

## EXECUTIVE SUMMARY

**V**Iable Solutions:

**S**ix Steps to Transform Healthcare Now

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PRESENTED TO:  
Healthcare Leadership Council  
750 9<sup>th</sup> Street, NW  
Suite 500  
Washington, DC 20001

PRESENTED BY:  
NORC at the University of Chicago  
4350 East West Highway  
Suite 800  
Bethesda, MD 20814

**NORC**

*at the* UNIVERSITY *of* CHICAGO

## Executive Summary

There is a broad consensus in the United States among healthcare providers, payers, clinicians, patients, and consumers that the nation's healthcare system does not operate at a level that generates optimal value. There is significant room for improvement in elevating quality, cost-efficiency, and sustainability. There is a gap between the innovations being developed in all sectors of healthcare and the ability to deliver those improved products and practices to patients.

While the Affordable Care Act focused on extending health coverage to tens of millions of Americans, a comparable effort is needed to address the health system's continuing cost, quality, and value challenges.

Through the Healthcare Leadership Council's National Dialogue for Healthcare Innovation (NDHI) initiative, companies from all sectors of healthcare joined with leaders of patient advocacy organizations, federal government officials, and academic health policy experts to build consensus on a broad spectrum of steps necessary to strengthen health system value and enable health innovation to have a greater positive impact on the entirety of the healthcare continuum.

NDHI participants came to the conclusion that healthcare in the U.S. can be significantly improved by focusing on actions that are readily achievable via legislation, regulation, or voluntary actions by various health system players. Positive health system transformation does not require a wholesale remaking of health delivery structures, but rather the enabling and acceleration of patient-centered innovation.

The diverse companies, organizations, and policy experts participating in the NDHI process agreed that focused actions in the following areas can significantly elevate health system value:

- Comprehensive care planning
- Medication therapy management
- Health information interoperability
- Changes to federal anti-kickback and physician self-referral (Stark) laws
- Health information flow improvements focused on patient privacy laws and regulations
- Food and Drug Administration (FDA) reforms

In these areas, there is consensus that the following actions should take place:

### Comprehensive Care Planning

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Today, over 80% of older adults have at least one chronic condition such as diabetes, congestive heart failure or hypertension, and one of every two seniors have at least two of these illnesses. The need for coordinated care for these individuals is clear. Yet, integrated, comprehensive care has been lacking. This fragmentation can lead to a myriad of difficulties such as lack of patient adherence. For decades,

significant numbers of patients have failed to take the medications prescribed by healthcare professionals. Studies have shown that, on average, 50% of medications for chronic disease are not taken as prescribed. This non-adherence problem may be costing the healthcare system as much as \$300 billion annually. Improved care coordination and adherence can have a dramatic effect on population health while significantly reducing health system costs.

In evaluating the most effective mechanisms to address the care coordination challenge, NDHI participants focused on diabetes – a disease with rapidly growing incidence rates and a patient population with consistently poor care coordination and adherence practices. Current Medicare reimbursement practices exacerbate this problem by, among other flaws, not paying for care coordination or coaching for diabetes management (including remote services), not reimbursing for participating in National Diabetes Prevention Programs, and not recognizing continuous glucose monitoring as a covered benefit.

NDHI participants believe there are three principles that should inform comprehensive care plans and serve as the rationale for government reimbursement of care activities. They are:

- *Comprehensive care planning must address the population’s multiple co-morbidities and complex care needs.* This principle addresses the fragmentation of the health delivery system for people with diabetes (and other chronic illnesses). Team-based care should be viewed as essential in care planning.
- *Chronic disease programs must address these illnesses across the entire continuum of care.* Care planning must promote not only screening and identification of risk factors for patients all along the disease spectrum, but also focus on hospital-to-home care transitions for chronic disease patients.
- *Comprehensive care planning must be cognizant of issues related to the individual and community-level context.* Care plans must equip patients with tools they need to successfully manage their conditions and proactively address the challenge of inadequate health literacy in the patient population as well as specific cultural beliefs about health.

