such efforts, in addition to waivers, require not only IT infrastructure, but dedicated work with physicians to demonstrate that by modifying practice patterns quality and efficiency can be improved. Gainsharing not only gives physicians an incentive to change their own practices, but also to identify ways in which the hospital can streamline its operations.

**ACHIEVING POSITIVE RESULTS**

CHP's initial data indicate that the average incentive for physicians was

\$96 on a medical case and \$140 on a surgical case. During the first two years of the program, CHP had a savings of approximately \$900 (a 12.5% decrease) per case for participating physicians. While some of the savings may be attributed to other hospital initiatives, a large portion can be attributed to the gainsharing initiative. A key component of this and similar programs is that the providers – as opposed to the government or payer – is responsible for allocating revenues and therefore assuring that incentives are appropriately aligned and that the efficiencies undertaken do not reduce the quality of the care provided to patients.

To position themselves for this new payment and competitive environment, hospitals are considering how they can increase the extent of their clinical integration, particularly with physicians on their medical staff. Clinical integration cannot

be achieved instantly. It requires leadership from both hospitals and physicians, development of an appropriate culture, organizational changes, support from payers, and a great deal of effort. It also requires sufficient infrastructure, which

includes not only hard assets such as information technology, but also staff such as advanced practice nurses who can work with physicians – and their staff – to develop and implement improvements and greater coordination in clinical processes.

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## The Clinical Integration Spectrum

Hospital efforts at clinical integration span a broad spectrum of arrangements. At one end are targeted initiatives by a hospital and a subset of its voluntary medical staff to address a particular clinical condition or procedure. For example, a hospital and its orthopedic surgeons work together on an initiative to reduce the costs of knee or hip implants by developing specific protocols and concentrate implant purchases from a smaller number of manufacturers. At the other end of the spectrum are health systems in which physician groups and hospitals are under the

same ownership or are otherwise fully integrated economically. There are arrangements at all points along the continuum. For example, hospitals in the “middle” of the spectrum would include those who employ a substantial number, but far less than all, of their physicians. Another example in the middle of the continuum would be a hospital that has a very active physician-hospital organization (PHO) that includes independent (non-employed) physicians who are involved in an extensive clinical integration program that covers a wide range of

initiatives and involves joint negotiations with health plans.

While some hospitals and physicians have long-established clinical integration approaches, others are just embarking in this area, often starting with more limited initiatives with the goal of expanding if these prove successful. Moreover, hospitals vary with respect to the extent to which they are integrated with other sites of service, such as home health care, post-acute care, long term care and hospice, as well as integration with payer functions through an affiliated or wholly-owned health plan.

## Efforts at clinical integration span a broad spectrum.

Chart 4: Clinical Integration Spectrum

Less Integrated

More Integrated

Bundled payment for single episode of care	Bundled payment for chronic care management	Clinically Integrated PHO	Medical staff includes both employed and independent physicians	Medical Staff includes only (or almost only) fully-employed physicians
<ul style="list-style-type: none"> <li>Fairview Health (Minneapolis)</li> <li>Geisinger Proven Care Program for Coronary Artery Bypass Graft Surgery (Danville, PA)</li> </ul>	<ul style="list-style-type: none"> <li>Fairview Health (Minneapolis)</li> <li>Sutter Health (California)</li> <li>Park Nicollet Health (Minneapolis)</li> </ul>	<ul style="list-style-type: none"> <li>Advocate Health Care (Chicago)</li> <li>Tri-State Health (Maryland)</li> </ul>	<ul style="list-style-type: none"> <li>Presbyterian Health (Albuquerque)</li> <li>Virginia Mason Hospital (Seattle)</li> <li>Geisinger Hospital (Danville, PA)</li> <li>Intermountain Health Care (Utah)</li> </ul>	<ul style="list-style-type: none"> <li>Cleveland Clinic (Ohio)</li> <li>Billings Clinic (Montana)</li> <li>Kaiser Permanente (multi-state)</li> </ul>

Source: American Hospital Association

### Fairview Health Services: Working with Four Different Physician Models

“The only way we can change the way care is provided is by working closely with the people who provide the care.”

