THIRD WAY

Clearing a Regulatory Path for Value-Based Health Care

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Getting the right health care is often daunting. If you have a chronic condition or undergo a major operation, you have to deal with multiple providers and multiple bills. While health professionals can do a great job when you are with them, your care may fail or slip through the cracks away from their office. A growing number of health care providers and biopharmaceutical and device manufacturers want to change that and offer a simpler experience with a more reliable outcome. They are running up against federal laws that haven't kept up with changes in the delivery and payment of health care.

This movement to simpler, more reliable care in the United States is part of a dramatic shift away from paying for volume to paying for value. Instead of paying a fee for every service, public and private health care plans are increasingly turning to alternative payment models and value-based contracts that pay for health care based on an overall level of performance for patients. Coordinating care to improve patients' experiences and outcomes and guaranteeing results for whole groups of patients are a few of the many innovations underway. They are part of alternative payment models and contracts that hold providers and manufacturers accountable for the cost and quality of care across groups of patients.

This is good news for patients. But these new payment models face hurdles based on their interaction with well-intentioned laws and regulations that prevent fraud and abuse under the traditional fee-for-service payment system.

Among the many hurdles to implementing new value-based models of care are the Anti-Kickback Statute, the Stark Law (which prevents physician self-referral), Medicaid prescription drug pricing rules, and Food and Drug Administration (FDA) restrictions on communications about prescription drugs and medical devices. A hodge-podge of ad hoc guidance and one-time exemptions has given providers and manufacturers an opening to proceed with legal certainty on a limited basis. Even less has been done to permit value-based deals for biopharmaceutical or medical device products. More needs to be done, however. The shift to value-based contracts will not reach a tipping point without simpler and broader ways to have legal certainty. At the same time, fraud and abuse laws must remain effective (and even be improved) within the fee-for-service payment system, which will continue to play a role in payments even as value-based payment models and private contracts expand.

It's time for Congress to modernize regulations so they promote value-based care without undermining critical fraud and abuse protections that police fee-for-service payments. This report explains value-based health care, the legal hurdles that are limiting value-based care, and the steps Congress can take to provide legal certainty for health plans, providers, and manufacturers.

Value-Based Health Care—Overview

Goal	Legal Hurdles	Solutions
Enable health care stakeholders to align financial incentives to deliver high-value care across medical services.	The Anti-Kickback Statute and Stark Law prevent excess fee-for-service billing. But they also inhibit the use of incentives for high-value care.	Expand partial protections from the Stark Law and Anti-Kickback Statute to include new financial incentives. Keep laws in place for fee-for-service billing.
Permit drug and device manufacturers to guarantee an outcome for a group of patients.	Anti-Kickback and Stark Laws limit the use of guarantees. Medicaid's prescription drug best-price rule discourages refunds for unsuccessful treatment. FDA regulations inhibit flow of information for value-based care and coverage.	Extend protections listed above. Allow Medicaid's best-price rule to accommodate guarantees and refunds. Modernize FDA regulations to improve the use of value-based health care.

What is Value-Based Health Care?

Value-based payment models and contracts tie payment for health care services to a complete health care result for patients instead of a series of individual payments. That may sound complicated, but it is designed to make health care simpler like many other areas of the economy. Just think—auto manufacturers charge for a whole car, not the parts. Why can't we do that for health care?

Value-based models try to do just that by holding health care providers accountable for the cost and quality of care.[1] Their goal is to transition away from paying for

quantity (i.e., fee-for-service payments), to paying for quality (i.e., payments aligned with outcomes).[2]

Health care entities of all types—health systems, hospitals, physicians, pharmaceutical companies, device manufacturers, health insurers, employer-based plans, and more—are looking to establish value-based contracts. One example of this is a bundled payment, which is a single price for all the services needed for a procedure like a knee replacement. Accountable care organizations (ACOs) are another example; they cover all the health care services that a patient receives with financial rewards or penalties for the cost and quality of care. Yet another example is a payment from a hospital to a physician for reducing costs during a patient's stay in the hospital.

A value-based model or contract has three essential elements:

1. A way to measure patient benefit (the quality of care) from a health care service, drug, or device;
2. Information about the cost of a health care service, drug, or device; and
3. A financial arrangement where a plan, provider, or manufacturer of a biopharmaceutical or medical device commits to deliver a specific patient benefit or a group of services at a target price. Such services can include a bundle of services (as in a knee replacement) or a drug or device packaged with support services that improve its use.

Care coordination and guarantees are two easily understood types of value-based health care among the many types of innovative models and contracts. Here's how they work:

Care Coordination. When patients leave the hospital after a complex procedure, they often need help with nutrition, physical therapy, medications, follow-up appointments, and other tasks necessary for a full recovery. When a Medicare patient is cared for by an ACO, that ACO becomes responsible for the cost and quality of the patient's care. Therefore, the ACO has an incentive to coordinate a patient's transition of care effectively and prevent a readmission to the hospital. In order to do that, an ACO may wish, for example, to enter into a contract with a skilled nursing facility for patients who are not yet ready to return home. This type of contract may align electronic health information systems across the two providers, incentivize the skilled nursing facility to follow established care protocols to help ensure quality outcomes, and provide financial rewards when certain patient outcomes are achieved.

Pharmaceutical Guarantees. A pharmaceutical manufacturer could offer a money-back guarantee to a health plan for patients who take a drug as prescribed by their physician but do not receive the intended therapeutic benefit. Particularly for newer drugs that carry a higher price tag but may be more effective than existing treatment options, a money-back guarantee may encourage health plans to cover the drug or reduce cost-sharing requirements for patients. Under this kind of arrangement, the manufacturer could refund the cost of the drug or cover the cost

of any care associated with the drug not working as promised. This is comparable to hospitals that pay a financial penalty to Medicare when their patients have to be readmitted. Pharmaceutical guarantees are much newer than value-based payments to providers and do not yet have a publicly proven track record, but health care industry stakeholders have also reported that current laws and regulations make such contracts daunting.[3]

Medical Device Guarantees. A medical device company with a less invasive hip implant, for example, could warrant that the implant will reduce the number of patients who are readmitted following surgery. The company would also provide surgeons with best practices and decision support tools that the company has developed from the data it collects on the use of its implant. These practices and tools can make the patient's preparation for surgery and the recovery after surgery more successful. If a readmission occurs and a replacement surgery is necessary, the manufacturer could pay for it under this kind of guarantee.

