American Hospital Association®

Legal (Fraud and Abuse) Barriers To Care Transformation and How to Address Them

Wayne's World

Introduction

Hospitals, physicians and other health care providers and professionals are facing significant changes in how they practice and are reimbursed for the care they provide. Instead of payment based on volume (the number of services provided), payment is increasingly tied to value. Public and private payers are using financial incentives to drive behavior to achieve quality outcomes, clinical efficiencies and cost savings – the goals of value-based models. At the same time, the legal framework controlling how, if at all, hospitals and physicians can share the risks and rewards in achieving the goals of these new models has remained static.

In the 2015 Medicare Access and CHIP Reauthorization Act (MACRA), Congress called for a re-examination of the fraud and abuse laws and requested recommendations for legislative changes. Hospitals welcome Congress' recognition of the need for change. In this report, we respond to that call by **identifying the practical barriers to achieving the goals of a value-based payment system created by current laws and recommending specific legislative changes.** We begin with an overview of the payment and legal landscapes. We then describe how specific types of collaborative arrangements between hospitals and physicians are being impeded and propose the creation of a "safe harbor" under the Anti-Kickback Statute and reforms to the Stark Law to foster and protect arrangements designed to achieve the goals of payment-for-value programs. In addition, we address how outdated barriers limit hospitals' ability to advance the health and wellness of patients. We conclude by following a hypothetical patient who could and should be greatly benefiting from collaboration among his providers but is prevented from doing so by outdated regulatory barriers in desperate need of modernization.

> **"…the Secretary of Health and Human Services, in consultation with the Inspector General of the Department of Health and Human Services, shall submit to Congress a report with legislative recommendations to amend existing fraud and abuse laws, through exceptions, safe harbors, or other narrowly targeted provisions, to permit gainsharing or similar arrangements between physicians and hospitals that improve care while reducing waste and increasing efficiency."**
> – The Medicare Access and CHIP Reauthorization Act of 2015

Evolving Payment Models to Reward Value

In pursuit of a value-based payment system, Congress has created alternative payment models (APM), such as the Medicare Shared Savings Program (MSSP), and has authorized the creation of other models by the Secretary of Health and Human Services (HHS) as demonstration programs. Also, in the MACRA, Congress changed the reimbursement system for physicians, tying a greater percentage of physician fee-for-service payment to value-based outcomes and creating incentives to encourage increased physician participation in APMs.

As of December 2014, the Center for Medicare & Medicaid Innovation (CMMI) reported having launched 22 new payment and service delivery initiatives aimed at reducing expenditures and enhancing the quality of care for beneficiaries. More than 2.5 million Medicare, Medicaid and CHIP beneficiaries were estimated to be, or would soon be, receiving care furnished by providers participating in the models.

In early 2015, the HHS Secretary announced specific targets for Medicare payments tied to value and made through APMs: 85 percent of Medicare fee-for-service payments would be tied to quality or value by the end of 2016, and 90 percent by the end of 2018; 30 percent of Medicare payments would be made through APMs by the end of 2016, and 50 percent by the end of 2019. In March of this year, HHS announced it had met its target ahead of schedule: ***"An estimated 30 percent of Medicare payments are now tied to alternative payment models that reward the quality of care over quantity of services provided to beneficiaries."*** The clear direction of these initiatives is to move Medicare to a value-based payment model.

Legal Barriers to Delivering Value

The new payment models create accountability for the health of a patient beyond an inpatient admission, an outpatient procedure or an office visit – a responsibility that can be achieved only if hospitals, physicians and other health care providers and professionals work as a team, which means they need both common goals and aligned incentives. The coordinated care brought about by these new payment models transforms the prior system of care,

which was built on silos of medical services—where physicians, hospitals and other providers each performed separate and detached components of the patient's care, where each provider was paid separately based on the amount of services it provided, and where financial relationships between providers were viewed with rigid scrutiny. Yet the Stark, Anti-Kickback and Civil Monetary Penalty (CMP) Laws (collectively the fraud and abuse laws) presume that any shared financial incentive is suspect and are designed to keep hospitals and physicians in the silos on which the fee-for-service payment models were built. Implementation of the APMs to date has been feasible only because Congress authorized, and the HHS Secretary has repeatedly issued, waivers of the fraud and abuse laws specific to those APMs. In a recent promising development, a report from the Senate Committee on Finance, Majority Staff, acknowledged that hospitals attempting to follow and build on these alternative models are facing fierce regulatory barriers to implementing incentives for innovative care delivery. "The Stark Law has become increasingly unnecessary for, and a significant impediment to, value-based models that Congress, the Centers for Medicare & Medicaid Services (CMS), and commercial health insurers have promoted. The risk of overutilization, which drove the passage of the Stark Law, is largely or entirely eliminated in alternative payment models."