“Regardless of what health care package passes, we need to change the way we pay for the care that is provided.

And the direction that we are going at Fairview will make sense no matter what payment model is adopted.”

Mark Eustis, CEO, Fairview Health Services

Fairview Health Services (FHS), which includes a major academic medical center in Minneapolis, has embarked on a number of innovations to improve care, such as, creating a “health home” to fundamentally change how primary care is furnished, developing a single electronic health record for the entire continuum of health services and expanding the use of virtual medicine. One innovation that focuses on greater clinical integration is the development of 12 “care packages,” each covering a set of clinical best practices for a particular clinical condition. These packages will create more consistent, high quality care, and also will involve a change to the payment system so that providers are paid based on a single fee covering the entire package of services, instead of being paid for each test or visit. Care packages range from chronic conditions (low back pain, diabetes, migraine) to

specific medical care (prenatal care) or surgical procedures (total knee replacement). Some of the packages are being developed at the request of specific employers, such as Target or 3M.

In implementing these innovations, FHS must collaborate with physicians who practice in four different arrangements with FHS:

- About 500 physicians, mostly primary care physicians, are employed by FHS
- About 700 physicians, mostly specialists, are in the University of Minnesota faculty practice plan
- About 1,000 physicians are in a PHO (some of whom are also employed by FHS or are in the faculty practice plan)
- About 1,500 physicians are in separate independent practices

These arrangements present different challenges and opportunities.

For example, to the extent the care packages involve financial incentives, they can raise gainsharing, Stark or anti-kickback issues that may be difficult to address for the physicians in independent practices (at least for Medicare and Medicaid patients), but are unlikely to present issues for the employed physicians. Similarly, antitrust should not be an issue if FHS wishes to negotiate payments on behalf of its employed physicians, but likely would preclude such negotiations on behalf of the faculty practice, independent or PHO physicians, unless the arrangement involves the requisite financial or clinical integration. Navigating the different rules that apply to different physicians depending upon the nature of their relationship to FHS can impede system-wide innovations that otherwise might be applied to the entire FHS medical staff.

## Presbyterian Healthcare Services: An Affiliated Large Multi-specialty Group Practice and Health Plan

“Our medical group provides us with an opportunity to innovate in providing care.”

Jim Hinton, President and CEO, Presbyterian Healthcare Services

Presbyterian Healthcare Services (PHS), headquartered in Albuquerque, New Mexico, is using its affiliated Presbyterian Medical Group (PMG) of 600 physicians and practitioners, eight hospitals across the state, and its affiliated Presbyterian Health Plan that serves 450,000 members statewide, to explore new ways to deliver health care.

While there are roughly the same number of independent physicians on the medical staff as in the employed medical group, PMG offers an advantageous environment to innovate to increase quality and efficiency. For example, Presbyterian is developing a pilot program to test a Medical Home initiative that will require

physicians to perform many services for which they would not be separately paid under the typical fee schedule. This approach would be difficult to implement with independent physicians who rely on fee-for-service reimbursement. This is not an obstacle, however, for physicians on salary in PMG, who also can be rewarded through payments that take into account the quality of patient outcomes and efficiency of services.

Once Presbyterian gains experience with the Medical Home, it can then roll out the concept to its independent physicians. In taking this next step, PHS can use its health plan to

structure quality performance-based payments to participating providers.

Many hospitals shed affiliated health plans that they developed in the 1990s. But Presbyterian believes that the experience that it is obtaining with its affiliated plan may serve it well to the extent health care reform encourages the development of “accountable care organizations” that will be responsible for providing a broad range of healthcare services to a defined set of patients.

Employed physicians and an affiliated health plan give Presbyterian more tools and greater flexibility to align incentives among the hospital and the provider community.

## Virginia Mason: Mostly Fully-employed Medical Staff

Virginia Mason Medical Center (VMMC) traces its roots to eight physicians who formed a group practice modeled after the Mayo Clinic and, in 1920, built an 80-bed hospital in Seattle. Today more than 440 physicians at Virginia Mason are employed by VMMC and account for about two-thirds of the hospital’s admissions. The remaining admissions are primarily from two other fully-integrated group practices, the Pacific Medical Centers (a 140-physician multi-specialty group) and Group Health Cooperative, a staff-model HMO.

