FINAL REPORT

VIable Solutions:

Six Steps to Transform Healthcare Now

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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

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

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

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

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

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

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.

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Introduction

In 2010, the Healthcare Leadership Council (HLC), a coalition of chief executives from all sectors of healthcare – payers, providers, manufacturers, distributors, pharmacies, health information technology firms, and more – created the National Dialogue for Healthcare Innovation (NDHI). The purpose of NDHI is to create a platform through which these various health industry sectors can collaborate with patients, employers, academicians, and government to examine, discuss, and build consensus on how to address the most important issues affecting the course of 21st century healthcare progress.

On March 2, 2015, under the auspices of NDHI, an unprecedented summit meeting took place in Washington, D.C. Leaders of more than 70 of the most influential organizations in healthcare – including high-ranking officials from the Department of Health and Human Services (HHS), the Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration (FDA) – convened to identify the barriers impeding progress toward a high-value, innovation-driven healthcare system, and how to remove those barriers. This was a rare meeting focused not on a single, narrow healthcare issue, but rather on how to create a sustainable system equipped to address persistent cost and quality challenges.

As HLC President, Mary R. Grealy said at the March 2 summit, "There are a lot of voices out there talking about healthcare costs, value, affordability, and sustainability. We're never going to develop a pathway, though, that will incentivize innovation and strengthen health system value until we bring everyone to the same table."

Once leaders from across the healthcare spectrum came to the NDHI table, they decided to continue working to develop consensus solutions aimed at achieving greater healthcare quality and cost-efficiency. Following the summit, NDHI participants established three workgroups focusing on (1) Patient Engagement and Adherence, (2) Data Strategy and Electronic Health Records Interoperability, and (3) Outdated and/or Ineffective Laws and Regulations.

The workgroups collaborated throughout 2015 to agree upon policy approaches that transcend the theoretical and are viewed as clearly achievable, whether through legislation, regulatory action, or proactive steps initiated by healthcare organizations.

What emerged from this process is a blueprint that will be offered to executive and legislative branch policymakers and healthcare leaders. The recommendations in this paper, taken in total, can drive health system transformation and a movement toward value and innovation. The consensus viewpoints contained in this report are also consistent with steps currently being taken by the federal government to guide a health system transition from fee-for-service to pay-for-value and toward more integrated, coordinated care.

Figure 1.   Drivers of Increased Value and Innovation
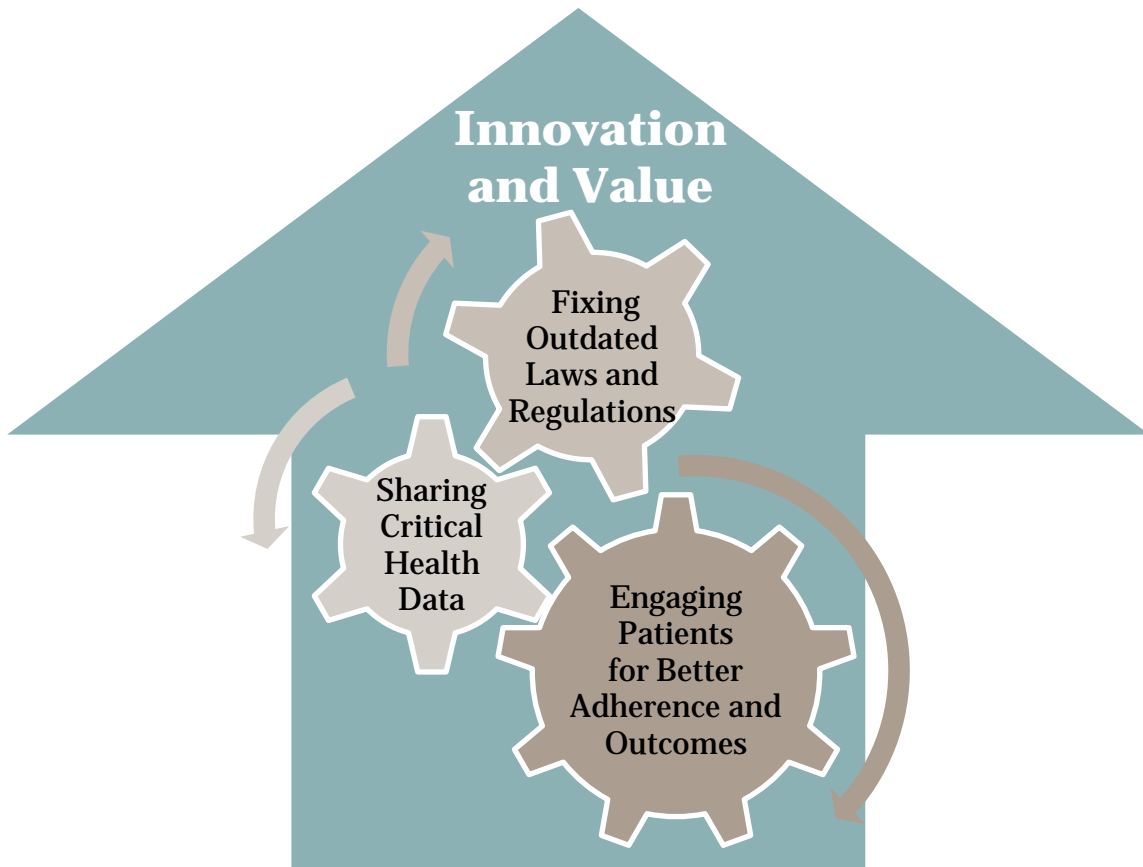
Seldom have such diverse interests and perspectives reached a shared view on how to advance value and innovation within the healthcare system. These recommendations can serve as a catalyst for further debate and, optimally, decisive action.

Approaches to Accelerating Healthcare Innovation

Addressing Three Key Areas

The following sections describe key findings from NDHI, which cover three key topic areas:

- Patient Engagement and Adherence;
- Data Strategy and Electronic Health Records Interoperability; and
- Outdated and/or Ineffective Laws and Regulations

Each section provides a framing of the salient issues, potential strategies for addressing these issues, and recommendations to elevate health system value.

Patient Engagement and Adherence

Patient-centered care is the key to value-driven, quality healthcare. By asserting more responsibility in healthcare planning and decision making, the consumer can drive change throughout the healthcare system. Likewise, without an engaged healthcare consumer, it is difficult for health organizations to drive patient-centered, coordinated quality care.

One key component of value driven care is **patient engagement and adherence**. Patient non-adherence can take many forms. These can include the failure to keep appointments, to follow recommended dietary or other lifestyle changes, or to follow other aspects of treatment or recommended preventive health practices. Medication

> **Medication adherence and compliance are synonymous terms, while medication persistence is a related but distinct term.**
>
> - *Compliance (or its synonym adherence)*: "the act of conforming to the recommendations made by the provider with respect to timing, dosage, and frequency of medication taking. Therefore prescription medication compliance may be defined as 'the extent to which a patient acts in accordance with the prescribed interval and dose of a dosing regimen.' Compliance is measured over a period of time and reported as a percentage…"
> - *Persistence*: "the duration of time from initiation to discontinuation of therapy"[i]

non-adherence is a particularly complex and growing public health concern to clinicians, healthcare systems, and other stakeholders[ii]. The lack of adherence to a prescribed treatment regimen is associated with poorer patient outcomes, including unnecessary disease progression, reduced quality of life, and even premature death. It also creates a significant societal burden, including increasing healthcare costs from hospitalizations and invasive procedures to address complications that may have been prevented with continuous intervention.

Reasons for non-adherence are multifactorial and difficult to identify. Patient therapeutic compliance may be associated with certain types of diseases, for example. Evidence shows that non-compliance is less common in acute illness or illness of short duration. In contrast, patients who are suffering from chronic diseases, in particular those with fluctuation or absence of symptoms are more likely to be non-compliant.

While the issue of patient adherence has been extensively researched, the rates of non-adherence have not shown significant improvement in the past three decades.

Today, about 80% of older adults have at least one chronic condition, and 50% have at least two. Diabetes, congestive heart failure, and hypertension represent three of the top five most prevalent conditions among Medicare beneficiaries.[iv] Given that many chronic

> **Scope of the Medication Adherence Issue**
>
> "Studies have shown that 20 to 30 percent of medication prescriptions are never filled and that, on average, 50 percent of medications for chronic disease are not taken as prescribed. This lack of adherence to medications is not only prevalent but also has dramatic effects on individual- and population-level health. Non-adherence has been estimated to cost the U.S. healthcare system between $100 billion and $289 billion annually in direct costs. Strong evidence suggests that benefits attributable to improved self-management of chronic diseases could result in a cost-to-savings ratio of approximately 1:10."[iii]

diseases can be treated and managed through behavior change and medication, this is a ripe area for action to promote patient adherence.

To address the complex issues described above, NDHI participants selected two key policy areas for further exploration**:**

1. Comprehensive Care Planning Principles (with diabetes as a case study); and

2. Medication Therapy Management (MTM) Models

The NDHI sought to identify specific opportunities to improve patient adherence through: (a) improving adherence along the continuum of care via the development of common principles that should be incorporated into any care plan for patients with diabetes; and (b) reforming federal MTM programs by reviewing and making recommendations for streamlining and/or improving these programs. Addressing these issues supports NDHI's overarching objective of enhancing value in healthcare by using innovative therapies, policies, and practices to support improved patient adherence that maximizes quality outcomes.

The next section describes the Comprehensive Care Planning Principles for diabetes in detail.

Comprehensive Care Planning Principles: Diabetes

Background

Definitions and Policy Context

The concept of comprehensive care planning is patient-centered, participatory, and nested within the broader concept of care coordination for people living with chronic illnesses.[v]

CMS offers a basic definition of a care plan: *"A written plan for your care. It tells what services you will get to reach and keep your best physical, mental, and social wellbeing."*[vi] CMS also provides an operational definition of a care plan that is more detailed and relevant for addressing the complexities facing patients who live with chronic illnesses: "It typically includes but is not limited to the following elements: problem list, expected outcome and prognosis, measurable treatment goals, symptom management, planned interventions, medication management, community and social services ordered,

direction and coordination of the services of agencies and specialists unconnected to the practice, identification of the individuals responsible for each intervention, requirements for periodic review, and, when applicable, any revisions."[vii] The issue of comprehensive care planning is receiving considerable attention among policymakers. For example, The Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014,[viii] which mandates common patient assessment data and quality measure reporting requirements for post-acute care (PAC) providers, also establishes new discharge requirements for general acute-care, critical access hospitals, and post-acute providers that are intended to facilitate the flow of patient information to the next healthcare setting. Beginning in late 2016, CMS will require long-term care facilities to develop a care plan for each resident within 48 hours of admission.[ix] CMS also proposes to require long-term care facilities to document in a beneficiary's care plan their goals for admission, assess the potential for future discharge, and include discharge planning in the comprehensive care plan for the beneficiary. The agency also proposes to add to the post-discharge plan of care a summary of arrangements for a beneficiary's follow-up care and post-discharge services, and the discharge summary must include a reconciliation of a beneficiary's current medications with those that the beneficiary was taking before entering the facility. Additionally, the Care Planning Act of 2015 (S. 1549) is pending legislation that would help severely ill patients (e.g., patients with late-stage diabetes) improve care coordination through patient-centered care planning – via the establishment of "planning services" as a Medicare benefit. Separately, the Government Accountability Office (GAO) recently released a report noting that under the Patient Protection and Affordable Care Act (ACA), there remain concerns that low-income individuals transitioning from Medicaid to exchange coverage may experience coverage gaps, due to the complex nature of coordinating policies and procedures.[x] Furthermore, the U.S. Senate Committee on Finance announced in May 2015 the formation of a Chronic Care Working Group that aims to improve care coordination and ensure high quality care for people living with chronic illnesses; notably, the Committee will place a strong emphasis on care coordination.[xi]

There are a myriad of types of patient non-adherence (i.e., non-adherence related to medication, lifestyle, or exercise guidance from health providers), and the reasons for patient non-adherence are complex as well.[xii] For example, a 2009 systematic review by RAND[xiii] found four major types of barriers to medication adherence:

- cost-sharing
- regimen complexity
- medication beliefs
- depression (in patients with diabetes)[xiv]

(However, it is important to note that much of this research predates the passage of the ACA, which has improved coverage to many individuals who were previously uninsured or underinsured.)