10 Fraud and Abuse Waivers Issued by HHS to Enable APMs

1. Dec. 8, 2011, Pioneer Accountable Care Organization (ACO) Model;
2. Sept. 13, 2012, Bundled Payment for Care Improvement (BPCI) Model 1;
3. July 26, 2013, BPCI Model 2;
4. July 26, 2013, BPCI Model 3;
5. July 26, 2013, BPCI Model 4;
6. Jan. 20, 2015, Health Care Innovation Awards (HCIA) Round Two;
7. July 15, 2015, Comprehensive ESRD Care (CEC) Model;
8. Oct. 29, 2015, Medicare Shared Savings Program;
9. Nov. 16, 2015, Comprehensive Care for Joint Replacement (CJR) Model;
10. Dec. 9, 2015, Next Generation ACO Model

CMP Barrier Tackled by Congress. In the MACRA, Congress remedied one of the fraud and abuse law impediments to implementation of the new payment models. It removed a barrier created by the HHS Office of Inspector General's (OIG) interpretation of the CMP prohibiting incentives to reduce or limit services (sometimes referred to as the "gainsharing" CMP). In the OIG's view, the statute prohibited use of an incentive that resulted in any change in a physician's practice without regard to whether it was good medical practice or had no adverse effect on a patient's care. In the MACRA, Congress made clear that a penalty was intended only if a hospital made payments to a physician to reduce or limit medically necessary care. As a result, a change in practice alone is clearly not subject to a penalty. Hospitals and physicians can now share the rewards for improving quality of care or reducing unnecessary costs through implementation of evidence-based care pathways and cost savings initiatives, including standardization of items used in delivering care without fear or running afoul of this regulatory barrier.

> **"The modification will ensure that physicians and hospitals can align incentives, which is especially important since they are being called upon to do this more often in the pursuit of providing improved care at a lower cost. In the movement to replace fee for service medicine with a model that emphasizes quality, this legislation will facilitate relationships that will allow movement in this direction... This legislation recognizes that in the new delivery system models, the emphasis should be on reducing the provision of medically unnecessary services for patients. ...Such services also are not in furtherance of the goal of operating a more efficient, higher quality health care system."**
> – Hon. Jim McDermott, May 13, 2014, Statement of Introduction, H.R. 4658, proposing changes to the "gainsharing" CMP ultimately enacted in MACRA

The Stark and Anti-Kickback Barriers Remain Unchanged

The Stark Law controls whether a physician may make

referrals to a hospital with which he or she has a financial relationship. While current law limitations on the activities of physician-owned hospitals is perfectly appropriate, its oversight of compensation arrangements is built for a nearly outmoded system where physicians were selfemployed, hospitals were separate entities, and the payment system treated them as operating in distinct silos. It micromanages the circumstances in which a compensation arrangement is permitted, the amount paid and the manner in which the compensation is calculated.

The Stark Law is a strict liability statute. Any violation is subject to the same penalty – return of any amount paid by the Medicare and Medicaid programs for services provided to a beneficiary based on a physician's self-referral – without regard to whether the services were, in fact, medically necessary or the nature of the infraction was highly technical, such as failing to sign a form. In addition, a CMP specific to the Stark Law may be imposed.

The Anti-Kickback Law prohibits the exchange of remuneration (anything of value provided by a hospital) intended to influence a physician's ordering of services or the purchase of items that are paid for by a federal health care program. Enforcement of the law has effectively made any financial relationship between hospitals and physicians subject to regulatory scrutiny and serious punishment.

The Anti-Kickback Law is a criminal statute. Anyone who knowingly and willfully receives or pays anything of value as an incentive to influence the referral of federal health program business can be held accountable for a felony. In addition, a CMP specific to the Anti-Kickback Law may be imposed.

Achieving Congress' goals for APMs can be accomplished only through teamwork among hospitals, physicians and other health care providers across sites of care. An essential component for the success of their efforts is the use of arrangements that align incentives – specifically, financial incentives to promote more coordinated and efficient care and also improve the patient care experience. ***The key challenge is that hospitals cannot safely implement an incentive program for physicians unless it meets both an exception under the Stark Law and a safe harbor under the Anti-Kickback Law.*** However, the core requirements of existing exceptions and safe harbors are not in sync with the collaborative models that reward value and outcomes. While an advisory opinion process exists for each law, seeking clearance from HHS is an arduous, expensive and inefficient process that can take years to complete. Moreover, it is designed to provide protection in specific sets of circumstances, and protects only the hospital making the request.

The Secretary's MACRA-mandated 2016 report to Congress concurs that the fraud and abuse laws are an impediment. The report offers no legislative or regulatory proposals. Instead it provides observations on the effect of fraud and abuse laws, concluding that they can be an "impediment to robust, innovative programs that align providers by using financial incentives to achieve quality standards, generate cost savings, and reduce waste." More specifically, the report calls out the physician self-referral law as a significant problem, saying that "the physician self-referral law presents a particularly difficult obstacle to structuring effective programs that do not run afoul of the fraud and abuse laws."