What Are the Legal Hurdles to Value-Based Health Care?

Four significant statutes and regulations in Medicare, Medicaid, and the FDA code make implementation of value-based health care payment models and contracts challenging for a wide variety of health care organizations. These include:

1. The Anti-Kickback Statute
2. The physician self-referral law (commonly known as the "Stark Law" after the initial bill's sponsor, former Representative Pete Stark (D-CA))
3. FDA rules and policies on communication by pharmaceutical and medical device manufacturers about medical products
4. The Medicaid best-price rule

All four of these areas of law remain critical for preventing excessive use and pricing of care within the fee-for-service payment system. But they also are significant hurdles to value-based care. The Anti-Kickback Statute and Stark Law directly inhibit the creation of value-based payment models and contracts in all segments of the health care industry. FDA restrictions and the Medicaid best-price rule limit value-based purchasing from the pharmaceutical and medical device industry by limiting, in certain circumstances, the assessment of clinical benefits of care, the sharing of cost information, and the degree of cost savings.

Here's how they each work:

The Anti-Kickback Statute and the Stark Law

The Anti-Kickback Statute and Stark Law were enacted separately during the 1970s and 1980s. Both were aimed at preventing abuses stemming from fee-for-service

payments. Because fee-for-service reimbursement rewards volume, it runs the risk of overutilization—when providers are paid more for doing more, they are incented to do more which can drive up health care costs. These laws were designed to curb financial arrangements that could induce overutilization in a world of fee-for-service reimbursement.

For example, in 2015, dozens of doctors and employees of a New Jersey medical testing laboratory company pleaded guilty to a scheme that bilked Medicare and commercial insurance companies for unnecessary tests on patients.[4] The lab had paid doctors bribes in cash, meals, and sports tickets in exchange for generating over $100 million in fraudulent medical bills.

Originally established in 1972, the Anti-Kickback Statute prohibits anyone from "knowingly and willfully" receiving or soliciting payment, including non-cash incentives, to induce or reward the referral or purchase of any items or services covered by any federal health program.[5] The prohibition extends to all sources of referral, including patients, and severely limits providers in waiving copayments, for example, unless certain criteria are met, including a determination of financial hardship.[6] For example, one doctor cannot waive the Medicare copayment for patients referred from another doctor in order to encourage more referrals. That helps to ensure referrals are made for good medical reasons, not for financial benefit.

The Anti-Kickback Statute is a criminal law and each party's intent is a key element in determining liability. Criminal and civil penalties include substantial fines, up to a five-year prison term per violation, program exclusion, and more.[7] Of those enforcement mechanisms, the possibility of a health care entity being barred from participating in federal health care programs is the most powerful because it could put that company or organization out of business. These risks cause most entities to settle cases with the government rather than risk losing the company. As a result, very few cases go to court, which limits the amount of case law around the federal enforcement of the statute. Notably, proof of patient harm or financial loss to federal health programs is not required to support violation of the Anti-Kickback Statute.[8]

While it serves a critical purpose, the Anti-Kickback Statute is a hurdle to many other types of modern value-based models and contracts. For example:

- ACOs are currently discouraged from providing financial incentives to high-quality skilled nursing facilities that are very good at preventing hospital readmissions because they could be seen as a payment to encourage referrals (except under a limited waiver, described below).[9] Further, the ACO can only provide a skilled nursing facility with a subsidized compatible electronic health record, which facilitates better care coordination, if it meets a limited safe harbor for such records.
- Pharmaceutical or medical device guarantees are inhibited because the manufacturer may be uncertain about whether federal enforcement agencies will view payment for non-performance as an inducement for the health plan to cover the drug and, when patient cost-sharing amounts are returned to the

patient, an inducement for the patient to take the drug. While safe harbors have been created to protect discounts and other arrangements between manufacturers and plans, these safe harbors may not address all arrangements that manufacturers and plans are interested in pursuing.

- A medical device company that wants to provide computer-based assistance to providers about the best ways to use a less invasive hip implant will also face hurdles. The Anti-Kickback Statute prevents that company from giving such technology to providers unless the providers pay for it separately or guarantee a level of success with the implant if providers use the technology. That leaves a massive amount of data collected by the company unused for the benefit of a patient's health and for lowering costs because providers generally do not pay for such data analysis and technology.

The Stark Law prohibits physicians from referring Medicare and Medicaid patients for certain designated health services to an entity with which the physician or an immediate family member has a financial relationship.[10] In addition, the entity may not bill Medicare or Medicaid for services furnished under a prohibited referral.[11] The designated health services include clinical laboratory testing, physical therapy, inpatient and outpatient hospital services, and more.[12] Violations of the Stark Law may be subject to denial of payment, refunds of improperly paid claims, civil monetary penalties, and exclusion from the Medicare and Medicaid programs. Civil penalties may be up to $15,000 or $100,000, depending upon the nature of the violation. The Stark Law is a strict liability statute; proof of intent is not required.[13]

The Stark Law could also prohibit financial incentives to physicians and other care providers. Extending the care coordination example above, consider an ACO that establishes a procedure where patients discharged from the hospital receive care at a skilled nursing facility to avoid hospital readmission. The Stark Law could be an obstacle to the ACO providing a financial incentive for physicians to order these services and for the skilled nursing facility to follow the prescribed care.

In addition to the civil and criminal penalties under the Anti-Kickback Statute and the Stark Law, enforcement is also conducted through the False Claims Act.[14] Under the False Claims Act, it is illegal to submit fraudulent claims for payment to the government.[15] A fraudulent claim that results from a kickback or violation of the Stark Law may invoke liability under two or more laws. The civil False Claims Act includes a whistleblower provision allowing a private citizen to file a lawsuit on behalf of the government and collect a certain percentage of any funds recovered. While these laws are primarily focused on Medicare and Medicaid patients, the hurdles they create for value-based health care have a permeating effect on non-government, commercial contracts as well, stifling innovation that might otherwise occur.[16]

FDA Communication Regulation

The FDA regulates product promotion by pharmaceutical and device manufacturers in order to ensure the public gets reliable information. Accurate information from manufacturers about the clinical benefits and risks of medical products is critical to value-based care in many ways. Health care professionals and health plans use this information for choosing the best medical care for each patient, making trade-offs between treatment options and costs, and determining value-based models and contracts.