In response to concerns about patient adherence, CMS recently announced the Medicare Part D Enhanced MTM Model,[xv] which will place an emphasis on "right sizing" MTM and testing innovative regulatory

flexibility and payment incentives to target high-risk beneficiaries and provide them with the appropriate level and intensity of services.

Maximizing the potential for coverage of therapies and care management and assuring that all payers, providers, and patients recognize the value of patient adherence is key to the long term solution to this complex issue.

The Need to Focus on Diabetes

The NDHI developed a set of policy principles on comprehensive care planning for patients living with chronic diseases, using diabetes as a case example. These principles will inform future efforts to provide legislators and policymakers with evidence-based recommendations for addressing the complex needs of people with diabetes – as well as other chronic diseases. Diabetes is an important test case for comprehensive care planning because of its complexity as well as prevalence in the United States (U.S.). Although diabetes is a well-understood disease, individual patients may encounter many different obstacles that would prevent them from reaching optimal health. These barriers range from socioeconomic factors or lack of diabetes management education to the competing demands of family responsibilities and dynamics.[xvi] Cost of care may also be a barrier to good adherence.

The American Diabetes Association (ADA) cites compelling national statistics in its *Standards of Medical Care in Diabetes—2015* report[xvii] that underscore the need for effective disease management interventions: "[B]etween 33 and 49% of patients [with diabetes] still do not meet targets for glycemic, blood pressure, or cholesterol control, and only 14% meet targets for all three measures and nonsmoking status." Furthermore, diabetes, along with congestive heart failure (CHF) and hypertension, represent three of the top five most prevalent conditions among Medicare beneficiaries. These conditions share many of the same common, modifiable risk factors and comorbidities, including obesity and physical inactivity.

Finally, diabetes presents opportunities to intervene at multiple stages of the disease continuum. Those at high risk for diabetes, even if they are asymptomatic, should be screened consistent with screening guidelines (The U.S. Preventive Services Task Force (USPSTF) recommends screening as part of cardiovascular risk assessment in adults aged 40 to 70 years who are overweight or obese.[xviii]) so that the disease does not progress unchecked before diagnosis. Even those diagnosed with prediabetes, a condition where blood sugar is higher than normal but not high enough to be diagnosed as diabetes,[xix] can take steps to delay or prevent progression to Type 2 diabetes.

Diabetes Care Challenges

In spite of the tremendous toll of diabetes, numerous challenges for reimbursement of diabetes-related care hamper efforts to improve patient health:

- Currently in fee-for-service Medicare, CMS provides little or no reimbursement for remote care, care coordination, or coaching (e.g., phone visits, follow-up text messages, online) for the care and management of diabetes.

- Certified Diabetes Educators (CDEs) are not statutorily recognized providers of Diabetes Self-Management Training (DSMT) services, including DSMT by telehealth, under Medicare Part B. Additionally, diabetes case managers and educators receive differential reimbursement and medical nutrition therapy (MNT) and DSMT providers are not reimbursable on the same day.

- The new care coordination Healthcare Common Procedure Coding System (HCPCS) G-code has not been interpreted to include remote care coordination or coaching. Beyond basic evaluation and management services, few other avenues exist to compensate diabetes care providers for the intensive time and effort necessary to provide comprehensive management and support to patients with diabetes. This patchwork of regulation and reimbursement creates unnecessary gaps in patient care and makes healthcare more expensive overall.

- For patients with prediabetes, Medicare does not reimburse for participation in National Diabetes Prevention Programs (DPP, a lifestyle change program that can help prevent or delay the onset of type 2 diabetes) or MNT for people at high risk for developing diabetes.

In addition to undermining provider support, the current reimbursement structure makes it difficult for patients with diabetes to monitor the disease themselves. Medicare does not cover the tools and devices that some individuals need to most effectively monitor their diabetes:

- Medicare does not recognize continuous glucose monitoring (CGM) as a covered benefit. In numerous clinical trials, CGM systems have demonstrated improvement in overall glucose control and reductions in dangerous episodes of hypoglycemia when compared to self-monitoring of blood glucose (SMBG). Since CGM technology is covered widely outside of Medicare, beneficiaries entering Medicare may be forced to give up the diabetes blood glucose monitoring system that they had become accustomed to using with another payer.

- The 2013 competitive bidding program limits choices and access to certain types of diabetes testing supplies, such as blood glucose testing strips, purchased through mail order. If beneficiaries have difficulty finding replacements for familiar products, they may be inappropriately influenced to switch test systems. Product switching can have negative health and economic consequences.[xx]

Additional challenges include patient adherence for individuals with hypoglycemia, or abnormally low blood glucose levels. Hypoglycemia is the largest single barrier to achieving glycemic control in type 1 and type 2 diabetes[xxi] and is a significant cause of emergency department visits and hospitalizations, which increases the cost of treatment. Consideration of education and alternate therapies for individuals who experience hypoglycemia may help to alleviate the incidence of hypoglycemia.

Another care management challenge to consider in effective diabetes management are cases of clinical inertia – inadequate intensification of therapy by the provider. For example, newly diagnosed patients

often stay on a specific oral medication alone for about 14 months without additional agents (e.g., insulin) being added, even though they have not met their A1C goal.

Greater alignment between reimbursement structures and appropriate care steps could also lead to better outcomes for both patients and payers. At the healthcare system level, physicians of patients with multiple providers are not incentivized to work as a team, which creates challenges for persons with diabetes receiving coordinated, consistent care across numerous encounters. A 2014 RAND study of nearly 300,000 Medicare recipients[xxii] found that individuals with better continuity of care were less likely to be hospitalized, less likely to visit hospital emergency departments, had lower rates of complications, and had lower overall costs for their episodes of care.

Diabetes management also faces hurdles in the area of reporting and quality. There is a lack of uniform quality metrics across government programs, coupled with limited diabetes quality measures and alignment across Medicare Part A, B, and D. Payment is not currently tied to meeting appropriate standards of care for all services delivered. These gaps do not incentivize comprehensive diabetes care and make it harder for quality to be assessed and for providers and payers to monitor and respond to data.

Finally, quality diabetes care is often impeded by cost—both to the system and to patients. Every effort should be made to design diabetes care protocols that address this barrier. For example, the provision of additional tools for the patient or the provider or the promulgation of value-based benefit design could help address this issue. Additionally, it is crucial to recognize that the enormous prevalence of diabetes has significant consequences for health system stability as a whole, and efforts must be made to make investments in quality care that focuses on halting or slowing disease progression and the onset of complications.

Comprehensive Care Planning Principles

Below, we describe three Care Planning Principles for diabetes, along with key components/practices that should be included in comprehensive care plans and rationale for government reimbursement of these activities. These components can also inform the promulgation of quality measures related to comprehensive care plans for diabetes. These principles support NDHI's twin objectives of enhancing value in healthcare by using innovative therapies, policies, and practices to support improved patient adherence that maximizes quality outcomes.

These principles closely align with the ADA's *Standards of Medical Care in Diabetes—2015,[xxiii]* which provide four core recommendations for improving diabetes care, overall:

1. A patient-centered communication style that incorporates patient preferences, assesses literacy and numeracy, and addresses cultural barriers to care should be used.

2. Treatment decisions should be timely and founded on evidence-based guidelines that are tailored to individual patient preferences, prognoses, and comorbidities.

3. Care should be aligned with components of the Chronic Care Model (CCM) to ensure productive interactions between a prepared proactive practice team and an informed activated patient.

4. When feasible, care systems should support team-based care, community involvement, patient registries, and decision support tools to meet patient needs.[xxiv]

Principle 1: Comprehensive care planning must address the population's multiple co-morbidities and complex care needs.

Comprehensive, patient-centered care planning must address a key underlying health system issue: the fragmentation of the health delivery system for people with diabetes. The notion of "team-based care" is one that should be championed as part of care planning.

Component 1.1: Care plans should incorporate evidence-based care coordination strategies (defined by the Agency for Healthcare Research and Quality's (AHRQ's) as "deliberately organizing patient care activities and sharing information among all of the participants concerned with a patient's care to achieve safer and more effective care"[xxv]) that address underlying patient comorbidities (e.g., depression). The ADA suggests that addressing missed treatment goals may require evaluation of barriers such as diabetes-related distress or depression [xxvi] and the American Association of Clinical Endocrinologists and American College of Endocrinology's evidence-based clinical practice guidelines for diabetes makes the following recommendation for patients with diabetes and depression: "Patients with depression or [diabetes]-related distress should be referred to mental health professionals who are integrated into the [diabetes] care team."[xxvii] For example, Katon and colleagues conducted a trial of "collaborative care" in 14 clinics in the state of Washington, in which nurses provided "guideline-based, patient-centered management of depression and chronic disease." The researchers found significant 12-month improvements along a number of measures related to both diabetes and depression (e.g., glycated hemoglobin, patient satisfaction, and perceived quality of life) due to the intervention.[xxviii]

Comprehensive care plans, by definition, should address the full range of health problems of a particular patient – i.e., not limited to diabetes. For example, diabetes care plans should explicitly address comorbidities such as cardiovascular disease. The American Heart Association recognizes a strong correlation between cardiovascular disease (CVD) and diabetes. Heart disease and stroke are the number one causes of death and disability among people with type 2 diabetes and adults with diabetes are two to four times more likely to have heart disease or a stroke than adults without diabetes.[xxix] In this regard, the ADA notes the need for "a comprehensive plan to reduce cardiovascular risk by addressing blood pressure and lipid control, smoking cessation, weight management, and healthy lifestyle changes that include adequate physical activity" for patients with diabetes.[xxx]

Component 1.2: Comprehensive care planning should include the use of care coordinators to address the multitude of daily issues facing persons with diabetes. For example, the use of care coordination programs may have potential for managing care transitions and obviating hospital readmissions. Care planning for people living with diabetes needs to include interdisciplinary teams that can meet the holistic needs of individuals and engage community resources outside the hospital sector.