Recent developments in False Claims Act litigation involving the Stark Law will no doubt chill, and could extinguish, the development of new relationships essential to the success of the new reimbursement models. "It seems as if, even for well-intentioned health care providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure – especially when coupled with the False Claims Act."
– U.S. ex rel. Michael Drakeford v. Tuomey, Wynn, Circuit Judge, 4th Circuit Court of Appeals, concurring.

A chart detailing the current legal barriers can be found in Appendix A on page 12.

Collaborative Arrangements Necessary to Achieve Value-Based Care... and the Legal Barriers Preventing Them

1. Collaborative Arrangement: *Shared EHR infrastructure to coordinate care*

Under new models of payment, hospitals are financially responsible for creating an efficient care team that achieves lower costs and higher quality. The underpinning for a care team to do its best in meeting the needs of a patient – enabling him or her to achieve and maintain

the best health outcome – is to have ready access to the information necessary to make informed decisions about the patient's care. In today's world, that requires building and maintaining electronic systems for securely transmitting information and making it available to support those caring for the patient – across sites, among professionals and over time. When hospitals assume ultimate accountability for financial and quality outcomes for episodes of care, they need the latitude to bear the full cost of the investment, if necessary. The certified electronic health record (EHR) is one component of the shared infrastructure that is necessary for a well-coordinated care team. When providers across the care continuum utilize certified EHRs that are connected, all benefit from having the ability to access and use information about the patient's condition and history that supports their role on the care team. Another component is access to the most current and authoritative information to support a physician in diagnosing and ordering treatments for a patient. This requires both the data and the analytical tools to support a physician's decision making, as well as ongoing quality assurance and quality improvement programs.

Acquiring, maintaining and updating this infrastructure requires a major investment. While providing access to all who care for a patient increases the investment required, it is necessary when the health of the patient is the objective. The result of a procedure, a test or a visit should be available across the care team to best serve the patient.

Current Regulatory Barrier: The fraud and abuse laws place unreasonable constraints on how hospitals may finance the needed infrastructure. Any financial support by a hospital for establishing the shared infrastructure creates a financial relationship under Stark and is remuneration under the Anti-Kickback Law. The current rules for providing an EHR do not allow hospitals to bear the full cost; instead, physicians must bear a portion of the costs, without regard to the contribution they otherwise make to the collaborative effort. And there are no exceptions for a hospital to provide data analytic tools to assist physicians in making treatment decisions for patients – tools that would enable physicians to assess data from various sources and identify clinical pathways for specific conditions, medical histories and patient populations. Investing in needed infrastructure is a pre-condition for implementing new payment models. The Stark and Anti-Kickback Laws should be modernized to permit hospitals to subsidize the start-up costs needed to meet the objectives of these new payment models.

> **"When information is available to the treating physician across all settings of care, patients can rest assured that all their relevant information is being tracked accurately and they are not asked to repeat information from recent hospitalizations or laboratory tests. Doctors can get electronic alerts from a hospital letting them know that their patient has been discharged and can proactively followup with special care transition management tools. And doctors can use health care data to make improvements in their care delivery strategies."**
> – Better Care. Smarter Spending, Healthier People: Why It Matters, Centers for Medicare & Medicaid Services Press Release, Jan. 26, 2015

2. Collaborative Arrangement:
Incentives for care redesign to improve outcomes

At the core of improving health outcomes for patients is the ability of physicians and other clinicians to have and act on the best information available to assist them in making treatment decisions for each patient. Through a consensus process, physicians evaluate the data and research and develop care pathways to improve efficiencies and achieve the best outcomes for patients. Hospitals want to implement incentive programs to encourage and reward physicians who adhere to the care pathways in treating their patients. Consistent use of the care pathways results in a greater likelihood of good outcomes for a patient.

Current Regulatory Barrier: Hospitals are confronted with trying to cobble together protection using exceptions and/or safe harbors designed for silos, not collaboration: the exceptions or safe harbors for fair market value (FMV) compensation, employment or personal services. All are designed with the same fundamental barrier – a productivity approach: how many hours were worked or resources were expended; while the objective of the new models is outcomes – following evidence-based care pathways and achieving the best outcomes most efficiently. In addition, the bedrock of these protections is that compensation, in this case an incentive, cannot be related to the value or volume of services ordered by the physician. Yet, to achieve the best outcome, linking incentives to whether the care pathway was appropriately

followed for individual patients can be the most effective means to achieve the goals of quality and efficient care.

3. Collaborative Arrangement: *Incentives for more efficient treatment options*

In order for hospitals to assist in reducing unnecessary health care expenditures, it is helpful to encourage the physicians who are responsible for making key medical decisions affecting hospital care to select the most efficient (and effective) treatment options, including those that are less expensive for the patient. One primary tool for achieving this objective is sharing a portion of bottomline cost savings with physicians who help reduce overall costs in collaboration with hospital staff, while maintaining or improving the clinical outcomes for patients. Hospitals may establish programs, for example, with specific costsaving actions – such as promoting the use of standardized devices or drugs from a formulary list that are available to the hospital at lower cost – and then share a portion of the cost savings with groups of physicians responsible for achieving lower costs. Such programs would include hospital and physician collaboration on determining the most efficient care in specified circumstances, ensuring that patient care continues to meet objective clinical standards.