## Medication Therapy Management

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Misaligned incentives have prevented the medication therapy management (MTM) program, part of the Medicare Part D prescription drug program, from achieving significant benefits. In September 2015, the Centers for Medicare & Medicaid Services (CMS) announced its intent to form a Part D Enhanced MTM Model to better align prescription drug plan sponsor and government financial interests while creating incentives for robust investment and innovation in better MTM targeting and interventions.

There are many ways this Enhanced MTM Model should be optimized to achieve greater levels of patient adherence and, thus, improved health outcomes. These include:

- *An accelerated implementation of the Enhanced MTM Model. As it currently stands, the model does not start until 2017, will run for five years and then be evaluated. This means a potential delay of seven to 10 years before the model’s benefits can be extended to all Medicare beneficiaries.*

- *The design should be expanded to offer benefits to all Part D members, including those in Medicare Advantage plans, to better align the financial interests of government and prescription drug plan sponsors.*
- *CMS should provide participating plans an opportunity to participate in developing quality measures, measures that should be formed through an intensive, transparent development and evaluation process.*
- *CMS should conduct robust education of providers and pharmacies on the Enhanced MTM model to better achieve optimal therapeutic outcomes.*
- *CMS should reconsider its stance regarding collaboration between pharmaceutical manufacturers and health plans. Such collaboration can encourage appropriate interactions that will result in improved medication adherence.*

## Health Information Interoperability

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Achieving high-value care requires a system that provides relevant health data to the right individuals at the right time. Comprehensive, readily accessible data is essential for both individual care decisions and population health management. A 2015 report by the Bipartisan Policy Center noted that billions of dollars are being invested in new healthcare delivery and payment systems that will reward better costs and quality outcomes, but that these arrangements will only be successful if greater information sharing and interoperable systems are in place.

Progress in this area had been lagging. As of 2013, only 62% of hospitals had reported being able to exchange electronic health information with any provider outside their organization; but recently the private sector has been driving improvements at a rapid pace. In fact, over the past 18 months the private sector has demonstrated through efforts such as the CommonWell Health Alliance, the Sequoia Project, and the Argonaut Project, among others, that there is a will to make progress toward interoperability through innovative efforts that are not driven solely by government regulation. The participants of NDHI believe that the private sector should continue to lead this progress with a limited role for government. Appropriate government involvement could include a governance structure that defines the “rules of the road,” such as prohibiting information blocking through certification authority or requiring a basic set of standards that the private sector could innovate from (such as open, publicly-available application program interfaces or APIs). Importantly, the participants of NDHI agree that any interoperability incentives from the federal government should be “technology neutral” and focused on outcomes in order to promote accessible and rapid innovation in health information connectivity.

NDHI participants identified challenges to achieving full-system interoperability, including conflicting and competing standards, the need for dissemination of emerging best practices in patient identification and matching, the lack of consensus on clinical workflow and payment reform best practices, and the complex provider collaborations involved in new delivery and payment models.

All of the companies and organizations involved in the NDHI initiative support the establishment of a December 31, 2018 deadline for health information interoperability, on or before which the nation must achieve nationwide exchange of health information through interoperable certified electronic health records (EHR) technologies. According to NDHI participants, this date of December 31, 2018 is achievable if driven by the private sector and the parameters and barriers noted above are sufficiently addressed.

Consumers should also have easy and secure access to their electronic health information, be able to direct it to any desired location, learn how their information can be shared and used, and be assured that this information will be effectively and safely used to benefit their health and that of their community.

### Federal Anti-Kickback and Physician Self-Referral (Stark) Laws

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To achieve improved care quality and cost containment, new healthcare delivery and payment models are designed to encourage greater integration among providers and other healthcare stakeholders. This raises the need to address the current federal fraud and abuse legal framework to make it more compatible with value-focused, integration-oriented health system transformation.

NDHI participants have focused on two of the primary fraud and abuse laws – the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law – and prioritized both regulatory and legislative options that should be pursued, independently or concurrently, to better support innovative payment and delivery reforms.