Care coordinators can be deployed to provide a variety of services, including: assessing treatment adherence, coordinating with providers about patient treatment needs, ensuring that patients have transportation, language translation, and other support services needed to access care, and providing health education. An increasingly multidisciplinary approach to the care of these patients may be one answer for improving patient clinical outcomes and healthcare resource utilization. Community health

workers or other non-licensed health providers can also provide critical care coordination services and should be considered a vital part of the care team.

Component 1.3: Comprehensive care planning should be supported by improved communication and data sharing among providers on the interdisciplinary diabetes care team. For example, the National Diabetes Education Program cites the importance of timely information-sharing via the use of health information systems by care teams, which comprise "the primary care provider, endocrinologist, nurse, diabetes educator, dietitian, mental health provider, exercise physiologist, other team members and specialists, as well as hospital-based providers."[xxxi] The contributions of non-licensed, community-based health providers should also be integrated into electronic medical record systems so that records reflect the entirety of patient treatment.

One strategy for achieving communication and data sharing is the increased use of telehealth. While the scientific literature is still emerging on the full benefits of telehealth applications, promising initiatives have been described. For example, a recent randomized clinical trial of a telehealth remote monitoring intervention, in which patients remotely sent their paired glucose tests (i.e., before and after a meal or physical activity) via tablet and subsequently received feedback from certified diabetes educators, led to improvements in A1C levels.[xxxii] Also, the DiaTel randomized, controlled trial of active care management supplemented by home telemonitoring intervention, demonstrated long-term (> 6 months) reductions in A1C levels in a population of veterans.[xxxiii]

The use of patient-centered health information technologies for diabetes is one way to ensure communication between patients and providers in care planning and empower patients to express their values, needs, and preferences about their care. Patient adherence can often be improved either through personalized care coordination or through simpler systems of reminders and educational materials. Greater data connectivity can also be used to identify gaps in diabetes care for other important treatment indicators, such as blood glucose monitoring.

For example, remote patient monitoring (RPM) technology enables monitoring of patients outside of conventional clinical settings (e.g., in the home), which may increase access to care and decrease healthcare delivery costs. Incorporating RPM in chronic disease management can significantly improve an individual's quality of life. It allows patients to maintain independence, prevent complications, and minimize personal costs. RPM is used to monitor a variety of chronic illnesses, including diabetes, and transmit alerts to both the patient and the physician.

Principle 2: Chronic Disease programs must address chronic disease across the entire continuum of care.

Component 2.1: Care planning should promote screening and identification of risk factors for patients all along the disease spectrum. Risk factor identification, screening, and interventions have been successful in identifying and preventing chronic diseases and their associated morbidity and mortality in older adults. Greater impact in this area will require extensive collaboration among stakeholders (providers, health plans, pharmacists, and patients) in order to identify high-risk individuals.

Better effort needs to be made to identify patients with chronic diseases such as diabetes. The 2014 draft USPSTF factor-based screening guidelines for diabetes would have helped address the fact that many people living with Type 2 diabetes currently are not diagnosed with the disease. Prediabetes affects more than 1 out of 3 American adults, but 9 of 10 of them do not know they have it.[xxxiv] While the final guideline, released October 27, 2015, backtracked from the 2014 draft, it still opened the door for screening for prediabetes.

In patients diagnosed with prediabetes or diabetes, care plans should focus on early intervention to prevent disease progression and complications. Health plans or other providers use data from claims, enrollment, and pharmacies to look for patterns of non-adherence or identify at-risk members. The use of in-home risk assessment also supports early identification of at-risk members, including those with and without diagnosed conditions.

Component 2.2: Comprehensive care planning must focus on care transitions for patients with diabetes. One of the IMPACT Act's stated reasons for collecting standardized data from long-term care hospitals (LTCHs), skilled nursing facilities (SNFs), home health agencies (HHAs) and inpatient rehabilitation facilities (IRFs), is to "improve hospital and PAC [post-acute care] discharge planning." And as the ADA notes in its 2015 *Standards*, "Diabetes discharge planning should start at hospital admission, and clear diabetes management instructions should be provided at discharge." [xxxv]

Numerous ongoing projects are testing evidence-based models for patient transitions from hospitals into their communities. For example, the Patient-Centered Outcomes Research Institute (PCORI) is funding the $15 million Project ACHIEVE (Achieving Patient-Centered Care and Optimized Health In Care Transitions by Evaluating the Value of Evidence), which will "develop recommendations on best practices for the design, implementation and large-scale national spread of highly effective, patient-centered care transition programs."[xxxvi] The identification of evidence-based strategies for transitions, including patient-engagement activities, post-discharge, will be crucial for comprehensive care planning for patients with diabetes.

AHRQ's *Care Transitions from Hospital to Home: IDEAL Discharge Planning Implementation Handbook*[xxxvii] describes best practices in the management of heart failure, heart attack, and pneumonia, among four high-performing US hospitals (with respect to readmissions). This information could be useful for developing care transition strategies *for diabetes*.

- "A focus on improving clinical quality and patient care with the belief that reductions in readmissions will naturally occur as a result of these improvement efforts.

- Attention to discharge planning from the first day of patients' stay, typically within 8 hours of admission. This includes staff assessment of patients' risk factors, needs, available resources, knowledge of disease, and family support.

- Care coordination after discharge. Two hospitals scheduled follow up appointments for most of their patients prior to discharge. Because of limited resources, the two other hospitals made follow up appointments on an ad hoc basis for the neediest patients. All hospitals coordinated with home health agencies and connected patients to community resources.

- Empowering patients through educational activities throughout the stay to help patients understand their conditions; manage their diet, activities, medications, and care regimens; and know when to seek care."[xxxviii]

AHRQ also provides specific guidance on sound practices in discharge planning: (a) medication reconciliation (e.g., "The patient's medications must be cross-checked to ensure that no chronic medications were stopped and to ensure the safety of new prescriptions"); and (b) structured discharge communication ("Appointment-keeping behavior is enhanced when the inpatient team schedules outpatient medical follow up prior to discharge. Ideally, the inpatient care providers or case managers/discharge planners will schedule follow-up visit(s) with the appropriate professionals, including primary care provider, endocrinologist, and diabetes educator").[xxxix]

Component 2.3: Care planning should also include end-of-life planning and discussions. Such conversations go beyond a narrow focus on resuscitation and address the broad array of concerns shared by most patients and families. These include fears about dying, understanding prognosis, achieving important end-of-life goals, and attending to physical needs. Good communication can facilitate the development of a comprehensive treatment plan that is medically sound and concordant with the patient's wishes and values.[xl]

Principle 3: Comprehensive care planning must be cognizant of issues related to the individual and community-level context.

As noted above, missed treatment goals may have myriad contributing causes. Complex care planning must be aware of and seek to address issues related to the individual patient and their context in which they live.

Component 3.1: Care plans must empower and equip patients with the tools they need to play an active role in managing their diabetes. To best help patients when they return home from the clinical setting, it will be essential for care plans to mobilize and incorporate outpatient resources that help support patient engagement and adherence.

Various studies have been conducted to test outpatient strategies to improve medication adherence for patients with diabetes. For example, the Joslin Diabetes Center developed the Diabetes Outpatient Intensive Treatment (DOIT) program is an interactive, 3.5 day-group education and skills training experience that was supplemented with daily medication management. The program led to significant improvements in A1C levels.[xli] Furthermore, tailored "health coaching" interventions have also been shown to improve medication adherence among patients with diabetes.[xlii] Additionally, a community pharmacy-based medication therapy management (MTM) program for patients with both hypertension and diabetes was found to improve blood pressure control.[xliii] Finally, the American Pharmacists Association has coined the concept of diabetes "patient credentialing" as part of disease self-management interventions to describe "people who have a certain diagnosis and have achieved certain levels of competency in understanding and managing their disease."[xliv]

DSMT programs are another important tool. For type 2 diabetes, the 2015 AHRQ Evidence Report on behavioral interventions for diabetes notes that intensive in-person DSMT programs (11 or more hours of contact time) are most effective at achieving glycemic control, and that targeting interventions for particular populations (i.e., minority groups) may also be beneficial: "our analyses showed limited benefit

in glycemic control from DSME programs offering ≤10 hours of contact with delivery personnel and suggested that in-person delivery of behavioral programs is more beneficial than communicating the information with incorporation of technology. Behavioral programs seem to benefit individuals having suboptimal or poor glycemic control more than those with good control. Tailoring programs to ethnic minorities appears to be beneficial."[xlv] Currently, DSMT participation rates are extremely low (7% among those with private insurance and 4% among those with Medicare coverage[xlvi]), so increased communication among patients and providers about the benefit is needed, as well as greater reimbursement as noted above.

Registered dieticians also play a role in providing patients with the tools needed to manage their disease. Nutrition therapy is an integral component of diabetes prevention, management, and self-management education, and the ADA recommends all individuals with diabetes should receive individualized medical nutrition therapy, preferably provided by a registered dietitian nutritionist (RDN).[xlvii]

This guidance is consistent with the final recommendation of the USPSTF regarding abnormal blood glucose: "Clinicians should offer or refer patients with abnormal blood glucose to intensive behavioral counseling interventions to promote a healthful diet and physical activity."[xlviii]

This type of education has also been shown to improve quality of life for patients. In adults with type 2 diabetes, one study of quality of life assessment reported that self-perception of health status improved and participants receiving MNT from RDNs felt very knowledgeable and motivated after seeing a dietitian. In another study of adults with type 2 diabetes receiving case management from RDNs, 12-month quality of life scores were significantly better than adults receiving usual care. Emotional stress was also decreased in adults with type 2 diabetes. In persons with type 1 diabetes, three studies reported significant improvements in quality of life (satisfaction with treatment and psychological well-being) despite increases in insulin injections or diet requirements.[xlix]

The use of community health workers (CHWs) to implement diabetes-focused programs – as well as for obesity management, more generally – have been described in the literature. For example, the Mexican American Trial of Community Health Workers (a randomized, controlled trial in which CHWs delivered diabetes self-management training via home visits over 2 years) led to improvements in A1C levels at both the end of Year 1 as well as Year 2 of the intervention. Regarding obesity management as a whole, a 2014 *JAMA* systematic review found evidence for the effectiveness of intensive behavioral weight loss counseling led by trained interventionists, such as medical assistants and registered dieticians.[l] Furthermore, trials testing the Weight Watchers program have found promising results with respect to weight loss outcomes.[li]

Additionally, Aging and Disability Resource Centers (ADRCs) are one example of a community resource that may provide an opportunity for elderly people living with diabetes to utilize existing community resources. (ADRCs have 5 core functions: "1) information, referral and awareness, 2) options counseling, advice and assistance, 3) streamlined eligibility determination for public programs, 4) person-centered transitions, and 5) quality assurance and continuous improvement. ADRCs perform these functions by

integrating, coordinating, and strengthening different pieces of the existing long term supports and services systems, including Area Agencies on Aging, Centers for Independent Living, state and local Medicaid offices, and other community-based organizations."[lii])

As the health system seeks to mobilize and incorporate community-based health and support, it may be helpful to draw on the experience of Medicare Advantage (MA) plans. Currently, the only tool health plans have to offer flexibility to the individual are medical management tools that must be offered to an entire population regardless of need (e.g., waiving or eliminating copays on certain medications for one population, providing additional transportation to individuals with more frequent medical appointments or waiving the copay on a type of specialist visit based on an individual's health needs). MA plans should be given flexibility to permit providers to develop individualized care plans that tailor tools to support patient needs. Further, some services plans want to provide do not fall within medical necessity. Examples of such services are: homemaker services, home-delivered meals, personal care services (assistance with bathing and dressing), transportation escort services, inpatient custodial level care, in-home caregiver relief, adult day care services, and non-Medicare-covered medical and safety equipment (e.g., the purchase of a refrigerator to store insulin, an air conditioner in geographies with severe summer temperatures or railings to help prevent falls).

