THIRD WAY

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Executive Summary: 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. These new payment models and contracts 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. 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.

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. 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). 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.

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, including the Anti-Kickback Statute, the Stark Law, FDA rules and policies on communication by pharmaceutical and medical device manufacturers about medical products, and the Medicaid best-price rule.

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. All four of these areas of law remain critical for preventing excessive use and pricing of care within the fee-for-service payment system.

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.

What Are the Solutions?

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. The Administration is considering regulatory changes, which are not the subject of this framework, but could serve a similar purpose.

Part 1: Legal Certainty for Value-Based Purchasing

1. Codify protections for existing value-based payment models.

2. Extend legal protections for additional value-based payment arrangements.

3. Ensure that Medicare and Medicaid rules do not ensnare value-based arrangements in private health care plans.

4. Revise the FDA's policies on communications in a targeted manner to enable better communication between drug and device manufacturers and health care plans and providers. These changes should be made without disrupting the integrity of the information or discouraging manufacturers from pursuing FDA approval for additional uses of an approved drug.

5. Modify the Medicaid best-price rule for prices established under value-based models and contracts as defined in the new legal protection.

Part 2: Enable Preparation for Value-Based Health Care

1. Encourage data collection and analysis as well as educate providers' staff in the use of data systems and in monitoring patients' progress.

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