Current FDA laws and regulations present hurdles to manufacturers disseminating information that is necessary for value-based health care in two areas:

1. Product information that is not included in the FDA's approved label about unapproved uses of approved medicines, often called off-label uses.
2. Product information that health plans may seek in making coverage and formulary decisions.

The first hurdle comes from the fact that health care professionals can lawfully use or prescribe an approved drug or device for non-approved uses. Off-label uses can start as a way to treat a condition that lacks an approved treatment. If successful, they may become recognized as recommended uses in a compendia of drug information used by Medicare and other health plans for coverage decisions.[17] Off-label uses are particularly common with cancer drugs. Patients can face greater safety risks from off-label uses than for on-label uses unless there is strong scientific evidence for the off-label use.[18]

FDA rules on off-label communications protect patient safety, and they can also create gaps in the distribution of key information about the risks and benefits of a drug or device. Specifically, they limit the ability for manufacturers to help overcome obstacles to the adoption of new treatments. These obstacles range from doctors lacking time to do their own investigation of new treatments to the time it takes for a manufacturer to receive approval to update their labels to include new uses.[19] Nonetheless, the benefits from spreading information widely and quickly need to be balanced against the risk of inaccurate or incomplete information.[20]

The FDA has been working toward a better approach to off-label communications over the course of the last three administrations.[21] It has aimed to strike a balance among complex and sometimes conflicting public health concerns. The FDA has also had to contend with court rulings that may limit its regulatory power on the basis of commercial free speech. And it has needed to ensure that allowing off-label communication doesn't substantially diminish manufacturers' incentives to seek formal approval for off-label uses. Recently, the FDA has recently launched a new review of off-label communications, which continues an earlier effort from 2011.[22] Despite these multiple efforts, the FDA has not issued final versions of key guidance that would create legal certainty around off-label communication.[23]

The second hurdle with FDA communication regulation is the production of information that health plans need when making coverage and formulary decisions. Ambiguity in FDA policy has also created challenges in manufacturers' communication of product efficacy, safety, and cost-effectiveness that plans may seek in making coverage and formulary decisions. Often, this health care economic information is different from the information the FDA reviews in order to make approval decisions.

Previous Congressional efforts to improve communication about product economics did not significantly change the flow of information, but new efforts have been more promising. The Food and Drug Administration Modernization Act of 1997 (FDAMA) attempted to increase the health care economic information that manufacturers are allowed to share with "a formulary committee or other similar entity," but this did not significantly improve the flow of such information.[24] More recently, the 21st Century Cures Act aimed to clarify the changes made under FDAMA. In addition, the FDA allows manufacturers to share certain health care economic information proactively with plans and similar entities.[25] The FDA has drafted guidance and background information to outline its thinking regarding the changes made by the 21st Century Cures Act and generally improve communications.[26] While the guidance is still in draft form, it has the potential to improve communications on health care economic information, which will help to better facilitate value-based models and contracts.[27]

The 21st Century Cures Act did not, however, address in much detail communications about drugs and devices under development (beyond what the FDA currently allows under certain circumstances). It also did not address the efficacy and safety information about off-label uses of drugs and devices already in the market, which have the potential to spur the use of value-based contracts for emerging therapies. In today's insurance markets, health plans set premiums many months in advance of the coverage year using estimates of utilization of services, including prescription drugs. In setting premiums, a plan can estimate the impact of drugs it anticipates will receive FDA approval and become available during a plan year. Yet, without any drug efficacy, safety, or economic information available until a drug hits the market, plans' premium levels may not be sufficient to cover the cost of new, highly priced drugs. In addition, the need for communication between plans and manufacturers regarding drugs in the FDA pipeline, as well as new uses of approved products, is critical. Collaboration helps avoid missed opportunities to make more precise predictions about costs based on appropriate use of the drug. Plans can use those more accurate predications to avoid premium increases that are higher or lower than necessary.[28] While the FDA recently addressed these issues in a draft guidance, they are not yet permanent.

These restrictions on how and what pharmaceutical and device manufacturers may communicate hinder the first two elements required for value-based contracts: a measurable, clinical benefit of a procedure, drug, or device as well as information about the cost of a procedure, drug, or device. The FDA asserts that in certain circumstances,

it can take action against manufacturers that share false or misleading information about new clinical benefits of their products that do not yet appear on the FDA-approved labeling for that product. Because of this legal uncertainty, manufacturers have diminished incentives for tracking data related to these new outcomes, which in turn denies information to patients and plans. In addition, with only limited exceptions for the sharing of cost and cost-effectiveness information, manufacturers and plans lack a shared knowledge base on which to build value-based contracts.

The Medicaid Best-Price Rule

The Medicaid best-price rule is designed to ensure that state Medicaid programs get the best-price for drugs available on the market. Specifically, the federal Medicaid drug rebate program requires that brand-name drug manufacturers who wish to have their medicine covered by Medicaid pay a rebate to the state programs across the country. This rebate reflects the greatest discount given to anyone in the country if that price is below a mandated discount (with certain exceptions like the sales to other government programs such as the Veterans' Administration). The mandated discount is provided in the form of a rebate that ranges from 13% to 23% of the average manufacturer price depending on the type of drug.[29] This effectively means that Medicaid gets the biggest rebate available in the commercial market.

In a value-based purchasing contract, a drug manufacturer that wants its drug to be on a health plan's preferred list for lower patient cost-sharing (known as a formulary) might offer the plan a deal: the manufacturer would accept a lower price (by paying a higher rebate) on a drug for any patient in whom the drug does produce the intended result. But under current regulations, that lower price could become the new price for that drug for calculating the Medicaid rebate. That is because current regulations are unclear about whether the lowest price must be based on the price for a single patient instead of the average price across a population of patients.[30] Understandably, manufacturers would not want to enter into a value-based contract that would cause them to receive a lower net price across all of their Medicaid business.