Online and community-based and health providers such as Weight Watchers, Y-USA, and Omada Health that provide CDC-certified diabetes prevention programs offering DPP are also examples of organizations that care plans should look to for assistance in helping patients maintain adherence to treatment plans. Community-based programs such as these are especially important for patients in traditional underserved and minority communities or communities with a high level of mistrust of the traditional medical system.

Component 3.2: Diabetes care plans should use health literacy assessments as a tool to inform appropriate interventions for individual patients. A study in *JAMA* on health literacy and diabetes[liii] found that patients with inadequate health literacy were less likely than patients with adequate health literacy to achieve tight glycemic control, were more likely to have poor glycemic control, and report having diabetic retinopathy. By using data to identify which patients are most at risk of becoming non-adherent, physicians can best determine which patient engagement strategies to utilize. This also reduces the level of outreach to low-risk patients (those most likely to adhere) and ultimately allows for more targeted deployment of resources and time to the most at-risk patients.

Furthermore, care plans should adopt best-evidence practices in reaching low-literacy patients. As an article in the *American Journal of Health Behavior* on health education for low-literacy audiences noted, "Materials should be focused on offering practical strategies for behavior change, the 'need to do', rather than focused on teaching facts, the 'need to know.'"[liv]

Component 3.3: Diabetes care plans should incorporate best practices in person-centered, culturally-appropriate guidance for patients with diabetes to address specific cultural beliefs about health (e.g., in some cultures one does not seek healthcare until symptoms have already developed). To the extent that these beliefs modify health-seeking behaviors, care plans need to adopt strategies described in the

literature, such as the use of culturally-salient metaphors for describing diabetes as a disease in terms that certain community members will identify with.[lv]

Guidance from the American Association of Diabetes Educators and the National Standards for Diabetes Self-Management Education and Support may be particularly useful guidelines in this regard:

"[T]he prudent diabetes educator provides important information, care, and support to persons affected by diabetes in a manner that:

■ Acknowledges that cultural perceptions of health can be unique for each individual.

■ Considers the context of learning experiences already present when developing collaborative efforts with the patient to identify barriers to diabetes care success.

■ Conveys accurate information in a fashion that is understandable to the learner. Proactively addresses limitations to self-management plan adherence and designs/brokers culturally appropriate goals.

■ Utilizes educational materials and resources appropriate for culture, age, literacy level, and learning readiness.

■ Includes resources that address access limitations to diabetes-care needs and considers the milieu in which the care plan is to be executed.

■ Incorporates sensitivity and respect when educating all people irrespective of ethnicity, race, age, and socioeconomic status."[lvi]

Conclusions

Comprehensive care planning for diabetes requires a holistic, patient-centered approach that spans the continuum of care. These three principles and their components underscore NDHI's vision to ensure patient adherence and maximizing quality outcomes for diabetes. Thus, comprehensive care planning for diabetes may provide useful lessons for action to address other chronic diseases.

Medication Therapy Management (MTM) Models: Standard versus Enhanced MTM

A critical component of providing coordinated care includes medication adherence. This section explores improvements to a specific program -- Medicare's medication therapy management (MTM) program, which needs to be improved in order to provide better value.

The Medicare Modernization Act (MMA), which created the Part D program, requires that every Part D plan offer a medication therapy management (MTM) program as a quality improvement feature. However, misaligned incentives inhibit the program from achieving significant benefits. In September 2015, CMS announced its intent to form a Part D Enhanced MTM Model to test changes to the Part D program that would achieve better alignment of prescription drug plan (PDP) sponsor and government financial interests, while also creating incentives for robust investment and innovation in better MTM targeting and interventions.[1]

Below, we examine the new "enhanced" model and areas for improvement.

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[1] All quotes in this document are from Centers for Medicare & Medicaid Services. CMS Part D Enhanced Medication Therapy Management Model Fact Sheet, September 28, 2015.

Table 1. Part D Enhanced MTM Model: Positive Features and Areas for Improvement

POSITIVE FEATURES	AREAS FOR IMPROVEMENT
GENERAL	
■ **Emphasis on regulatory flexibility** will allow targeting of high-risk beneficiaries and provide appropriate level and intensity of services (allows PDPs to stratify services by beneficiary risk; allows different levels and types of MTM services). ■ **Waivers** will allow various providers to offer interventions of a type that are not usually furnished in traditional MTM programs.	■ Timing of the model delays beneficial change. The model will result in a potential delay of seven to 10 years from today before the model's benefits can be extended to all beneficiaries since the model does not start until 2017, runs for five years, and will be evaluated. ■ The design does not address the value of offering these benefits to all Part D members (including MA-PD plans) to achieve better alignment of PDP sponsor and government financial interests and optimize therapeutic outcomes. ■ Restriction of the model over the five year demonstration creates unfair competitive disadvantage for plan sponsors outside the designated regions. Additionally, all PDF plans under a single contract should be able to participate, rather than be forced to split the contract (creating administrative burden for CMS and plans, as well as denying the benefits of the enhanced model to some patients served by the contract).
SPECIFIC	
Payment Incentives ■ "Prospective payment for more extensive MTM interventions that will be "outside" of a plan's annual Part D bid"; and ■ "A performance payment, in the form of an increased direct premium subsidy, for plans that successfully achieve a certain level of reduction in fee-for-service expenditures and fulfill quality and other data reporting requirements through the [Enhanced] model."	■ CMS should invest in research to determine whether these payment incentives will offset participating plan sponsors' increased resources in the Enhanced MTM model.
Quality Measures ■ "CMS will develop new MTM-related data and metric collection requirements for both monitoring and evaluation purposes."	■ CMS should provide participating plans with an opportunity to participate in developing the quality indicators that comprise the uniform set of MTM data elements. ■ CMS should rely on measures that have been developed through an intensive, transparent development and evaluation process such as employed by national quality organizations like the Pharmacy Quality Alliance (PQA) and the National Quality Forum (NQF). ■ CMS should work with stakeholders to choose measures that address clinical outcomes for the conditions selected by plans for enhanced MTM services to determine any potential effect that these services have on overall quality of care. ■ CMS should employ a public comment process that allows a full range of stakeholders to provide input into the final measure set, performance standards (e.g., for purposes of determining performance-based payments), and evaluation methods.

POSITIVE FEATURES	AREAS FOR IMPROVEMENT
	■ CMS should address the expected differences in Star Ratings between Part D regions CMS has selected to participate in the demonstration and those that are prohibited from participating so as not to penalize those non-selected regions. ■ CMS should consider the different requirements of plans with high levels of low-income subsidy (LIS) enrollment (e.g., any application of financial incentives to plan payments must be appropriately adjusted for plans serving high concentrations of LIS members who may be more difficult to reach out to and serve—especially as this could impact LIS benchmarks also). ■ CMS should also consider how to fairly measure quality for plans serving many LIS-eligible enrollees as they develop quality metrics for monitoring and evaluation of the model.
Emphasis on learning activities and plans to promulgate lessons	■ CMS should be more explicit about how plans' proprietary information can be appropriately protected. ■ Lessons learned should be shared with plans outside of the model's geographic limitations. ■ CMS should take the lead in robust education of providers and pharmacies on the Enhanced MTM model test, particularly as it compares to the standard MTM program. Additionally, increased plan flexibility to customize their communications about the model could create confusion for many physicians and members about how this model test relates to the traditional MTM benefit.
Stakeholder Collaboration	■ CMS should reconsider its stance regarding manufacturer and health plan collaborations to allow for appropriate interactions that will result in improved medication adherence.

Health Information Interoperability

Beyond patient engagement and adherence, a key goal of NDHI was establishing a learning health system[2] that operationalizes high-value care through the provision of relevant data to the right individuals at the right time. Providers must be able to use patient data from many different sources for individual care decisions and population health management. NDHI recognizes that integrated information collection and sharing through expanded data and electronic health records (EHR) interoperability is critical to achieve this goal. Ultimately, a system in which health information technology (HIT) systems interoperate will increase trust in the health system by all stakeholders and reduce the need to rely on expensive and burdensome tracking and reporting systems to demonstrate safety and quality.

> **"[I]nteroperable EHR systems could better enable patients and providers to:**
> - view results from diagnostic procedures conducted by other providers to avoid duplication;
> - evaluate test results and treatment outcomes over time regardless of where the care was provided to better understand a patient's medical history;
> - share a basic set of patient information with specialists during referrals and receive updated information after the patient's visit with the specialist to improve care coordination;
> - view complete medication lists to reduce the chance of duplicate therapy, drug interactions, medication abuse, and other adverse drug events; and identify important information, such as allergies or preexisting conditions, for unfamiliar patients during emergency treatment to reduce the risk of adverse events."[lvii]

While challenges still remain, the past decade has brought tremendous progress towards the adoption and meaningful use of HIT. As a first step toward building a system for electronic health data exchange among providers, Congress passed the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009. The Act included provisions for Medicare and Medicaid EHR Incentive Programs to promote the adoption and meaningful use of qualified electronic health records through financial incentives, and mandated that the Office of the National Coordinator for Health Information Technology (ONC) coordinate nationwide efforts to implement HIT.[lviii] Since the law passed, the federal government has invested over $28 billion in HIT and has established requirements and measures for Meaningful Use (MU) stages that providers must meet in order to receive incentive payments;[lix] and the adoption of EHRs among hospitals and physicians has increased significantly. In 2008, 9.4% of hospitals and 16.9% of doctors had adopted an EHR system.[lx] As of 2014, 75% of hospitals and 80% of physicians had adopted an EHR system.[lxilxii] Interoperability of EHR systems has not been achieved at similar rates, however. For example, as of 2013 only 62% of hospitals had reported being able to exchange electronic health information with any provider outside their organization.[lxiii]

Since the passage of HITECH, several other major efforts by the public and private sectors have been undertaken to move toward an interoperable healthcare system. All stakeholders agree on the fundamental components of interoperability, but definitions of and timing for national interoperability differ. In an effort to move toward comprehensive interoperability, Congress passed the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, which declares that achieving interoperability by

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[2] According to IOM, a learning health system is one "in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience."
http://iom.nationalacademies.org/~/media/Files/Activity%20Files/Quality/VSRT/Core%20Documents/LearningHealthSystem.pdf

December 31, 2018 is a national objective and directs HHS to establish related metrics. Congress also directed the GAO to review the efforts of non-government organizations to develop the infrastructure needed to support nationwide interoperability of healthcare information. In addition to reviewing selected nonfederal interoperability initiatives, they described key challenges related to EHR interoperability and the extent to which selected private sector initiatives are addressing these challenges. GAO noted that private sector stakeholders are using different approaches to address these key challenges: (1) insufficiencies in health data standards, (2) variation in state privacy rules, (3) accurately matching patients' health records, (4) costs associated with interoperability, and (5) the need for governance and trust among entities, such as agreements to facilitate the sharing of information among all participants in an initiative."[lxiv] Although many efforts focus on the interoperability of EHRs, leaders in HIT are also working to incorporate other types of data into an interoperable system. For example, Ascension Health's Center for Medical Interoperability is working to incorporate medical device data into an interoperable system that includes EHR data and other HIT data.[lxv]

Figure 2.   Key HIT and Interoperability Pending Legislation and Laws

2009
HITECH

Funding for research on interoperability and infrastructure for the "promotion of the interoperability of clinical data repositories or registries."