Because a large majority of the medical staff is VMMC employees, it is

easier to align the physician and hospital interests. This has enabled VMMC to embark on an ambitious system-wide program to change the way it delivers care. Modeled on the Toyota Production System, it is called the “Virginia Mason Production System” (VMPS) and began in 2001. Utilizing VMPS, staff members make measurable improvements in safety, quality, service, staff and patient satisfaction, and cost performance.

VMPS uses a variety of strategies to improve efficiency, ranging from small-scale ideas tested and implemented immediately to long-range planning that redesigns new spaces and processes. The strategies involve

“kaizen” or continuous improvement activities, which are based on the view that staff who do the work know what the problems are and how best to find solutions. VMPS embraces the view that by measuring and standardizing performance, it is possible to substantially improve efficiency and quality. While some are skeptical that this approach – which is more readily identified with automotive assembly lines – can be adapted to deal with individualized patient care, VMMC is able to try it because so many of the medical staff are working under the integrated management of hospital and physician leaders.



VMPS initiatives have included the following:

- **A Patient Safety Alert System** to ensure situations that are likely to harm a patient are reported and investigated immediately, with complete commitment of all employees, including hospital staff, physicians, and senior medical leadership. The result has been an increase in patient safety and a decrease in medical claims.

- **One-stop Care for Cancer Patients**, which includes a redesigned cancer center to eliminate the need for patients to travel long distances in the hospital to obtain chemotherapy.

- **Evidence-Based “Bundles”** to improve care. VMMC had 34 cases of ventilator-associated pneumonia (VAP) in 2002. After implementing the ventilator bundle (a set of specific steps proven to reduce the incidence of VAP) in 2004, Virginia Mason

had only four cases. Compliance with bundle elements remains at or near 100 percent, with 0-3 VAP cases/year for the past two years.

Due to an overwhelming number of requests for Virginia Mason staff to share their knowledge in applying these principles to health care, VMMC established the Virginia Mason Institute to educate and train other health care providers in VMPS management techniques.

## Advocate Physician Partners: A Clinically Integrated PHO

“A key component to a successful program is to invest in physician leadership. At the end of the day, the doctors have to drive it – surrounded and supported by good management.”

Lee Sacks, M.D., President, Advocate Physician Partners

In metro Chicago, Advocate Health Care is the largest health system with eight acute hospitals and over 5,200 physicians on its medical staff. Through the Clinical Integration Program of Advocate Physician Partners (APP), the system collaborates with 3,400 of these physicians (of whom about 800 are employed by the system or one of its affiliates) in one of the largest clinical integration efforts in the nation.

Advocate’s program evolved from efforts by its PHOs to provide care on a capitated basis to HMOs. Advocate currently is implementing 37 key clinical initiatives that address clinical outcomes, efficiency, medical and technological infrastructure, patient safety and patient satisfaction. Physicians receive feedback in the form of quarterly “report cards” that are the basis of financial incentives which reflect performance both individually and at the PHO level. In 2008,

participating Advocate physicians earned \$28 million in incentive payments, or about \$9,000 per physician. Advocate has achieved significant clinical and efficiency results, which it summarizes in an annual “Value Report” that is given to employers and payers, and is available at [www.advocatehealth.com](http://www.advocatehealth.com). Every major health plan in the Chicago area contracts with APP and participates in its clinical integration program.

Implementing the clinical integration program has required substantial resources over an extended time period. Advocate estimates that the program currently employs 24 dedicated FTEs, and also piggybacks on about \$100 million in investments in IT infrastructure that Advocate has made in electronic health records, an eICU, and a computerized patient order entry system. In a new initiative announced in early September, APP will contribute an additional \$15,000

to each of its physicians who agreed to install the ambulatory electronic record selected by APP. This contribution, along with money from the federal stimulus package, should help ensure that most APP physicians use a common electronic medical record system in their office. This should enable APP to more efficiently coordinate care.