The regulatory options include:

- *Create Federal Anti-Kickback Statute and Stark Law waivers for all Accountable Care Organizations that meet certain conditions.*
- *Extend existing Anti-Kickback and Stark Law exceptions for donation and financial support of EHR software, and related interoperability-enabling technologies and training beyond 2021.*
- *Clarify how to establish, document and apply the “volume or value of referrals” standard within the changing healthcare payment environment.*
- *Expand and revise the definition of fair market value to account for new payment models that incentivize performance.*
- *Eliminate the “one-purpose” test for Anti-Kickback Statute liability and replace with a balancing test that would require the HHS Office of Inspector General (OIG) to prove either increased costs or actual harm to patients.*
- *When considering potential regulatory changes to the Federal Anti-Kickback Statute, stakeholders should also consider related changes to the Civil Monetary Penalties (CMP) Law, where appropriate, to ensure consistency in interpretation and application across both laws to encourage patient engagement and improved outcomes.*

The legislative options include:

- *Require the Department of Health and Human Services Secretary to review and assess the Federal Anti-Kickback Statute and Stark Law as well as the Civil Monetary Penalties (CMP) Law (expansion of current MACRA requirements) in the context of health system transformation, specifically addressing whether the laws create unnecessary barriers to new integrated care models and whether these laws are effective in limiting fraudulent behavior. Changes identified through this assessment may yield opportunities to amend fraud and abuse laws to foster healthcare arrangements that promote increased quality and lower costs.*
- *Grant OIG and CMS broader flexibility and discretion to develop exceptions and safe harbors to the Federal Anti-Kickback Statute and the Stark Law consistent with current health policy objectives (e.g., increased efficiency and quality, decreased cost).*

### Health Information Flow Improvements

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As healthcare systems make the transition to value-based care, accessibility and use of data takes on an exponentially greater importance. Unnecessary barriers to data sharing may impede a physician's ability to accurately diagnose patients and prescribe the most effective treatments, can lead to workflow inefficiencies, and potential inaccuracies in matching records with the correct patient.

At the same time, in today's environment, it is essential that patients be assured that their personal health data is protected and only accessed by those with legitimate and essential reasons to view it. Today, inconsistent interpretations of federal privacy laws as well as varying state privacy laws are leading to confusion and, with it, counterproductive restrictions on the necessary movement and sharing of health data.

NDHI participants have the consensus view that there is a need for a national health privacy standard to mitigate problems deriving from the variation among state laws and regulations. There is also a need for updated and harmonized federal privacy rules to align with new and innovative healthcare research capabilities. All privacy structures must enable the matching of records to the right patients with minimal time and effort.

### FDA Reforms

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Today, there are unnecessary delays in bringing new, improved treatments and technologies to patients due to redundant and counter-productive regulations from the FDA. Encouraging policy changes that streamline the agency's responsibilities, while ensuring that manufacturers remain accountable, could enable FDA to focus on high-priority activities and speed the approval of new medicines and healthcare products. NDHI participants also identified a series of unnecessary and redundant regulations that, if addressed, can accelerate patient access to new innovations. These include:

- *Eliminate the prohibition on using a single Institution Review Board of record for medical device trials, reducing the cost and time involved in product approvals.*
- *Allow companies to make certain changes to devices without a premarket submission, as long as the companies' quality systems have been certified as capable of evaluating such changes.*
- *Timelier recognition of standards established by international or nationally-recognized standards organizations. This will improve regulatory efficiency and reduce the time to bring medical technology to patients.*
- *Expand the definition of valid scientific evidence to include evidence described in well-documented case histories, including registry data, studies published in peer-reviewed journals and data collected outside the U.S.*
- *Provide greater training and achieve improved understanding of the use of 'least burdensome provisions' to increase efficiency and consistency for the FDA and manufacturers.*
- *Increase the flexibility for biopharmaceutical manufacturers, payers and providers to share scientific and healthcare economic information in order to optimize the clinical benefits of prescribed treatments. This type of information is critical for developing value-based payment systems.*

Each of these recommended steps, implemented individually, will strengthen healthcare quality and improve cost-efficiency. Adopted collectively, they can usher in a new era of healthcare reform, one that will make our health systems more value-focused and financially sustainable while bringing about an unprecedented level of improved population health through greater access to innovative cures, treatments, and medical technologies.

**For a copy of the complete report, please visit [www.ndhi.org](http://www.ndhi.org).**