Current Regulatory Barrier: While the barrier to costsaving initiatives was diminished when Congress amended the gainsharing CMP to make clear that penalties under that law will apply only if a hospital makes payments to a physician to reduce or limit medically necessary care, the Anti-Kickback and Stark Laws still apply. Neither law has express protections specifically in sync with costsaving financial incentive programs among hospitals and physicians. Under the Anti-Kickback Law, hospitals run the legal risk of being charged with using cost-saving incentives to attract referring physicians to align with the hospital. Under Stark, hospitals again must try to cobble together protections using disparate exceptions ill-suited for achieving reduced costs through collaboration.

HHS has recognized that lower cost does not mean lower quality. It was CMS that established the early hospital-physician gainsharing demonstrations and took the initiative in approving programs designed to reduce hospital costs and share savings with the physicians. Those programs were effective and now hospitals and physicians should be permitted to share savings resulting from the adoption or performance of practices designed to reduce inefficiencies in the delivery of care without adversely affecting or diminishing the quality of patient care services.

4. Collaborative Arrangement: *Team-based approach that includes non-physician practitioners*

Increasingly, care for a patient in the community includes a physician, as well as other clinical staff who collectively serve as the primary provider and coordinate implementation of the entire care plan. Including other professionals can expand access and provide care most efficiently. With the team approach, each member brings unique skills. While all are working from the care plan established by the physician, success of the plan can be achieved most effectively when all fulfill their specific roles, whether monitoring medications, counseling for dietary needs or ensuring appointments for other services are made and met. To that end, advance practice nurses, social workers, dieticians and others play an essential role. The team approach also provides the patient ready access to a knowledgeable professional with access to their medical history when a question or concern arises. A call to the team can avoid an unnecessary trip to the emergency department or prevent a cascade of difficulties for the patient that leads to a preventable hospital readmission. With this approach, the physician remains accountable for the overall care provided by the team and her or his compensation should recognize this additional accountability.

Current Regulatory Barrier: Compensating a physician for performing a care management and coordination role faces the same barriers as compensating a physician for care redesign. There is no exception to reward achievements – in this case, the results of the team effort. The FMV time-spent and resources-expended test is not readily applicable. Therefore, focusing on coordination and care management of individual patients could be seen as running afoul of the volume/value prohibition – linking payment for the physician to the volume of potential referrals for hospital services. Compensation of the physician should be permitted to recognize his or her oversight of a patient's entire care and the contributions team members make to efficient care that produces better outcomes.

5. Collaborative Arrangement:
Coordination of care when the patient leaves the hospital

Success in transitioning a patient from the hospital to the community often depends on a stay in a residential facility (sometimes for a short stay, sometimes as a long-term arrangement) or in-home services. In these situations, it is essential that post-acute providers be part of the care team. That means a relationship in which post-acute providers share the goals of the hospital and other care team members. Coordination is essential. It begins for each patient in preparation for discharge and continues during the course of the after-care plan. Hospitals want to provide support and reward the other caregivers for working towards the same goals for the patient's successful recovery and maintenance in the community, such as visits from the social worker who is part of the patient's primary care team, or incentives for the residential facility for implementing rehabilitation care pathways.

Current Regulatory Barrier: Any support or incentive provided by the hospital to the residential facility (such as a skilled-nursing facility), is remuneration under the Anti-Kickback Law. It could be viewed as an inducement for the facility to make referrals to the hospital for service. There is no exception in sync with these types of arrangements where collaboration of a hospital and post-hospital caregivers is essential. A potentially applicable safe harbor for personal service arrangements is problematic because its FMV hours-worked approach is inconsistent with the objectives of these incentives – the achievement of better outcomes, regardless of the time or expense it requires.

Hospitals Also are Limited in Working with Patients by Outdated Legal Barriers

6. Limitation:
Prohibition on assisting a patient with discharge planning

Hospital responsibility for patient care no longer begins and ends in the hospital setting or any other site of care provided by the hospital. While discharge planning has long been a condition of participation in the Medicare program, post-discharge monitoring of patient follow-up and treatment plans has become equally important from a patient care and payment perspective. Hospitals need certain tools and flexibility to promote the health of their patients in their communities while reducing unnecessary health care expenditures.

Current Regulatory Barrier: CMS's discharge planning regulations preclude a hospital from offering advice to a patient on the selection of a provider for post-hospital care or suggesting a specific facility. This rule, like the fraud and abuse laws, was not designed for the collaborative relationships essential to meeting the goals of the new payment-for-value models. The coordination of care will make the difference between a patient receiving the best of team-based care or the patient facing the daunting task of navigating solo across the silos of different caregivers.