2014
Consolidated and Further Continuing Appropriations Act, 2015

$60 million for development and advancement of interoperable HIT. New language to guide ONC on the certification and decertification of HIT products based on information blocking. Requested report to the Appropriations Committee regarding challenges and barriers to interoperability.

2015
MACRA

Established deadline for achieving EHR interoperability nationwide by December 31, 2018, and directed HHS to establish metrics for that process.

21st Century Cures Act (passed House)

Establishes requirements for interoperability and prohibits practices that discourage the exchange of health information.

Building on these efforts, ONC published the final "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap" in October 2015 that outlines a vision for interoperability with a timeline and public/private sector opportunities for achieving the goals of interoperability. ONC's goals for interoperability align with those identified by NDHI:

- Focus on value
- Be person-centered
- Protect privacy and security in all aspects of interoperability and respect individual preferences
- Build a culture of electronic access and use
- Encourage innovation and competition
- Build upon the existing health IT infrastructure
- One size does not fit all
- Simplify
- Maintain modularity
- Consider the current environment and support multiple levels of advancement

Stakeholders Identified by ONC Who Can Affect or Are Affected by Interoperability:

- People who receive care or support the care of others
- People and organizations that deliver care and services
- Organizations that pay for care
- People and organizations (governmental) that support the public good
- People and organizations that generate new knowledge, whether research or quality improvement
- People and organizations that provide health IT capabilities
- People and organizations that govern, certify and/or have oversight
- People and organizations that develop and maintain standards[lxvi]

ONC calls on the private sector and many other stakeholders to join in "helping consumers easily and securely access their electronic health information when and where they need it most; to enabling individual health information to be shared with other providers and refrain from information blocking; and to implementing federally recognized, national interoperability standards and policies so that we are no longer competing between standards, but rather innovating on a set of core standards."[lxvii]

Despite progress in the public and private sectors towards interoperability, NDHI also identified the following remaining challenges:

- Not all EHR vendors are members of initiative alliances
- Point-to-point transfer does not focus on content exchanged or complex scenarios
- Conflicting and competing standards
- Lack of consensus on clinical workflow and payment reform best practices
- Limited funds to achieve patient-centered interoperability
- Integrating clinical, billing and administrative data
- New payment models and complex provider collaborations

In an effort to show how all stakeholders can move towards an interoperable system, NDHI identified three key goals to support patient-centered interoperability that are shared across the public and private sectors. Together, these keys will move the U.S. toward achieving a patient-centered interoperable health system (Figure 3).

Figure 3.   Keys toward Achieving Patient-Centered Interoperability
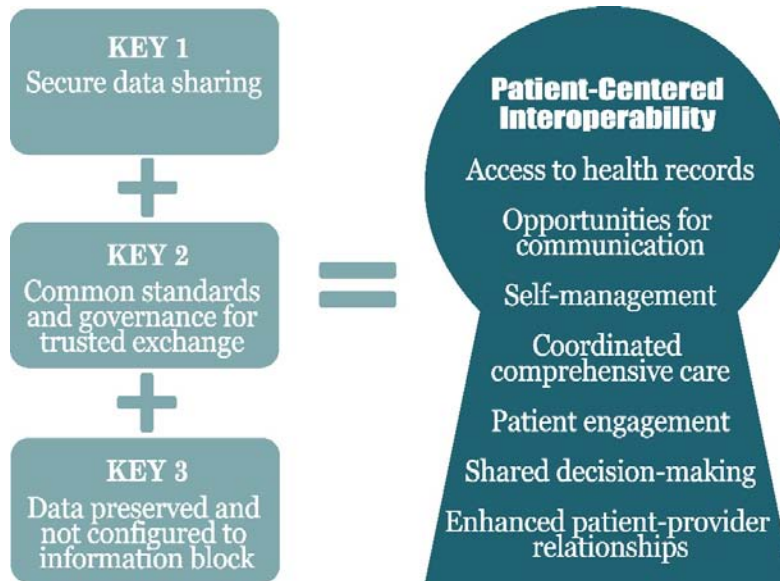
Figures 3 and 4 highlight examples of public- and private-sector initiatives, and the "keys" (i.e., goals) to patient-centered interoperability they aim to achieve: (1) Secure Data Sharing; (2) Common Standards and Governance for Trusted Exchange; and (3) Data Preserved and Not Configured to Information Block.

Figure 4.   Key Public and Private Sector Interoperability Initiatives
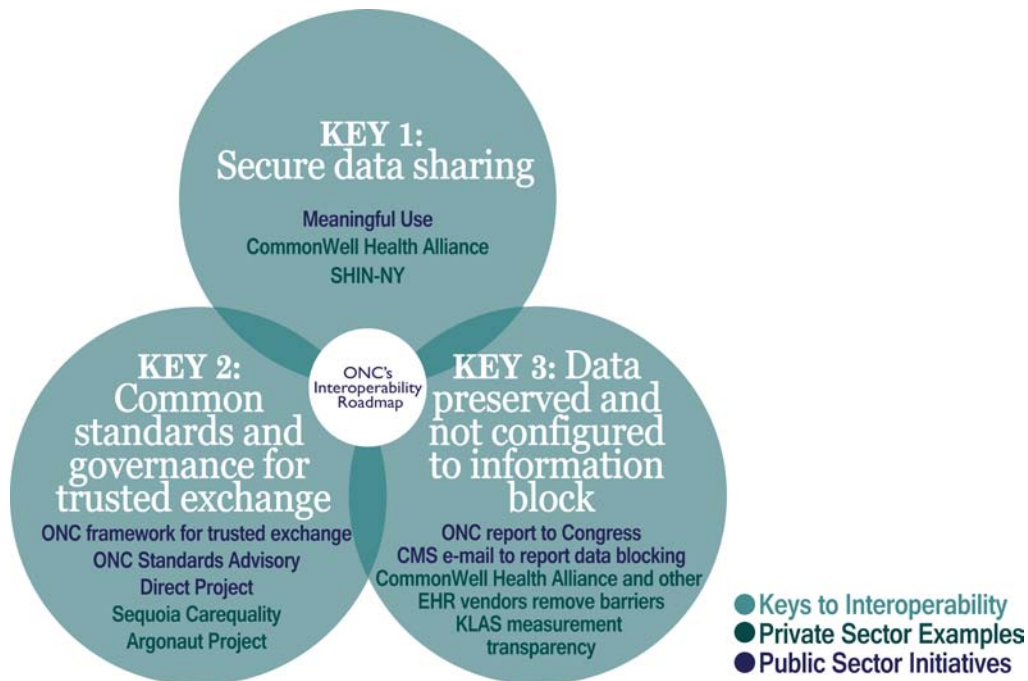
Patient-Centered Interoperability

NDHI participants recognize that the patient must be the focus of emerging interoperable systems, and that an interoperable system facilitates patient-centered care. According to the Institute of Medicine (IOM), patient-centered care is defined as "providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions."[lxviii]

A December 2015 report by the Bipartisan Policy Center (BPC) also emphasizes the need to create a patient centered system and notes that "billions of dollars are being invested by federal, state, and private sector organizations in new healthcare delivery and payment arrangements that reward better cost and quality outcomes. These arrangements will require greater information sharing and interoperable systems. For example, clinicians and care teams will need to have access to information about the patient—regardless of where care has been delivered—as well as clinical decision support tools, to inform coordinated, clinical decision-making at the point of care and between visits."[lxix] The BPC also notes that patients will play a critical role in improving cost and quality outcomes and that information sharing is critical to helping patients manage their health, make informed healthcare decisions, and navigate the healthcare system.[lxx]

Ultimately, interoperability allows for patient-centered communication mechanisms that meet the needs of patients, providers, and caregivers and has positive effects on a variety of outcomes (see Table 2). Those outcomes include: provider and patient access to health records; patient self-management support; increased opportunities for communication between providers, providers and patients, and providers and caregivers; patient engagement; shared decision making among the provider, patient, and/or caregiver; enhanced patient/caregiver/provider relationships; and coordinated, comprehensive care.[lxxi]

Table 2. Patient-Centered HIT Interoperability[1]

HIT User	Key HIT Functionality	Patient-Centered Communication Mechanisms	Patient-Centered Care Outcomes
Patient	■ Access to health records and reports ■ Information exchange ■ Prevention modalities and wellness strategies ■ Evidence-based data on risks/benefits of treatments ■ Self-management ■ eVisit	■ Facilitation of patient-physician interactions ■ Increased opportunities for communication ■ Educated patients have increased decision control ■ Increased patient engagement ■ Opportunity to discuss psychological and social context	■ Patient health behaviors ■ Symptom management ■ Healthcare process outcomes ■ Disease specific outcomes ■ Health knowledge ■ Reduced medical cost and time ■ Reduced medical error ■ Access to care
Caregiver	■ Continuity of care ■ Access to patient records and reports ■ Caregiver resources ■ Partnership with provider	■ Caregiver involvement reinforces patient-provider interactions ■ Patient advocate provides insight on patient perspective ■ Assists in translating health information to patient ■ Caregiver support in decision making ■ Partnership fosters relationships	
Healthcare Provider	■ Coordinated and comprehensive care ■ Collaboration between providers ■ Electronic Medical Record access ■ Standardized reporting ■ Pharmaceutical dosing systems ■ Intervention management	■ Improved and efficient communication between providers and patient ■ Behavioral management and support outside of clinic context ■ Improved communication on decision making with other providers and patients	

[1]Table recreated from "Figure 1. Using health information technology (HIT) to impact patient-centered care through patient-centered communication" in Finney Rutten LJ, Agunwamba AA, Greene SM, et al. Enabling patient-centered communication and care through health information technology. *Journal of Communication in Healthcare*. 2014; *7*(4): 255-261.

The following section provides additional details about the three keys to achieving patient-centered interoperability.

Key #1: Secure Data Sharing

Secure data sharing ensures that patients' privacy is protected in the process of data exchange--and while the data is stored. ONC explains the importance of secure data sharing: "[I]t serves as the basis for trust by ensuring that electronic health information can be shared in a secure and private manner and not altered in an unauthorized or unintended way, while still making the information available when needed by those authorized to access it."[lxxii] The initiatives in Table 3 are examples of private and public sector efforts that promote secure data sharing (e.g., Meaningful Use), or have been successful in implementing systems that practice secure data sharing (e.g., Statewide Health Information Network of New York).