The clinical integration program had to withstand a multi-year antitrust investigation by the Federal Trade Commission that ultimately declined to challenge Advocate’s joint negotiations with health plans on behalf of its independent physicians. In July 2007, FTC Commissioner Pamela Jones Harbour spent an entire day visiting Advocate to gain a better understanding of its program, and afterwards reported back “that clinical integration, when done right, has tremendous potential to create efficiencies and improve health care quality.”<sup>13</sup>

## Legal Barriers to Clinical Integration

Hospitals face a number of legal and regulatory barriers as they seek to improve clinical integration with their physician staffs. Perhaps the biggest barrier to innovative arrangements are the provisions of the Civil Monetary Penalty statute that prohibit gainsharing, and the Stark and anti-kickback laws – as they apply to Medicare and Medicaid patients; in some states, there may be similar state prohibitions that apply to other patients. These laws are aimed at curbing arrangements that involve financial incentives to providers that could result in either over-utilization, under-utilization (i.e., the withholding of necessary items or services), or referrals

that are based on considerations other than what might be in the best interest of the patient. While well intended, the statutes are either broadly written or interpreted so as to also prohibit – or create uncertainties about – a broad range of benign arrangements that could better align hospitals and physicians and pose little or no potential risk of abuse.

Providers also have expressed reluctance to engage in clinical integration because of perceived antitrust risks. The antitrust concern arises when providers who are in independent practices and offer competing items or services jointly negotiate with payers. But if such joint

negotiations are needed for the clinical integration to succeed, and the providers collectively lack market power, the effort should survive antitrust scrutiny. Nevertheless, because the antitrust laws do not provide bright-line rules in this area, uncertainty about whether their clinical integration efforts would attract antitrust review has deterred some hospitals and physicians from embarking on innovative arrangements.

Other legal concerns can arise from IRS provisions applying to tax-exempt organizations, state corporate practice of medicine statutes, state insurance regulations and malpractice litigation. See Chart 5.

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## Conclusion

While there are divergent views about the role of government in health care reform, there is a growing consensus that there is a need for significant health care delivery change, and that such change must involve increased clinical integration among health care providers. Clinical integration holds the promise of greater quality and improved efficiency in delivering patient-centered care. Such efforts are likely to be particularly important if, as is widely expected, government and private health plans change to payment methodologies

that put a premium on the ability of providers to collaborate effectively.

There is no single path to clinical integration. Rather, hospitals and physicians have embarked on clinical integration in a variety of ways, and are likely to develop many more approaches in the future. These efforts have required hard work, development of a culture that facilitates alignment, investment in infrastructure, support from health plans and leadership on the part of both the hospital and physicians. Some have proceeded despite legal and regulatory

barriers that have made it more difficult for hospitals and physicians to collaborate. The AHA and others have urged that steps be taken to reduce these barriers, including changes to anti-kickback, Stark and Civil Money Penalty prohibitions, as well as greater guidance from the antitrust agencies and the IRS regarding their review of clinical integration initiatives. Such regulatory reforms are important to ensure that hospitals and other health care providers can engage in the type of clinical collaborations that can significantly improve U.S. health care.

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*from the field*

“To end the current fragmentation, waste and complexity, physicians and other care providers should be rewarded, through financial and nonfinancial incentives, to band together into traditional or virtual organizations that can provide the support they need to practice 21st century health care.”

The Commonwealth Fund, “A High Performance Health System for the United States” (November 2007)

## A look at the legal barriers to clinical integration and proposed solutions.

Chart 5: Legal Barriers 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

- Other than removing legal and regulatory barriers, how can policymakers encourage doctors, hospitals and other caregivers to work together to provide more coordinated care to patients?
- Is greater financial, technical or other support required to facilitate information sharing among doctors, hospitals and other caregivers that are engaged in efforts to better coordinate care and/or track the results of coordinated care?
- How can we incorporate learnings from clinical integration models underway in the private-sector with those from government-initiated clinical integration pilot projects to help accelerate the pace of change to more coordinated care?

### ENDNOTES

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