The rule requires hospitals to give the patient a list of providers without regard to quality or coordination of care. CMS already has recognized that the rule is an impediment to achieving the goals of new payment models by providing some flexibility for participants in the Comprehensive Care for Joint Replacement (CJR) bundled payment initiative. Instead, hospitals should be able to direct the patient to providers that share the same goals and incentives. It will ensure better communication among providers and the patient will experience the caregivers as one seamless team.

7. Limitation:
Prohibition on assistance provided to patients

Maintaining a person in the community requires more than direct patient care. It includes encouraging, supporting or helping patients to access care, or to make it more convenient. It would include removing barriers or hurdles for patients as well as filling gaps in needed support. Transportation is a prime example. It can literally mean the difference between a patient receiving or not receiving care, or enabling them to remain in their home, getting to the grocery store for food or to fill a prescription. In addition to transportation, support would include providing self-monitoring tools such as scales or blood pressure cuffs; post-discharge contacts by a clinician, by phone or other electronic means, or in-person to ensure follow-through with the patient's post-discharge plan; and the provision of educational materials. Access to care should also include non-clinical care that is reasonably related to the patient's medical care, such as social services, counseling, health coaching, non-reimbursable home visits and meal preparation. For some patients,

continuing a series of treatments such as physical therapy or rehabilitation services or a drug regimen will compete for the same dollars as other needs. This may lead to skipping appointments or medication. Offering discounts for combined copays, for example, could avoid having a medical condition worsen that results in a trip to the emergency department or a readmission to the hospital.

Current Regulatory Barrier: Another significant barrier results from limitations placed on the types of assistance a hospital may provide a patient to help maintain him or her in the community. The Anti-Kickback Law also applies to a hospital's relationship with a patient. The general prohibition on providing anything of value to "induce" the purchase or order of items or services paid for by the Medicare program also applies to assistance to patients. Providing vouchers for a cab ride, scales to monitor weight loss or cuffs to monitor blood pressure are "remuneration" that could be characterized as a prohibited inducement. There is no comprehensive exception in the Anti-Kickback Law protecting these patient benefits. In addition, a CMP specific to "inducements" to patients may be imposed. While there are exceptions for providing support that promotes access to care or is based on financial need, there are no clear and readily applicable protections for encouraging a patient's follow-through on post-discharge treatment plans.

A final rule issued by the OIG in December 2016 provides some relief for transportation assistance, but more is needed. A new Anti-Kickback safe harbor protects transportation assistance for patients to obtain medically necessary items or services under certain conditions. However, it does not cover transportation assistance for a patient to access nonmedical care or meet other needs related to health (e.g., social services, counseling, food bank). OIG's protection for assistance other than transportation is similarly too narrow. While the CMP statute creates protection for assistance that promotes access to care, the OIG, again, defines care to only include medical services and does not protect assistance for nonmedical care or other support related to health. Hospitals should be able to provide the type of assistance patients need to realize the benefits of their discharge plan and maintain themselves in the community.

Modernizing the Laws to Achieve Better Outcomes

The fraud and abuse laws need to be adapted to support not hamper the new payment models. To that end, Congress should create legal safe zones to support and foster arrangements designed to achieve the goals of payment-for-value rather than volume-based programs.

While granting broad waivers of the fraud and abuse laws for the new payment demonstration models was essential to allow hospitals to participate, going forward changes in law are needed to build and improve those models. Hospitals and physicians should not have to spend hundreds of hours or thousands of dollars in hopes of stringing together components from the existing exceptions and safe harbors or developing inefficient work-arounds to achieve the goals of APMs. Nor should hospitals be limited in their ability to provide patients the full spectrum of assistance they need to recover. There should be clear and comprehensive protection for arrangements designed and implemented to meet those goals.

The current patchwork waiver approach will not provide sufficient protection to providers as participation in integrated payment and delivery models increases.

HHS has used its statutory authority to grant waivers of the Anti-Kickback, Stark and CMP Laws for participants in certain programs testing alternative payment and care delivery models, such as the MSSP and bundled payment programs. Such waivers are essential for facilitating the collaboration between hospitals, physicians and other providers required to achieve the cost and quality goals of those models. However, as the health care system continues to shift to value-based care, the program byprogram approach will not provide sufficient protection from potential vulnerability under the fraud and abuse laws for providers engaged in efforts to transform care.

Currently, arrangements that comply with requirements of the applicable program are protected by waivers of the fraud and abuse laws. For providers who participate in multiple models to which waivers apply, navigating the different waiver requirements that may apply to their various arrangements with other providers can be complex. For example, a hospital that participates in both

an accountable care organization (ACO) and a bundled payment program would need to track compliance with both sets of waiver requirements not only with respect to the physicians who provide services under one or both programs, but also the population served by the physician.