Why Are Existing Work-Arounds Not Working?

Health care entities that wish to pursue value-based health care can currently try one of several different ways to ensure their payment models and contracts do not run afoul of the Anti-Kickback Statute and Stark Law. (A parallel path to encourage more value-based arrangements is not available for FDA communications restrictions or the Medicaid best-price rule.) While these processes provide a type of "work-around," the system is cumbersome and uncertain, and it often discourages the implementation of legitimate value-based contracts. For example, 28 voluntary safe harbors from the Office of Inspector General protect certain payment arrangements from enforcement under the Anti-Kickback Statute.[31] Similarly, 35 regulatory exceptions outline permissible financial relationships between physicians and entities under the Stark Law, applying to ownership or investment interests, compensation

arrangements, or both.[32] These exceptions are not the same as the Anti-Kickback Statute safe harbors, but there is some overlap between the two.[33]

Even with these work-arounds, there are two key problems:

1. Current legal exceptions do little to reduce uncertainty.
2. Advisory opinions have limited application.

1. Current legal exceptions do little to reduce uncertainty.

To qualify for full protection under an Anti-Kickback Statute safe harbor, a payment or business practice must "fit squarely" within the safe harbor and satisfy all requirements.[34] But existing Anti-Kickback Statute safe harbors do not define the full range of lawful activity. Moreover, the failure to comply with all requirements of a particular safe harbor does not imply that an arrangement is illegal.[35] In fact, the Office of Inspector General has latitude over how it enforces adherence to the requirements, which can further increase uncertainty.

In contrast, the Stark Law and its enforcement is rigid and doesn't readily provide useful guidance to newer value-based payment for drugs and devices. Under Stark, a financial relationship must fit completely within an exception in order to be considered lawful, regardless of intent.[36] Since plans, providers, and manufacturers wish to avoid legal uncertainty, value-based arrangements have had limited adoption to date except under the existing safe harbors and exceptions.

Another problem with many of the Stark Law exceptions is that value-based contracts must not take into account the "volume or value of referrals" and must ensure any payment reflects the "fair market value" of the items or services in question.[37] The application of these standards to value-based payment is unclear. Incentive payments tied to quality may partially reflect the volume or value of referrals, yet these types of payments will help drive the transition to a value-based health care payment system. In addition, Stark Law regulations do not define "fair market value" or identify how organizations wishing to make use of the exceptions should establish or document it. Under fee-for-service payment arrangements, fair market value of many items and services may be based on volume, while contracts that may require use of a Stark Law exception are value-based.

In order to advance value-based payment models and programs under Medicare, the Department of Health and Human Services' Office of Inspector General and the Centers for Medicare & Medicaid Services (CMS) have issued fraud and abuse waivers for several programs.[38] For example, five waivers of certain elements of the Anti-Kickback Statute and Stark Law were issued for the Medicare Shared Savings Program to provide protection for certain gain-sharing and performance-based payments, among other things.[39]

While these waivers are certainly helpful, their application is limited and complicated. In informing model participants of the availability of the waivers for the Medicare Shared Savings Program and other Innovation Center models, CMS notes, "...not all

model-specific waivers are necessarily available to all participants in a given model... ...a waiver will apply to their arrangement(s) only if they are eligible to use the wavier and all conditions of the waiver are met." CMS further encourages "all parties to consult with legal counsel to ensure that waivers are available to them and that arrangements for which they seek waiver protection meet all required conditions."[40] Further complicating reliance on waivers, the waivers available to participants in different CMS models "vary in content, scope, and duration."[41] This means that one health care organization participating in two different CMS models (where allowed) may be required to abide by the specific parameters of two different types of Anti-Kickback Statute and Stark Law waivers.

Here's an example of how the current legal exceptions limit an ACO. Taking the care coordination example outlined above, an ACO participating in the Medicare Shared Savings Program is prohibited by the Stark Law and Anti-Kickback Statute from making payments to incentivize a skilled nursing facility to deliver quality care according to an evidence-based protocol. The existing shared savings distribution waiver fails to protect this kind of value-based arrangement due to two limiting conditions:[42]

First, the waiver does not protect funds distributed to care partners unless they are ACO Participants or ACO Providers/Suppliers in the regulatory senses of these terms.[43] The limited scope of these regulatory definitions eliminates the possibility of a skilled nursing facility receiving incentive payments when they partner with an ACO outside the formal ACO structure as defined in regulations.[44] Second, regulatory requirements prohibit an organization that bills for primary care services, such as a skilled nursing facility, from being a formal participant with more than one ACO, which prevents a skilled nursing facility from earning incentive payments from multiple ACOs.[45]

2. Advisory opinions have limited application.

In addition to the legal protections like the safe harbors and waivers, health care organizations may seek clarification from the Office of Inspector General.[46] But these advisory opinions have a narrow and limited benefit.

An advisory opinion is a binding legal opinion issued by the Office of Inspector General about the application of certain fraud and abuse regulations to an existing or proposed business arrangement. While advisory opinions clarify the permissibility of a particular arrangement, they do have limitations. First, advisory opinions issued by the Office of Inspector General are publicly available (with certain information redacted), but third parties that did not request the opinion are not bound by and may not legally rely upon the opinion.[47] Second, requesting parties are required to pay for an advisory opinion at a rate of $176 per hour, which may discourage some organizations from seeking an opinion.[48] Finally, the opinion applies only to the exact facts and circumstances presented; a small change to a value-based contract could render an advisory opinion no longer applicable.

CMS, which has jurisdiction over the Stark Law, operates a similar advisory opinion process.[49] But these also have limitations. These opinions are binding upon the requesting party, which is the only entity that may rely upon an advisory opinion as legal advice, and they apply only to the facts and circumstances presented. Health care entities need more legal certainty in order to advance value-based contracting.

What Are the Solutions?

Congress needs to provide a robust protection for value-based payments where patients benefit from improved outcomes or reduced costs by creating new legal protection. It also needs to enable a foundation for more value-based deals by opening up the opportunities to develop and share information about patient outcomes and costs.