Table 3. Secure Data Sharing Initiatives

Sector	Initiative	Initiative Description
Private	CommonWell Health Alliance (CommonWell)	The interoperable network includes identity management, record locator, consent management, and trusted data access. CommonWell is committed to robust privacy and security for interoperability.[lxxiii]
Public/Private	Statewide Health Information Network of New York (SHIN-NY)	New York's health information exchange is an example of secure electronic data sharing between providers that participate in a statewide network.[lxxiv]
Public	ONC Interoperability Roadmap	ONC describes its commitment to helping consumers easily and securely access their electronic health information when and where they need it most, and outlines a strategy for accomplishing this goal.[lxxv]
Public	Meaningful Use	According to ONC, "MU privacy requirements address patients' rights both to: (1) have their health information protected from unauthorized access; and (2) access their health information…. The Meaningful Use security requirements protect Protected Health Information (PHI) against unauthorized access."[lxxvi] Meaningful Use Stage 3 includes a measure to "conduct or review a risk analysis including addressing the encryption/security of data stored in CEHRT, and implement security updates as necessary and correct identified security deficiencies as part of the EP's, EH's, or CAH's risk management process."[lxxvii]

Key # 2: Common Standards and Governance for Trusted Exchange

According to the GAO, standards "establish the language, structure, and data types required for integration among systems…. Consistent implementation of the standards by the vendors that build and sell EHR systems and by providers who use these systems is necessary for interoperability."[lxxviii]

ONC explains that the standards "must be accessible nationwide and capable of handling significant and growing volumes of electronic health information, to ensure no one is left on the wrong side of the digital divide."[lxxix] ONC describes its vision for a system in which "we are no longer competing between standards, but rather innovating on a set of core standards."[lxxx] Examples of private and public sector efforts working toward common standards and governance for trusted exchange are highlighted in Table 4.

Table 4. Initiatives to Establish Common Standards and Governance for Trusted Exchange

Sector	Initiative	Initiative Description
Private	Argonaut Project	The purpose of the Argonaut Project is to develop a first-generation Core Data Services specification to enable expanded information sharing for electronic health records and other health information technology based on Internet standards and architectural patterns and styles.lxxxi
Private	Sequoia Carequality	The public-private collaborative builds consensus among exchange programs to develop a common set of standards and specifications that enable an interoperable connection among them.lxxxii The collaborative established policy for linking data sharing networks, and a framework for implementing data sharing goals.lxxxiii
Public	Direct Project	"The Direct Project specifies a simple, secure, scalable, standards-based way for participants to send authenticated, encrypted health information directly to known, trusted recipients over the Internet."lxxxiv "The policy direction for the Direct Project is provided by the Nationwide Health Information Network Workgroup of the HIT Policy Committee, and oversight related to technology standards is provided by the HIT Standards Committee." lxxxv
Public	ONC Interoperability Standards Advisory (ISA)	ONC reports that the purpose of the ISA is: "1) To provide…a single, public list of the standards and implementation specifications that can best be used to fulfill specific clinical health information interoperability needs. 2) To reflect the results of ongoing dialogue, debate, and consensus among industry stakeholders when more than one standard or implementation specification could be listed as the best available. 3) To document known limitations, preconditions, and dependencies as well as known security patterns among referenced standards and implementation specifications when they are used to fulfill a specific clinical health IT interoperability need."lxxxvi
Public	ONC's Governance Framework for Trusted Electronic Health Information Exchange	"The Governance Framework for Trusted Electronic Health Information Exchange (the Governance Framework) is intended to serve as the Office of the National Coordinator for Health Information Technology's (ONC's) guiding principles on HIE governance. It is meant to provide a common conceptual foundation applicable to all types of governance models and expresses the principles ONC believes are most important for HIE governance. The Governance Framework does not prescribe specific solutions but lays out milestones and outcomes that ONC expects for and from HIE governance entities as they enable electronic HIE."lxxxvii

Key #3: Systems are Not Configured to Information Block

ONC defines information blocking as occurring "when persons or entities knowingly and unreasonably interfere with the exchange or use of electronic health information."lxxxviii ONC and CMS have made clear statements that they will not tolerate practices that block information exchange. ONC explains that consequences of this "blocking" of information exchange include:

- Compromising patient's safety, care quality, and treatment effectiveness because it withholds information from patients and providers for informed decision making;

- Impeding progress towards reforming healthcare delivery and payment because sharing information seamlessly across the care continuum is fundamental to moving to a person-centered, high-performing healthcare system;

- Undermining consumers' confidence in their healthcare providers by preventing individuals from accessing their health information and using it to make informed decisions about their health and healthcare; and

■ Preventing advances in biomedical and public health research, which require the ability to analyze information from many sources in order to identify public health risks, develop new treatments and cures, and enable precision medicine. [lxxxix]

Some key government initiatives to prevent and address data blocking, as well as some private sector initiatives to address the issue are described in Table 5.

Table 5. Initiatives to Prevent Information Blocking

Sector	Initiative	Initiative Description
Private	CommonWell and other EHR vendors	CommonWell believes health data should be available to individuals and providers regardless of where care occurs, and that provider access to this data be built-in health IT at a reasonable cost for use by a broad range of healthcare providers and the people they serve.[xc] Other EHR vendors have removed costs for providers to exchange data as well.
Private	KLAS measurement transparency	On October 2, 2015, a broad group of EHR stakeholders agreed by consensus to objective measures of interoperability and ongoing reporting and to have an independent entity publish transparent measures of health information exchange that can serve as the basis for understanding our current position and trajectory.[xci]
Public	CMS e-mail to report data blocking	In June 2015, CMS released an e-mail address for stakeholders to use to report instances of data blocking.[xcii] CMS hopes to use those reports to better understand and address the problem of data blocking.[xciii]
Public	ONC's Report to Congress	In response to the 2015 Appropriations Act, ONC was "urged to use its certification program judiciously in order to ensure certified electronic health record technology (CEHRT) provides value to eligible hospitals, eligible providers and taxpayers. ONC should use its authority to certify only those products that clearly meet current meaningful use program standards and that do not block health information exchange. ONC should take steps to decertify products that proactively block the sharing of information because those practices frustrate congressional intent, devalue taxpayer investments in CEHRT, and make CEHRT less valuable and more burdensome for eligible hospitals and eligible providers to use." Congress requested "a detailed report from ONC no later than 90 days after enactment of this act regarding the extent of the information blocking problem, including an estimate of the number of vendors or eligible hospitals or providers who block information. This detailed report should also include a comprehensive strategy on how to address the information blocking issue."[xciv] ONC issued the report in April 2015 and notes that information blocking occurs when persons or entities knowingly and unreasonably interfere with the exchange or use of electronic health information" and notes that "there is little doubt that information blocking is occurring and that it is interfering with the exchange of electronic health information."[xcv]

Conclusions

NDHI strongly believes that the nation must move towards an interoperable health IT infrastructure that is both beneficial to patients and their caregivers, and workable for industry. Functional interoperability is a critical component to support patient-centered care, value, and continued innovation in healthcare. A system built on accessible information and secure, meaningful data sharing will elevate healthcare delivery, advance quality and cost-efficiency, and enable new strides in medical research.

NDHI members agreed to build upon recommendations already offered to Congress and the Administration by HLC to continue to work toward achieving an interoperable health IT infrastructure. All NDHI members agreed that:

- Policymakers should **encourage exchange of material and meaningful health data** through the use of technologies and applications that enable bidirectional and real-time exchange of health data currently residing in EHR systems (e.g., open and secure API technology).

- Policymakers should use appropriate authority to **certify only those EHR technology products that do not block or otherwise inhibit health information exchange**. The HHS Office of the National Coordinator should decertify Meaningful Use products that intentionally block the sharing of information, or that create structural, technical, or financial impediments or disincentives to the sharing of information.

- The federal government, in collaboration with the private sector, should **build on current and emerging best practices in patient identification and matching** to identify solutions to ensure the accuracy of every patient's identity, and the availability and accessibility of their information, absent lengthy and costly efforts, wherever and whenever care is needed.

- Any interoperability **requirements or incentives should be "technology neutral" and focused on outcomes** – active interoperation between and among systems—rather than on adoption or use of specified technologies. It is critical that future policies do not stifle potential innovations in health system connectivity.

Furthermore, the multisector members of NDHI felt that recent advances in the state of interoperability collaborations and technologies allowed for even more ambitious goals and recommendations. Based upon these impressive accomplishments, members endorsed two additional declarations:

- There should be a national objective to achieve widespread exchange of health information through interoperable EHR technology nationwide on or before December 31, 2018 (in parallel to the recommendation made in the Medicare Access and CHIP Reauthorization Act).

- **Consumers should have easy and secure access 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.

NDHI believes that, by bringing together the ideas and technological expertise from both the public and private sectors, interoperability is an achievable goal that can and should be accelerated through innovation and partnership between government and the private sector. Interoperability is also key to achieving the goals set by HHS of tying 30% of fee-for-service Medicare payments to quality or value through alternative payment models, such as Accountable Care Organizations (ACOs) or bundled payment arrangements by the end of 2016, and 50% of payments to these models by the end of 2018. HHS has also set a goal of tying 85% of all traditional Medicare payments to quality or value by 2016 and

90% by 2018 through programs such as the Hospital Value Based Purchasing and the Hospital Readmissions Reduction Programs.[xcvi]

Therefore, as efforts to reform our healthcare system accelerate, all parts must move in tandem. Meaningful interoperation is a necessary tool to meet the ambitious goals laid out by both private sector organizations and the federal government to enact value-based payment reforms, new care models, and allow greater consumer access and control of their healthcare.

Outdated and/or Ineffective Laws and Regulations

As the healthcare system transforms to reward better value, increased coordination, and a more empowered consumer, NDHI finds that some laws and regulations that were once important to the healthcare system may no longer be applicable or may inhibit transformation efforts in unintended ways. These outdated and/or ineffective healthcare laws and regulations, enacted with the consumer's best interest in mind, no longer serve the best interests of the healthcare consumer or healthcare system as a whole. As our healthcare system shifts from fee-for-service to value-based models evaluated through outcomes, many burdensome rules governing process have become unnecessary and redundant. Once payment and outcomes are aligned, there is less need for government regulation on process, since consumers and healthcare organizations share healthcare goals and responsibility for achieving them. Laws designed to prevent anticompetitive behavior, for example, now sometimes hinder the coordination needed for the best patient care. Additionally, wide variation among the regulatory approaches of agencies, states, and others leads to compliance efforts that cause more harm to patient outcomes than the risks they are intended to mitigate. Duplicative and outdated laws and regulations may impose an unnecessary burden on various sectors of the health system, which can negatively affect innovation and hinder care coordination.