In addition, the waivers are limited in that they provide protection only with respect to services covered by Medicare. It is unclear what – if any – protection providers covered by the waivers have for parallel models with commercial health care plans. Similarly, models undertaken by providers – such as children's hospitals – that deal primarily with non-Medicare payers (Medicaid, for example) are not protected by the waivers.

New Comprehensive Safe Harbors

Safe Harbor for Incentive Payment and Shared Savings Programs to Achieve Care Transformation

Because the Anti-Kickback Law provides oversight for compensation arrangements that cuts across all providers, professionals, federal health care programs and financial arrangements, it is the most logical place to create a clear and comprehensive statutory safe harbor. The safe harbor would be designed to foster collaboration in the delivery of health care and incentivize and reward efficiencies and improvement in care. Arrangements protected under the safe harbor also would be protected from financial penalties under the Anti-Kickback CMP. In addition, the Stark Law impediments to care transformation would be removed by returning the focus of that law to govern ownership arrangements. That means that compensation arrangements would be subject to oversight solely under the Anti-Kickback Law.

The safe harbor should establish the basic accountabilities for the use of incentive payment or shared savings programs:

- Performance standards must use an objective methodology for evaluation, be documented and verifiable, and be supported by credible medical evidence; they must
  - » be separately identified and measured;
  - » be reasonable for patient care purposes; and
  - » be monitored throughout the term of the arrangement to protect against reductions or limitations in medically necessary patient care services;
- Payments must reflect the achievements of the participant receiving payment (or another under his or her oversight);
  - » payments (or the formula) must be set in advance in writing.

The safe harbor should not, and need not, try to supplant, duplicate or recreate existing quality improvement processes or the mechanisms for monitoring quality of care in hospitals. There is both internal and external oversight. State licensing agencies and accrediting organizations have an ongoing role. The Medicare Quality Improvement Organizations (QIOs) continuously review the quality of care for beneficiaries. Other Medicare program oversight includes the hospital inpatient and outpatient quality reporting programs, readmissions program and value-based purchasing program.

The safe harbor would cover arrangements established for one or more of these purposes:

- Promoting accountability for the quality, cost and overall care for patients;
- Managing and coordinating care for patients; and
- Encouraging investment in infrastructure and redesigned care processes for high quality and efficient care delivery for patients.

The safe harbor would protect remuneration, including any program start-up or support contribution, in cash or in-kind.

Safe Harbor for Assistance to Patients to Achieve Care Transformation

A safe harbor similarly should be created under the Anti-Kickback Law so hospitals can provide the type of assistance patients need to realize the benefits of their discharge plan and maintain themselves in the community. Arrangements protected under the safe harbor also would be protected from financial penalties under the inducement to patients CMP.

The safe harbor should:

- Encompass encouraging, supporting or helping patients to access care or make access more

convenient.

- Allow access to care to go beyond medical or clinical care, and include the range of support important to maintaining health such as social services, counseling or meal preparation.
- Permit support that is financial (such as transportation vouchers) or in-kind (such as scales or meal preparation).
- Remove the regulatory prohibition on a hospital offering advice to a patient on the selection of a provider for post-hospital care or suggesting a specific facility (or through other legislation).

Congress previously has recognized that there are cases where the Anti-Kickback Law thwarts good practices and periodically created safe harbors to protect them. This is another case where the same is needed.

Patient Case Study: How Seamless, Coordinated Care Could Work in a Barrier-Free World

Below are real-life examples of how today's current regulatory barriers inhibit care coordination and better outcomes for patients.

Meet Wayne, a 75-year-old male with congestive heart failure (CHF), diabetes, coronary artery disease (CAD) and chronic obstructive pulmonary disease (COPD).* He has limited support at home. Wayne's care is managed by his primary care physician, who is not employed by his local hospital but participates in the hospital's clinically integrated network. Because of this, the hospital has provided Wayne's physician with an electronic health record (EHR) compatible with the hospital's system. In order to expand access to primary care, the physician has added a nurse practitioner and a social worker to the practice.

* *Wayne is not an isolated case, according to the Centers for Disease Control and Prevention, three in four adults 65 and older had two or more chronic conditions.* www.cdc.gov/chronicdisease

⚠ ***Barrier: Hospital cannot provide EHR to Wayne's physician or the data and analytic tools to support the physician's decision-making unless it meets the limited EHR exception.***

Hospitalization for COPD: Wayne is hospitalized because his COPD got worse. Because of Wayne's diabetes, hospital staff must manage his blood sugar to avoid elevated blood sugar levels, known as hyperglycemia. Management of Wayne's diabetes during his hospitalization is critical because, if he experiences hyperglycemia while hospitalized, he is more likely to have a longer stay in the hospital and other problems, such as infections, multiple complications and even death.