We propose a two-part framework to provide legal certainty for entities engaged in value-based models and contracts as well as to enable preparation for those not yet involved—all while maintaining a strong statutory and regulatory regime for fee-for-service payments. Unlike existing safe harbors and statutory exceptions, new statutory protection would offer legal certainty for a range of value-based payment models and contracts. The Administration is considering regulatory changes, which are not the subject of this framework, but could serve a similar purpose.[50]

Part 1: Legal Certainty for Value-Based Purchasing

In order to provide legal certainty for value-based purchasing, we recommend that Congress take the following five steps:

First, codify protections for existing value-based payment models. Certain arrangements should be granted legal protection from the Anti-Kickback Statute and the Stark Law.[51] This legal protection would apply only to contracts or payments made for a qualifying value-based payment model and not to fee-for-service payments an entity may also receive or make. Included in this are: 1) value-based payment models meeting the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) criteria of alternative payment models and 2) models and downstream providers with whom they have contractual agreements along with any other alternative payment models developed by CMS. It is important to note that the new legal protection could also be adopted through regulations as a new Stark Law exception for alternative payment models. This exception would allow the provision of an incentive payment, directly or indirectly, by various types of health care organizations and facilities to a physician participating in a qualified alternative payment model.

Second, extend legal protections for additional value-based payment arrangements. Congress should direct the Secretary of Health and Human Services to establish protection from the Anti-Kickback Statute and Stark Law specifically for value-based models and contracts that may not meet the criteria described above but that that still advance the concept of tying payment for health care services and items to value. For example, the pharmaceutical and medical device guarantees described

at the beginning of this paper might not qualify for existing legal protection using the MACRA or advanced alternative payment model criteria, yet these types of models and contracts are certainly value-based and should be encouraged. Such criteria would also need to ensure that the incentives of the model are sufficient to have an impact on cost and quality.

Third, ensure that value-based arrangements in private health care plans do not get ensnared by Medicare and Medicaid rules. Existing legal protections under Medicare and Medicaid as described above should be explicitly extended to organizations implementing similar alternative payment models in commercial contracts. For example, although the Stark Law is enforced through Medicare laws, it nonetheless applies to financial relationships regardless of the health plan.[52] In addition, given that providers and manufacturers often face varying demands for quality and cost information from commercial plans in terms of accounting and reporting standards, new legal protections from the Stark Law and Anti-Kickback Statute should be crafted without exacerbating incongruities in practices between public programs and commercial markets wherever possible.

Fourth, revise the FDA's policies on communications in a targeted manner to enable better communication between drug and device manufacturers and health care health plans and providers. This change should be made without disrupting the integrity of the information or discouraging manufacturers from pursuing FDA approval for additional uses of an approved drug. Congress should prioritize two areas for revisions: clinical information about off-label uses of drugs and devices and general information about emerging therapies. For clinical information about off-label uses, Congress should revise the law so that that drug and device manufacturers can more freely share information with health care providers and plans, which they generate themselves from their own research and receive from doctors treating patients. They should be allowed to share information about what can help and hurt patients as long as sharing such information does not discourage a manufacturer from going through the other critical steps for getting additional uses approved for a drug. Congress could constrain communication to recommended off-label uses of drugs found in the compendia that Medicare has recognized for coverage determinations.[53] And for general information about emerging therapies, Congress should revise rules governing communication by drug and device companies about emerging therapies to ensure plans are better prepared to provide their enrollees with timely access to new treatments. Plans need to have such information in order to provide access to new therapies in a way that maximizes value. In revising these rules, Congress should account for the target audience of expanded communication. Expanding communications about sophisticated clinical information may simply overwhelm unsophisticated audiences. The revised rules should allow the FDA to ensure that communications were targeted in appropriate ways based on the anticipated use of the information. Lastly, as the FDA moves forward in implementing its draft guidance and the 21st Century Cures legislation, Congress should ensure that the FDA finalizes their work expeditiously to ensure that changes in FDA

communication regulations do not create more regulatory uncertainty for the flow of information necessary to make value-based contracts successful.

Fifth, Congress should modify the Medicaid best-price rule for prices established under value-based models and contracts as defined in the new legal protection described above. That would free up health plans and drug manufacturers to negotiate contracts without having to worry about losing money in Medicaid programs, which today would automatically receive a lower price without participating in the contract. For example, for drugs sold under the new legal protection, Congress could specify that the average price of the drug would be used for calculating the best-price discount for Medicaid programs instead of using a single lowest price, which today discourages such arrangements. For example, a manufacturer that offers a 100% rebate as part of a guarantee for a group of patients where the drug fails to meet a quality standard for only 10% of the patients would be giving an average rebate of only 10%. Under this new calculation, the guarantee would not trigger the best-price rule because the 10% rebate level would be less than any of Medicaid's mandated discounts. It is important to note that the Administration may also have the authority to make such a change. In addition, Congress should require that manufacturers offer Medicaid programs the same opportunity and same terms for a value-based contract that was exempted from the Medicaid best-price rule. Such a measure would protect the intent of the best-price rule, which enables Medicaid programs to receive the best deals available for drugs.

Part 2: Enable Preparation for Value-Based Health Care

Because building the capacity to deliver value-based care takes time and effort, the second part of our framework would provide a clear legal path for health organizations to prepare for participation in value-based models and contracts.

The key change is to encourage data collection and analysis as well as educate providers' staff in the use of data systems and in monitoring patients' progress. For example, Congress should revise and extend existing Anti-Kickback Statute and Stark Law to allow the donation and financial support of electronic health record software, related technologies, and training.[54] Congress should also consider expanding the scope of covered technology to include technology related to information sharing, such as health information storage and exchange and cybersecurity, reflecting technological advances since these exceptions were created. In addition, Congress should extend these electronic health record-related exceptions for several more years.[55] A solid health information technology infrastructure is an essential element for the move to value-based models and contracts, and federal regulations should not impede organizations from acquiring this necessary technology.

Similarly, new legal protection for pharmaceutical guarantees should allow manufacturers to provide data analysis support to help alleviate the measurement burdens that can limit interest in value-based arrangements for drugs and devices.