For example, the Federal Anti-Kickback Statute and the Physician Self-Referral (Stark) Law are designed to ensure the integrity of federal healthcare programs and prevent inappropriate or undue influence on clinical decision-making that may lead to unnecessary overutilization of federal healthcare resources. These laws and their regulations prohibit certain financial arrangements between and among providers and other stakeholders. However, in their current form, they may inhibit current priority initiatives – such as medical homes, bundled payments and accountable care organizations (ACOs) – that are designed to promote value and care coordination among providers by aligning financial incentives for improved outcomes. For example, waivers of these laws and regulations were created to protect ACOs participating in the Medicare Shared Savings Program so that participants will not face liability for aligning financial incentives among providers provided certain requirements are met. Further, in the context of priority payment and delivery arrangements that can improve quality and lower costs (e.g. bundling, gainsharing), these laws and regulations may foreclose such arrangements because such arrangements were not envisioned when the laws and regulations were originally developed and any safe harbors and/or exceptions do not provide specific protection. For example, a physician who adopts a bundled payment arrangement in collaboration with a team of physicians and other providers may violate the Federal Anti-

Kickback Statute. Or, a physician who seeks to provide additional services like patient reward programs or add-on care management services, may implicate the Federal Anti-Kickback Statute or the civil monetary penalty (CMP) law prohibiting beneficiary inducements. While these laws and regulations are intended to protect patients and federal health programs from fraud and abuse, their broad scope and application implicates virtually all healthcare arrangements between and among providers and other industry participants. This complex web of laws and regulations and related compliance efforts may now inhibit arrangements designed to encourage hospitals and doctors to collaborate to improve patient care in a clinical integration program.

Further, various regulations create restrictions on data movement and usage, which often constrain providers from pursuing alternative payment models and even research initiatives. As health plans and providers and the medical research community continue to focus on outcomes research and innovation, it is important that the exchange and aggregated use of healthcare data be allowed. The HIPAA Privacy Rule strictly defines what constitutes protected health information (PHI) and defines certain institutions, or covered entities that hold such information. The Federal Policy for the Protection of Human Subjects or "Common Rule" defines the protection of human subjects in research. Without modifications to harmonize the rules, unnecessary barriers to data movement will continue to limit the innovative potential of the healthcare marketplace, especially as PHI continues to migrate out of the traditional healthcare system.

The misinterpretation and lack of alignment around privacy, security, and enforcement regulations - developed to safeguard patients' personal health information – hampers data sharing necessary for alternative payment models and research. Currently, researchers need to contend not only with the HIPAA Privacy Rules regulating research but also with state law, and in many cases, additional federal law, for example, the Federal Privacy Act of 1974, the so-called Common Rule, FDA Regulations, and other regulations. This results in a confusing and inconsistent set of requirements, often governing the same study (for example, in the case of a multi-site study in different states).

Finally, advances in technology and data sharing allow for better outcome tracking and faster iteration of improvements in breakthrough treatments and technologies while manufacturers are still limited by outdated regulations from the FDA that delay access to breakthrough treatments and technologies. Various policies within the FDA's purview have facilitated delays in both the approval of and access to innovative medical technology and treatments. Encouraging policy change that streamlines FDA's responsibilities, while ensuring that companies remain accountable, could reduce FDA's workload, allowing it to focus on higher-priority activities, and would represent a significant cost and time saving for the private sector and the federal government.

In an effort to accelerate the development of new treatments, improve care coordination, and facilitate health system transformation, NDHI identified three key categories in need of reform: the regulation of competition in healthcare, the flow of health information between health organizations, and modernization of key FDA rules and regulations—while ensuring that innovators remain accountable.

Possible Changes to the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law to Foster Integrated Care Delivery and Payment Models

As the U.S. healthcare system continues to move toward quality-driven, value-based care delivery and payment models, policy and implementation challenges arise as these models may implicate the federal fraud and abuse legal framework. In general, the fraud and abuse legal framework is designed to penalize arrangements between and among providers and other industry stakeholders that have the potential to encourage overutilization of healthcare resources, inappropriately influence provider decision-making, decrease competition among competitors, and harm patients. To improve quality of care and reduce costs, new care delivery and payment models are designed to encourage greater integration and coordination of care and payment between and among providers and other industry stakeholders. These models may align financial interests in ways that trigger fraud and abuse concerns.

As such, stakeholders across the healthcare system as well as policymakers, and legislators are considering whether changes to the current framework are needed to make it more compatible with healthcare delivery system transformation while retaining appropriate protections against fraud and abuse.

Many other federal statutes and regulations are potentially implicated by these new models (e.g., Civil Monetary Penalties (CMP) Law (including the beneficiary inducement and gainsharing provisions), the Civil and Criminal False Claims Acts (FCA), HIPAA, antitrust and tax law, and state laws that overlap with, mirror, or relate to these federal laws. However, NDHI participants decided to focus their efforts primarily on the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law as primarily and respectively enforced by HHS, Office of Inspector General (OIG), and CMS.

> **CMS Payment Waiver Policy**
>
> CMS should expand the waiver for patient incentives under the Medicare Shared Savings Program (MSSP) to all CMMI demonstrations. The current waiver gives ACOs the flexibility to encourage preventive care and patient compliance with treatment regimens without facing CMP due to beneficiary inducements. PPACA does authorize the waiver of the program integrity laws for CMMI demonstrations, but CMMI has largely issued guidance regarding such waivers on a case-by-case basis. While this information helps to ameliorate the concerns of would-be participants in CMMI demonstrations, concrete assurances in the form of prospective, bright line waivers could spur greater confidence and participation. Additionally, CMS should expand these permissions (such as the ability to waive copays) to private sector ACOs, which operate with the same incentives as those in CMS demonstration programs.

While this report does not address the other federal and state laws noted above, it is particularly important to note the relationship between the Federal Anti-Kickback Statute and the Civil Monetary Penalties (CMP) Law as they relate to both beneficiary inducement (i.e., providing anything of value to a patient in order to encourage the patient to utilize a particular provider, device, or pharmaceutical) and gainsharing (i.e., sharing savings among providers). It is common for arrangements between industry stakeholders (e.g., medical device and pharmaceutical manufacturers and providers) to potentially implicate both the Anti-Kickback Statute and the CMP law. For example, routinely waiving patient co-payments potentially implicates both the CMP Law's beneficiary inducement provisions as well as the Anti-Kickback Statute, which prohibits a co-payment waiver because it constitutes something of value provided to a patient. As

such, when considering potential changes to the Anti-Kickback Statute, stakeholders also should consider related changes to the CMP Law to ensure consistency in interpretation and application across both laws.

For reference, this report provides some background information on the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law as well as an overview of recent regulatory and legislative changes that provide additional context for the discussion of possible options to modify these legal frameworks.

It is important to note that alignment of the fraud and abuse legal framework with new care delivery and payment models is being discussed at multiple levels across the healthcare system. The recent Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) called for the HHS Secretary, in coordination with the OIG, to consider possible modifications to the legal frameworks to better align with integrated care delivery and payment models. In addition, CMS solicited feedback on possible changes to the Stark Law in the 2016 Physician Fee Schedule Proposed Rule indicating that the agency is thinking about these issues and open to dialogue regarding modifications. In the Final Rule, CMS stated that it will consider the comments received when preparing MACRA-mandated reports to Congress.

The Current Legal Framework

Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law

The Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law regulate arrangements between and among healthcare industry participants. The Anti-Kickback Statute prohibits any individual from knowingly and willfully offering, paying, soliciting, or receiving anything of value in return for a referral or to induce the generation of business reimbursable by a federal healthcare program.[xcvii] This prohibition applies to all healthcare industry participants, including institutional and individual providers and medical device and pharmaceutical manufacturers and suppliers. The Stark Law prohibits physicians from referring Medicare patients for certain services to an entity with which the physician (or an immediate family member) has a financial relationship.[xcviii] The Stark Law also prohibits healthcare organizations from billing Medicare for services provided pursuant to an improper referral.

The Anti-Kickback Statute is a criminal law and intent is required for liability to attach; penalties for violating the statute include imprisonment and substantial fines. In contrast, the Stark Law is a law of strict liability, meaning that no intent to violate the law is required. Civil monetary penalties may be levied for violations of the Anti-Kickback Statute and the Stark Law, and entities that violate either may be excluded from participation in federal healthcare programs.

There are exceptions to each law (referred to as "safe harbors" for the Anti-Kickback Statute and "exceptions" for the Stark Law) that protect certain types of business arrangements and transactions that are considered to present a minimal risk of fraud or abuse when structured appropriately (i.e., in accordance with exact requirements of an exception). The exceptions and associated requirements are not the same across both laws, though there is overlap. Generally, exceptions include payments made in the

course of legitimate business dealings (e.g., salaries paid to bona fide employees) and payments made for services integral to healthcare delivery (e.g., personal services contracts).

Recent Legislative and Regulatory Changes

1.) General Changes to Fraud and Abuse Laws: The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)[xcix] contained several provisions relevant to the fraud and abuse laws in general, including:

- Requiring the Secretary of HHS, in consultation with the OIG, to:

    i. Study the applicability of fraud prevention laws under alternative payment models (APMs), identify aspects of APMs vulnerable to fraud, and examine implications of waivers to APMs. The Secretary must report to Congress on its findings and provide recommendations on how to reduce APMs' vulnerability to fraud by April 16, 2017;[c] and

    ii. Submit a report to Congress by April 16, 2016 with options for amending existing Medicare and Medicaid fraud and abuse laws and regulations through exceptions or safe harbors to permit gainsharing or similar arrangements between physicians and hospitals that would improve care while reducing waste and inefficiency.[ci]

- Narrowing the gainsharing Civil Monetary Penalty Law[cii] so that it only applies to reductions or limitations of medically necessary services.[ciii]

2.) Stark Law Changes in Physician Fee Schedule: CMS routinely uses payment rules to amend the Stark Law regulations. In July 2015, CMS issued a proposed 2016 Medicare Physician Fee Schedule[civ] in which it referenced its history of using such rulemakings to make changes to the Stark law, detailed proposed changes to the law, and requested public feedback about these changes, which included:[cv]

- Two new Stark exceptions (covering payments to physicians to employ non-physician practitioners and timeshare arrangements for the use of office space, equipment, personnel, supplies, and other services that benefit rural or underserved areas);

- Guidance and clarification related to financial relationship documentation and requirements specific to certain financial relationships; and

- Clarifying Patient Protection and Affordable Care Act of 2010 (ACA)-mandated limitations on the whole hospital exception.