Wayne's hospital has worked with physicians to identify a best practice protocol for inpatient diabetes management. In the past, the widely used approach was to supply insulin to correct spikes in blood sugar after they have occurred. Currently, a more favored approach is to prevent hyperglycemia by administering a long-acting insulin to stabilize the patient's blood sugar. However, this approach can be more time-consuming for the physician, who must be periodically apprised of the patient's blood sugar level in case any adjustment to the insulin is needed. The additional time is not reimbursed by Medicare, making it appear to be a less valued treatment option. While hospitals encourage high adoption of such protocols to improve the outcomes for patients, they may be inconsistently implemented by individual practitioners since physicians may respond to changes in protocols at different paces. Recognizing this, the hospital provides financial incentives to encourage Wayne's physician to manage his diabetes using the preferred protocol, helping avoid a lengthier stay and improving Wayne's long-term outcomes.

⚠ ***Barrier: A hospital cannot provide financial incentives to physicians even one based on improved treatments provided to an individual patient because the Stark and Anti-Kickback Laws may treat that as an inappropriate payment to increase referrals to the hospital.***

Discharge to the Community: Wayne's physician sees Wayne during her morning rounds and orders testing then heads to her clinic to see patients during her office hours. She asks a physician assistant – a hospital employee – to look at the test results once they are in. Later that day, the physician assistant calls Wayne's physician, who determines based on the results that Wayne can be appropriately discharged. This allows Wayne to avoid an unnecessary night in the hospital, since otherwise the physician would not have discharged Wayne until the next morning when she reviewed the test results during her morning rounds.

⚠ ***Barrier: The support provided by the physician assistant could be interpreted as a prohibited financial incentive under the Stark and Anti-Kickback Laws to induce Wayne's physician to refer patients to the hospital.***

Upon discharge, Wayne is instructed to follow up with his physician within 48-72 hours. He is able to secure an appointment with his physician, who ensures that Wayne is stable following his discharge. Due to her previously scheduled patients, Wayne's physician is only able to spend 15 minutes with Wayne. To avoid

the need for Wayne to schedule another, longer appointment with the physician, which would not be available for several more days, the nurse practitioner meets with Wayne to determine what medications he is taking and that those are still the correct ones for him. This process, which takes 45 minutes, helps Wayne understand each of his medications, how they could interact and how he should take them. She also instructs Wayne to contact her if the ordered home health supports do not arrive within 24 hours, and then calls the home health company to follow up. The practice's social worker, who helped Wayne secure access to a ride to and from his appointment, also directs Wayne to a local program that can help him pay for his expensive medications and arranges for him to receive delivery of meals from another local program during his convalescence. The local hospital compensates Wayne's physician for her management of this team-based approach to care because it helps patients such as Wayne successfully navigate his discharge to home and will potentially help him avoid a rehospitalization.

⚠ Barrier: The compensation of the physician cannot recognize the quality and clinical outcomes of the care provided by the other team members and their coordination of the patient's care.

Joint Replacement Surgery: Wayne now needs a total knee replacement. His combined health conditions place him at higher risk for a longer stay in the hospital after the procedure and for developing complications within 90 days that may require him to return to the hospital. To ensure that Wayne receives the highest quality care during the surgery and to optimize his recovery time, the hospital has worked with its orthopedic surgery team – which includes surgeons, anesthesiologists, nurses, physical therapists and others – to develop a "care pathway" to guide all who are part of the care team beginning with the initial evaluation of Wayne and continuing through the preparation for discharge and the discharge process. The pathway includes:

- A thorough, pre-operative evaluation that (a) helps Wayne understand what to expect during his surgery and hospital stay, how to control his pain after the surgery, a physical therapy regimen, and his daily goals and strategies for getting around and taking care of himself after he gets home, and (b) includes a standardized set of tests to screen for risks of complications;
- A standardized clinical protocol for the procedure itself to decrease the amount of time that Wayne spends in the operating room and reduce the risk that Wayne will experience infections or other complications;
- An acute post-operative care plan that ensures that Wayne begins physical therapy on the same day as the surgery to enhance his early mobility;
- Joint daily visits by the care team – physician, nurse, pharmacist, physical therapist and case manager – to provide a streamlined and coordinated discharge planning process for Wayne;
- A discharge planning process involving the entire care team that results in a discharge plan addressing all of the needed follow-up care, such as medications, wound care and physical therapy. This will help provide Wayne with a complication-free path to independence once he is back in his home.

The hospital has developed compensation arrangements for its physicians to encourage and reward implementation of the care pathway for patients in need of a knee replacement.

⚠ Barrier: Compensating Wayne's physician for adherence to the pathway for individual patients or the outcomes of team-based care may be treated as inappropriate inducements to increase referrals to the hospital.

In addition, the hospital has partnered with orthopedic surgeons to develop a list of preferred implants, such as prosthetic knees, that are available to the hospital at lower cost but that have similar efficacy as more expensive models. To encourage physicians to select from this list, the hospital has implemented a program by which it will share with physicians who choose the more cost effective implants a portion of the savings realized by the hospital. Wayne's surgeon will receive this incentive since she selected a prosthetic knee from the list.