In order to ensure success from this two-part framework to advance value-based

arrangements, the Administration should regularly monitor and review all changes to ensure they are having their intended effect. For example, if providers and manufacturers increase prices under value-based arrangements without offsetting cost reductions or improvements in patient outcomes, then the new legal protection may have unintentionally given providers and manufacturers market power to increase prices. The HHS Office of Inspector General and CMS should be tasked with a periodic analysis of the economic impact of the new legal protection for value-based arrangements.

ENDNOTES

1. United States, Department of Health and Human Services, Centers for Medicare & Medicaid Services, HealthCare.gov, "Glossary: Value-Based Purchasing (VBP)." Accessed June 6, 2017. Available at: https://www.healthcare.gov/glossary/value-based-purchasing-VBP/.
2. Health Care Incentives Improvement Institute, "Value-Based Payment – Metrics for Transformation." Accessed June 6, 2017. Available at: http://www.hci3.org/tools-resources/metrics-tracking-transformation-us-health-care/value-based-payment-metrics-transformation.
3. Alison Sexton Ward et al, "Regulatory, Legal Uncertainties are Barriers to Value-Based Agreements for Drugs," Blog, Health Affairs, November 4, 2016. Accessed August 25, 2017. Available at: http://healthaffairs.org/blog/2016/11/04/regulatory-legal-uncertainties-are-barriers-to-value-based-agreements-for-drugs/.
4. Thomas Sullivan, "One of the Largest Medical Lab Bribery Prosecutions Continues in New Jersey," Policy and Medicine, January 12, 2016. Accessed March 22, 2018. Available at: http://www.policymed.com/2016/01/one-of-the-largest-medical-lab-bribery-prosecutions-continues-in-new-jersey.html.
5. 42 USC Sec 1320a-7b. Accessed May 12, 2017. Available at: https://www.law.cornell.edu/uscode/text/42/1320a-7b. See also Manatt Health, "Legal Issues Associated with Multi-Provider Alternative Payment Models," April 19, 2016. Accessed May 12, 2017. Available at: https://www.manatt.com/getattachment/599279ee-0b87-48dd-9a08-dc719fba1beb/attachment.aspx.
6. United States, Department of Health and Human Services, Office of Inspector General, "A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse," p. 5. Accessed May 19, 2017. Available at: https://oig.hhs.gov/compliance/physician-education/.
7. United States, Department of Health and Human Services, Office of Inspector General, Health Care Fraud Prevention and Enforcement Action Team, "Comparison of the Anti-Kickback Statute and Stark Law," undated. Accessed May 19, 2017. Available at: https://oig.hhs.gov/compliance/provider-compliance-training/files/starkandakscharthandout508.pdf.
8. United States, Department of Health and Human Services, Office of Inspector General, "A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse," p. 5. Accessed May 19, 2017. Available at: https://oig.hhs.gov/compliance/physician-education/.
9. American Hospital Association, "Legal (Fraud and Abuse) Barriers to Care Transformation and How to Address Them: Wayne's World," pp. 11-13, February 28, 2017. Accessed June 6, 2017. Available at: http://www.aha.org/content/16/barrierstocare-full.pdf.
10. Congressional Research Service, "Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview," p. 3, July 22, 2016. Accessed May 23, 2017. Available at: https://www.everycrsreport.com/files/20160722_RS22743_6e2c410ed24090f1764ea594bb6abf1f9b755406.pdf.
11. Under the Stark Law, a financial relationship consists of either an "ownership or investment interest" in the entity or a "compensation arrangement" between the physician (or immediately family member) and the entity. Congressional Research Service, "Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview," p. 4, July 22, 2016. Accessed May 23, 2017. Available at: https://www.everycrsreport.com/files/20160722_RS22743_6e2c410ed24090f1764ea594bb6abf1f9b755406.pdf.
12. 42 USC Sec 1395nn, May 22, 2017. Accessed May 23, 2017. Available at: http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section1395nn&num=0&edition=prelim.
13. United States, Department of Health and Human Services, Office of Inspector General, "A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse," p. 6. Accessed May 19, 2017. Available at: https://oig.hhs.gov/compliance/physician-education/.
14. Bob Belfort, Lisl Dunlop, Jocelyn Guyer, Edith Coakley Stowe, and Spencer Manasse, "Legal Issues Associated with Multi-Provider Alternative Payment Models," Presentation, Manatt Health, p. 19, April 19, 2016. Accessed May 23, 2017. Available at: https://www.manatt.com/getattachment/599279ee-0b87-48dd-9a08-dc719fba-1beb/attachment.aspx.
15. United States, Department of Health and Human Services, Office of Inspector General, "A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse," p. 3. Accessed May 19, 2017. Available at: https://oig.hhs.gov/compliance/physician-education/.
16. United States, Congress, Senate Committee on Finance, "Why Stark, Why Now," Majority Staff Report, June 30, 2016, p. 3. Accessed December 22, 2017. Available at: https://www.finance.senate.gov/chairmans-news/hatch-releases-white-paper-discussing-suggestions-to-improve-stark-law.
17. United States, Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Wolters Kluwer Clinical Drug Information Lexi-Drugs Compendium Revision Request," Posted Decision, August 12, 2015. Accessed December 22, 2017. Available at: http://go.cms.gov/2DzOHYw; See also Brown, "Gain a Solid Understanding of Compendia and its Impact on Patient Access," Formulary Watch, Modern Medicine Network, July 1, 2012. AccessedAccess December 22, 2017. Available at: http://formularyjournal.modernmedicine.com/formu-

lary-journal/news/clinical/clinical-pharmacology/gain-solid-understanding-compendia-and-its-imp.