⚠ ***Barrier: Compensating Wayne's physician for choosing a less costly and equally effective implant could be interpreted as a prohibited financial incentive under the Stark and Anti-Kickback Laws to induce her to refer patients to the hospital.***

Post-discharge Support: Although Wayne's long-term prognosis following his surgery is good, his ability to perform activities of daily living – such as walking and bathing himself – are still not adequate for him to return to his home, and it becomes clear that post-acute care is required. Wayne and his team decide he will go to a skilled-nursing facility (SNF) until he's ready to return home. The care team knows which SNFs near Wayne coordinate care with the hospital and have the most consistent, highest quality outcomes. The hospital has helped drive some of these high quality outcomes by partnering and providing financial incentives to highperforming SNFs. The team advises him to choose one of those facilities. As a result, he will receive the benefit of a more coordinated handoff between the hospital and the SNF. In addition, since the SNF's EHR is compatible with the hospital's, Wayne's care in the hospital, discharge plan and outpatient records are available to the SNF immediately upon his arrival, instead of waiting for a copy of the paper records to arrive. When Wayne is discharged to his home, a SNF that is highly coordinated with the hospital alerts the hospital's care coordinators of his discharge so that they can help Wayne better navigate his transition home despite his lack of home support.

⚠ ***Barrier: The Medicare hospital conditions of participation prohibit the hospital from making recommendations to Wayne; instead, they must provide only a list with names of SNFs without regard to performance or the level of care coordination.***

Further, the hospital's financial incentives to highquality SNFs is remuneration under the Anti-Kickback Law and could be seen as payment to induce referrals from the SNF to the hospital; and the hospital cannot provide the compatible EHR to Wayne's SNF unless it meets the limited EHR safe harbor.

Once home, Wayne would benefit from a number of supports, including:

- A scale so that he can weigh himself every day, which is important to manage CHF;
- Providing nutritional support, like meals, since he lives alone and has limited mobility;
- Making Wayne's house handicap-accessible (rails in showers, etc.);
- providing therapy services (physical, occupational) in the home;
- A cab voucher so he can receive legal consultation to discuss advance directives, power of attorney, etc. – decisions related to end of life care.

The hospital provides these supports to Wayne in order to improve his health and decrease the likelihood he will need a readmission to the hospital or other costly care.

⚠ ***Barrier: Hospitals are limited in what products and services they can provide to Medicare patients because the only applicable exception to the Anti-Kickback Law is extremely limited and the exceptions to the civil monetary penalty prohibition are ambiguous and unreliable.***

Appendix A: Current Legal Barriers to Collaboration

	Stark and Anti-Kickback Requirements	Barrier Created	Feature of Teamwork Impacted
Stark	Fair market value (FMV)	Confines physician compensation arrangements to an hours-worked model that, by definition, rewards time spent and resources consumed rather than outcomes achieved.	Shared infrastructure, care redesign program
	Volume or value prohibition	This requirement has been contorted to make incentive programs to reduce costs or improve care run afoul of the law. To incentivize desired outcomes, hospitals must almost necessarily tie compensation to the number of patients whose treatment a physician oversees and to the type of treatment provided at the facility, which government officials and some courts assert is a violation of the law.	Shared infrastructure, care redesign program
	Commercial reasonableness requirement	This requirement has been misstated and misapplied to establish a presumptive cap on a physician's compensation at the amount a physician could collect as an independent seller of physician services, without regard to the physician's contribution to quality and efficiency metrics as a member of an integrated team of providers.	Shared infrastructure, care redesign program, cost savings program, team-based care
	"Set in advance" requirement	This requirement does not allow for making mid-year adjustments, or to adjust payment mechanisms to meet changing needs.	Care redesign program, cost savings program, team-based care
	Requirement that the physician pay 15% of the cost of EHR	Given the significant cost of implementing, updating and maintaining EHR infrastructure, many physician practices – particularly primary care practices – are unable to bear even this portion of the cost.	Shared infrastructure
Anti-Kickback	Fair market value (FMV)	Confines physician compensation arrangements in an hours-worked model that, by definition, rewards time spent and resources consumed rather than outcomes achieved.	Shared infrastructure, care redesign program, cost savings program, team-based care, postdischarge care coordination
	Volume or value prohibition	This requirement has been contorted to make incentive programs to reduce costs or improve care run afoul of the law. To incentivize desired outcomes, hospitals must almost necessarily tie compensation to the number of patients treated and to the type of treatment provided at the facility, which government officials and some courts assert is a violation of the law.	Shared infrastructure, care redesign program, cost savings program, team-based care, postdischarge care coordination
	"Set in advance" requirement	This requirement does not allow for making mid-year adjustments, or to adjust payment mechanisms to meet changing needs.	Care redesign program, cost savings program, team-based care, post-discharge care coordination
	Requirement that the physician pay 15% of the cost of EHR	Given the significant cost of implementing, updating and maintaining EHR infrastructure, many physician practices – particularly primary care practices – are unable to bear even this portion of the cost.	Shared infrastructure