18. Tewodros Eguale et al., "Association of Off-Label Drug Use and Adverse Drug Events in an Adult Population," JAMA Internal Medicine, January 2016. Accessed August 31, 2017. Available at: http://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2467782.
19. C. Lee Ventola,"Off-Label Drug Information Regulation, Distribution, Evaluation, and Related Controversies," Pharmacy and Therapeutics, August 2009. Accessed February 26, 2018. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2799128/.
20. C. Lee Ventola,"Off-Label Drug Information Regulation, Distribution, Evaluation, and Related Controversies," Pharmacy and Therapeutics, August 2009. Accessed February 26, 2018. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2799128/.
21. United States, Department of Health and Human Services, Food and Drug Administration, "Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices," Guidance for Industry, January 2009. Accessed February 27, 2018. Available at: https://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm; See also United States, Department of Health and Human Services, Food and Drug Administration, "Responding to Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices Practices, Draft Guidance" December 2011. Accessed August 31, 2017. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatorylnformation!Guidances/UCM285145.pdf; See also United States, Department of Health and Human Services, Food and Drug Administration, "Guidance for Industry Distributing Scientific and Medical Publications on Unapproved New Uses —Recommended Practices, Revised Draft Guidance," February 2014. Accessed February 27, 2018. Available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM387652.pdf; See also United States, Department of Health and Human Services, Food and Drug Administration, "Memorandum—Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products," January 18, 2017, p. 1. Accessed May 12, 2017. Available at: https://www.regulations.gov/document?D=FDA-2016-N-1149-0040.
22. United States, Department of Health and Human Services, Food and Drug Administration, "Memorandum—Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products," January 18, 2017, p. 1. Accessed May 12, 2017. Available at: https://www.regulations.gov/document?D=FDA-2016-N-1149-0040; See also United States, Department of Health and Human Services, Food and Drug Administration, "Responding to Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices Practices," December 2011. Accessed August 31, 2017. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatorylnformation!Guidances/UCM285145.pdf.
23. United States, Department of Health and Human Services, Food and Drug Administration, "Responding to Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices Practices, Draft Guidance," December 2011. Accessed August 31, 2017. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatorylnformation!Guidances/UCM285145.pdf; See also United States, Department of Health and Human Services, Food and Drug Administration, "Guidance for Industry Distributing Scientific and Medical Publications on Unapproved New Uses —Recommended Practices, Revised Draft Guidance," February 2014. Accessed February 27, 2018. Available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM387652.pdf.
24. United States, Senate, "S. 830—Food and Drug Administration Modernization Act of 1997," 105th Congress, 1st Session, Introduced June 5, 1007, Became law November 21, 1997. Accessed May 18, 2017. Available at: https://www.congress.gov/bill/105th-congress/senate-bill/830/text?q=%7B%22search%22%3A%5B%22Food and Drug Administration Modernization Act%22%5D%7D&r=1; See also Eleanor M. Perfetto, Laurie Burke, Elisabeth M. Oehrlein, and Mena Gaballah, "FDAMA Section 114: Why the Renewed Interest?" Journal of Managed Care & Specialty Pharmacy, May 2015, p. 370. Accessed May 12, 2017. Available at: http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=19494.
25. United States, Congress, House of Representatives, "H.R. 34—21st Century Cures Act," 114th Congress, 1st Session, Sec. 3037, January 6, 2015. Accessed June 19, 2017. Available at: https://www.congress.gov/bill/114th-congress/house-bill/34/text.
26. United States, , Department of Health and Human Services, Food and Drug Administration, "Statement from FDA Commissioner Robert Califf, M.D. Announcing New Draft Guidances on Medical Product Communications," Press release, January 18, 2017. Accessed June 20, 2017. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm537371.htm.
27. Peter J. Neumann and Elle Pope, "Cures Act, FDA Draft Guidance Suggest Flexibility on Communication of Real-World Drug Impacts, Though Questions Remain," Blog, Health Affairs, February 2, 2017. Accessed June 20, 2017. Available at: http://healthaffairs.org/blog/2017/02/02/cures-act-fda-draft-guidance-suggest-flexibility-on-communication-of-real-world-drug-impacts-though-questions-remain/.

28. "Facilitating Open Communication About Emerging Therapies," Anthem and Eli Lilly, p. 6, January 29, 2016. Accessed June 19, 2017. Available at: https://lillypad.lilly.com/WP/wp-content/uploads/LillyAnthemWP2.pdf.
29. Other factors can increase the effective discount rate including the inflation adjustment, which is tied to the general consumer price index as opposed to the medical price index. United States, Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Medicaid Drug Rebate Program," February 15, 2017. Accessed September 7, 2017. Available at https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html.
30. Rachel Sachs, Nicholas Bagley, and Darius Lakdawalla, "Value-Based Pricing for Pharmaceuticals in the Trump Administration," Blog, Health Affairs, April 27, 2017. Accessed September 7, 2017. Available at: http://healthaffairs.org/blog/2017/04/27/value-based-pricing-for-pharmaceuticals-in-the-trump-administration/; See also, Rachel Sachs, Nicholas Bagley, and Darius Lakdawalla, "Innovative Contracting for Pharmaceuticals and Medicaid's Best-Price Rule," Journal of Health Politics, Policy and Law, February 2018. Accessed October 5, 2017. Available at: http://jhppl.dukejournals.org/content/early/2017/09/25/03616878-4249796.abstract?papetoc.
31. United States, Department of Health and Human Services, Office of Inspector General, "Safe Harbor Regulations." Accessed May 12, 2017. Available at: https://www.oig.hhs.gov/compliance/safe-harbor-regulations/index.asp; See also 42 CFR Sec. 1001.952, 2017. Accessed May 22, 2017. Available at: http://bit.ly/2EXIVUP.
32. 42 CFR Sec 411.355-411.357, 2017. Accessed May 23, 2017. Available at: http://bit.ly/2oxunkk.
33. Jane Hyatt Thorpe and Elizabeth Gray, "Health System Transformation: Revisiting the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law to Foster Integrated Care Delivery and Payment Models," Report, Healthcare Leadership Council, p. 10, February 2017. Accessed May 24, 2017. Available at: https://www.hlc.org/special-programs/reports-and-publications/.
34. United States, Department of Health and Human Services, Office of Inspector General, "A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse," p. 4. Accessed May 19, 2017. Available at: https://oig.hhs.gov/compliance/physician-education/.
35. Congressional Research Service, "Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview," p. 4, July 22, 2016. Accessed May 23, 2017. Available at: https://www.everycrsreport.com/files/20160722_RS22743_6e2c410ed24090f1764ea594bb6abf1f9b755406.pdf.
36. Congressional Research Service, "Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview," p. 4, July 22, 2016. Accessed May 23, 2017. Available at: http://bit.ly/2oufYWq.
37. 42 CFR Sec 411.357, 2017. Accessed May 23, 2017. Available at: http://bit.ly/2oxunkk; See also 42 CFR Sec 411.357, 2017. Accessed May 23, 2017. Available at: http://bit.ly/2CnqQoR.
38. The programs with fraud and abuse waivers include the Medicare Shared Savings Program, Pioneer Accountable Care Organization model, Next Generation ACO model, Comprehensive End Stage Renal Disease Care model, and Bundled Payments for Care Improvement model. See United States, Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Fraud and Abuse Waivers for Select CMS Models and Programs, Fraud and Abuse Waivers Issued by the Department," January 18, 2017. Accessed May 24, 2017. Available at: https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html.
39. United States, Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Fraud and Abuse Laws Regarding Gainsharing or Similar Arrangements between Physician and Hospitals, As Required by Section 512(b) of the Medicare Access and CHIP Reauthorization Act of 2015," Report to Congress, p. 7. Accessed May 23, 2017. Available at: https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Reports.html.
40. United States, Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Fraud and Abuse Waivers for Select CMS Models and Programs, Fraud and Abuse Waivers Issued by the Department," January 18, 2017. Accessed May 24, 2017. Available at: https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html.
41. Jane Hyatt Thorpe and Elizabeth Gray, "Health System Transformation: Revisiting the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law to Foster Integrated Care Delivery and Payment Models," Report, Healthcare Leadership Council, p. 7, February 2017. Accessed May 24, 2017. Available at: https://www.hlc.org/special-programs/reports-and-publications/.
42. United States, Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Medicare Program: Final Waivers in Connection with the Shared Savings Program," Federal Register, October 29, 2015, p. 66743. Accessed October 4, 2017. Available at: https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html.
43. United States, Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Medicare Program: Final Waivers in Connection with the Shared Savings Program," Federal Register, October 29, 2015, p. 66743. Accessed October 4, 2017. Available at: https://www.cms.gov/Medicare/Fraud-and-Abuse/

PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html; See also 42 CFR Sec. 425.20, 2016. Accessed October 4, 2017. Available at: https://www.gpo.gov/fdsys/pkg/CFR-2016-title42-vol3/xml/CFR-2016-title42-vol3-part425.xml.

44. 42 CFR Sec. 425.116, 2016. Accessed October 4, 2017. Available at: https://www.gpo.gov/fdsys/pkg/CFR-2016-title42-vol3/xml/CFR-2016-title42-vol3-part425.xml; See also 42 CFR 400.202, 2016. Accessed October 6, 2017. Available at: https://www.ecfr.gov/cgi-bin/text-idx?SID=2ce8644c3a751fd97081533472d1a4ce&mc=true&node=se42.2.400_1202&rgn=div8.
45. United States, Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Medicare Program: Final Waivers in Connection with the Shared Savings Program," Federal Register, October 29, 2015, p. 66743. Accessed October 4, 2017. Available at: https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html.
46. United States, Department of Health and Human Services, Office of Inspector General, "Advisory Opinions." Accessed May 23, 2017. Available at: https://www.oig.hhs.gov/compliance/advisory-opinions/index.asp.
47. United States, Department of Health and Human Services, Office of Inspector General, "Advisory Opinions." Accessed May 23, 2017. Available at: https://www.oig.hhs.gov/compliance/advisory-opinions/index.asp.
48. United States, Department of Health and Human Services, Office of Inspector General, "Advisory Opinions FAQ." Accessed May 23, 2017. Available at: https://www.oig.hhs.gov/faqs/advisory-opinions-faq.asp.
49. United States, Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Advisory Opinions," May 22, 2017. Accessed May 23, 2017. Available at: https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html.
50. Steven Porter, "Stark Law Review in the Works, Says Verma," HealthLeaders Media, January 23, 2018. Accessed January 24, 2017. Available at: http://www.healthleadersmedia.com/leadership/stark-law-review-works-says-verma.
51. United States, Congress, House of Representatives, "H.R. 2—Medicare Access and CHIP Reauthorization Act of 2015," 114th Congress, 1st Session, Title I, Introduced March 24, 2015, Became Law April 16, 2015. Accessed June 7, 2017. Available at: https://www.congress.gov/bill/114th-congress/house-bill/2/text?q=%7B%22search%22%3A%5B%22Medicare access and CHIP Reauthorization Act%22%5D%7D&r=1; See also United States, Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models," Final Rule with Comment Period, November 4, 2016. Accessed June 7, 2017. Available at: https://www.federalregister.gov/documents/2016/11/04/2016-25240/medicare-program-merit-based-incentive-payment-system-mips-and-alternative-payment-model-apm.
52. 42 U.S. Code Sect., 1395nn(a). Accessed January 26, 2018. Available at: https://www.law.cornell.edu/uscode/text/42/1395nn; See also "Question and Answer: Self-Referral/Stark Law and Anti-Kickback Regulations," American Speech-Language-Hearing Association. Accessed January 26, 2018. Available at: https://www.asha.org/practice/reimbursement/medicare/QAs/.
53. United States, Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Wolters Kluwer Clinical Drug Information Lexi-Drugs Compendium Revision Request," Posted Decision, August 12, 2015. Accessed December 22, 2017. Available at: http://go.cms.gov/2DzOHYw.
54. 42 CFR Sec 411.357, 2017. Accessed May 23, 2017. Available at: https://www.ecfr.gov/cgi-bin/text-idx?SID=98a64c6581d5a7488d148dc74773099e&mc=true&tpl=/ecfrbrowse/Title42/42cfr411_main_02.tpl; See also 42 CFR Sec 1001.952, 2017. Accessed June 7, 2017. Available at: https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=90f45f0c857144405b17a43c35600c16&ty=HTML&h=L&mc=true&r=SECTION&n=se42.5.1001_1952.
55. Jane Hyatt Thorpe and Elizabeth Gray, "Health System Transformation: Revisiting the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law to Foster Integrated Care Delivery and Payment Models," Report, Healthcare Leadership Council, pp. 16-17, February 2017. Accessed May 24, 2017. Available at: https://www.hlc.org/special-programs/reports-and-publications/.