CMS finalized the proposed changes with minor modifications on October 30, 2015 in a final rule with comment period.[cvi] In the proposed rule, CMS sought public comment regarding the impact of the Stark law on healthcare delivery and payment reform, and specifically asked for feedback on perceived Stark-related barriers to clinical and financial integration.[cvii] CMS also posed specific questions for stakeholder input regarding the need for guidance on the application of aspects of the Stark regulations to physician compensation unrelated to participation in APMs. In the final rule, CMS stated that it will carefully

consider comments received in response to these questions when preparing reports to Congress as mandated by MACRA[cviii] and in determining the necessity of additional rulemaking on these issues.[cix]

3.) Medicare Shared Savings Program: The ACA made several changes that impact the fraud and abuse laws. One major change was the creation of the Medicare "Shared Savings Program" (MSSP), which allows groups of providers to create ACOs and share in the savings generated by reducing the overall cost of providing care to an assigned population of Medicare beneficiaries. CMS and the OIG published interim final rules on November 2, 2011 waiving certain provisions of the Stark Law and the Anti-Kickback Statute that would limit ACO arrangements within the MSSP.[cx] These provisions were extended through November 2, 2015 by a continuation notice published in 2014. CMS has authority to issue waivers of the federal fraud and abuse laws as may be necessary to test models for improving care delivery or reducing expenditures and is likely to do so in relation to other CMMI models. Three other changes made directly to the fraud and abuse laws by the ACA include:

- Relaxed the Anti-Kickback Statute's intent requirement (clarifying that an individual or entity need not intend to violate the Statute or even know the Statute exists to have the requisite level of intent);

- Added disclosure requirements to the Stark Law's in-office ancillary services exception applicable to certain imaging services; and

- Removed the "whole hospital exception" (commonly referred to as specialty hospitals) to the Stark law, with limited grandfathering for existing arrangements.

4.) E-prescribing and EHRs: The Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003 mandated the development of an Anti-Kickback Statute safe harbor and a Stark exception to promote e-prescribing technology adoption. In 2006, CMS and the OIG issued final rules furthering this mandate via two exceptions: (1) certain providers and health plans may subsidize 100% of e-prescribing system hardware, software, training, and support for certain related entities; and (2) through 2013, any provider or health plan may subsidize up to 85% of electronic health record (EHR) software and/or related technology and training services for any provider.[cxi] The preambles of both final rules provide an illustrative but non-exhaustive list of EHR software and related technologies that would be considered covered technology within the donation exception.[cxii] These examples include: connectivity services, clinical and information support services related to patient care, maintenance services, and secure messaging. The final rules specifically exclude certain items and services, including storage devices and software with core functionality other than electronic health records, such as payroll software. On December 27, 2013, the OIG and CMS issued joint final regulations extending the EHR exception through 2021 and modifying some of its requirements.[cxiii] In response to stakeholder concerns about the scope of covered technology, the final rules note the importance of maintaining flexibility in the definition, particularly as health information technology evolves.[cxiv] The rules declined to expand on the illustrative list provided in the 2006 final rule or to memorialize that list within the regulatory text and noted that revising the definition could inadvertently narrow the exception. The final rules emphasize whether specific items and services are

considered covered technology under the exception is dependent on the particular items or services. Specifically, donated items or services must be necessary and used predominantly to create, maintain, transmit, or receive electronic health records to qualify for the exception. The final rules suggest the possibility of expanding the scope of covered technology in the future.[cxv]

Recent Guidance

1.) Information Blocking: The OIG issued an Alert on October 6, 2015 dealing with information blocking and the EHR safe harbor exception to the Anti-Kickback Statute.[cxvi] The Alert notes that donation of [EHR] items or services that have limited or restricted interoperability due to action taken by the donor or anyone on the donor's behalf would not fall within the EHR donation safe harbor. OIG believes that charging fees to deter non-recipient providers and suppliers and the donor's competitors from interfacing with the donated items or services would pose "legitimate concerns" that parties were improperly locking-in data and referrals and thus that the arrangement in question would not qualify for safe harbor protection.

2.) Medicare and Medicaid Discharge Planning Requirements: CMS released a proposed rule on October 29, 2015 revising Medicare and Medicaid discharge planning requirements for acute care, long-term care, and critical access hospitals, inpatient rehabilitation facilities, and home health agencies.[cxvii] The rule would implement the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014's discharge planning provisions, which modifies conditions of participation (COPs) to require post-acute care providers, hospitals, and critical access hospitals to account for quality, resource use, and similar measures in the discharge planning process. The rule would require these entities to use and share data on quality and resource use measures to assist patients in selecting post-acute care providers.

The list below represents potential priority regulatory and legislative options to modify two of the primary fraud and abuse laws (the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law) to better support innovative and integrated care delivery and payment models. These changes may be pursued independently or concurrently and some of the options may lend themselves to both regulatory and legislative action. It is not intended to be, nor should it be construed as an exhaustive analysis of the universe of potential modifications to these laws. The priority options, categorized as either Regulatory or Legislative, were selected by the National Dialogue for Healthcare Innovation initiative based on the following criteria:

Feasibility: Willingness of Congress, CMS and/or OIG to address
Impact: Potential to alleviate and/or eliminate perceived and/or real barriers to developing and implementing new models of care delivery and payment based on fraud and abuse framework
Timeliness: Whether meaningful action may/can be taken in the next 6-12 months

While the options are categorized as regulatory and legislative, it is important to note that they may be pursued independently or concurrently and some of the options may lend themselves to both regulatory and legislative action.

Regulatory Options

- Create Anti-Kickback Statute and Stark Law waivers for all ACOs that meet certain conditions, whether those ACOs are participating in the Medicare Shared Savings Program (MSSP) or not.

- Extend existing Anti-Kickback Statute and Stark Law exceptions for donation and financial support of EHR software, related technologies, and training beyond 2021. As part of an extension, ensure range of relevant and appropriate interoperable technologies that enable meaningful improvements in healthcare delivery and health information exchange are included based on the evolving technological environment.

- Clarify how to establish, document, and apply the "volume or value of referrals" standard within the changing healthcare payment environment.

- Expand and revise definition of fair market value to account for new payment models that incentivize performance[cxviii] (e.g., payment for consulting services or other professional services, such as medical directorships).

- Eliminate or redefine the "one purpose" test for Anti-Kickback Statute liability and replace it with a balancing test that would require the OIG to prove either increased cost or actual harm to a patient.[cxix] This would potentially allow, for example, arrangements where providers and/or medical device or pharmaceutical manufacturers provide items or services of value to patients to assist with prescription medication adherence or access to healthcare services. The OIG could assess the arrangement's overall impact on quality of care and weigh these benefits against the potential risk of fraud and abuse to determine whether the transaction is permissible, regardless of whether one purpose of the arrangement is potentially problematic.

- See references under Legislative Options to changes that may be made through legislation and/or regulation to the Anti-Kickback Statute, Stark Law, and the CMP Law based on the HHS Secretary's findings related to the assessment of the application of the laws in the current context of healthcare transformation.

Legislative Options

- Expand the parameters of the MACRA-mandated gainsharing report (due by April 16, 2016) and alternative payment model report (due by April 16, 2017)[cxx] and require the HHS Secretary to review and assess the Anti-Kickback Statute, the Stark Law, and the CMP Law in the context of the transformation of the healthcare system, specifically addressing: (1) whether these laws create unnecessary barriers to integrated care delivery and payment models; (2) whether these laws are effective in limiting fraudulent behavior; and (3) whether these laws should be modified to more effectively limit fraud and abuse without limiting new care and payment models aimed at providing better care at lower costs. The review process for both reports should include subject matter experts

from CMS and the OIG and the Secretary also should consult with the Department of Justice (DOJ), Internal Revenue Service (IRS), and the Federal Trade Commission (FTC). In addition, the Secretary should allow for opportunities for stakeholder input that would include medical practitioners and administrators, pharmaceutical and medical device manufacturers and suppliers, consumers, and legal and policy experts to review the Secretary's findings and assessment. Findings from the assessment along with stakeholders' feedback could be included in both reports, which also should include plans of action to address any suggested changes to the legal frameworks that arise from the assessment, as well as a description of the actions needed to achieve those changes.

- Changes identified through the assessment and reports noted above may yield opportunities for either legislative or regulatory action to amend the Anti-Kickback Statute, Stark Law, and CMP Law to protect arrangements that promote increased quality and lower costs.

- Congress also may consider granting OIG and CMS broader regulatory flexibility/rulemaking discretion to develop exceptions/safe harbors that are consistent with broad policy objectives (e.g., increase efficiency and quality and decrease costs) and adapt the Anti-Kickback Statute, the Stark Law, and the CMP Law to the current healthcare environment.[cxxi] Note that OIG and CMS already have statutory authority to create safe harbors and exceptions, but Congress could direct them to do so with respect to specific areas and/or in specific ways based on findings from the assessment and/or reports.

- The HLC and the NDHI will participate actively in opportunities for comment and will consider further suggestions based on the Secretary's findings.

Health Information Flow and Usage

There is growing interest in using data to better understand how to optimize the practice of medicine, the delivery of healthcare and new approaches to wellness and prevention of illness. At the same time, access to data needs to be balanced with the public's concern about the confidentiality and use of health data.

As data is appropriately accessed, it is vital to understand how to safely use these data to generate information for evidence-based care, share the data, analyze the data, and predict future needs of our complex healthcare delivery system. These data are fundamental to designing, implementing and evaluating innovative approaches to payment and financing reform and value-based delivery system reform, as well as medical breakthroughs.

Consistent Legal Requirements

Section 262 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) defines "health information" as "any information, whether oral or recorded in any form or medium, that (A) is created or received by a healthcare provider, health plan, public health authority, employer, life insurer, school or university, or healthcare clearinghouse; and (B) relates to the past, present, or future physical or mental health or condition of any individual, the provision of healthcare to an individual, or the past, present, or future payment for the provision of healthcare to an individual.".[cxxii] HIPAA was designed to ensure that individuals' health information is protected while allowing the flow of health information needed to

provide high quality healthcare. HIPAA was also designed to protect the privacy of individuals' electronic health information while allowing the adoption of new technologies that will improve the quality and efficiency of patient care. Therefore, as noted by ONC, it is important to reconcile barriers that may be caused by HIPAA at the same time that the goals and protections are maintained.[cxxiii]

One particularly burdensome barrier to nationwide health information exchange is the many diverse state laws across the country regulating health information alongside HIPAA. These many state privacy and information sharing laws create enormous complexity resulting in substantial impediments to the implementation of health information exchanges within and across state borders. Healthcare organizations have long advocated for the harmonization of national and state privacy and security requirements in order to simplify compliance and facilitate greater information sharing, and promote patient access. We believe that a broader harmonization that would clearly incorporate the Health Insurance Portability and Accountability Act (HIPAA) governing standards would benefit the healthcare system without creating any material adverse impact on individuals.

Recent work by ONC[cxxiv] to outline a path forward for harmonization of conflicting, confusing, and burdensome state privacy laws provides new hope for efforts to simplify the protection of health information. Efforts to educate states on existing federal standards and begin a dialogue on this important problem are important. With regard to the critical actions outlined in the roadmap, we believe there is both precedent and will for an accelerated timeline with stakeholders acting alongside ONC. Specifically, a discussion with nationwide stakeholders should include possible action items, such as harmonization of state and federal law.

Patient Matching

Creating a balance between safe and legal sharing of information with the need to consistently and accurately match patient data creates a number of problems for physicians and other healthcare providers. Without accurate sharing, providers may have an incomplete view of a patient's medical history, care may not be well coordinated with other providers treating the patient, patient records may be overlaid, unnecessary testing or improper treatment may be ordered, and patient confidence may be eroded. Barriers to data sharing may also cause providers to face costly clinical workflow inefficiencies and potential inaccuracies including identifying the correct patient record, ordering duplicate tests, and failing to protect patient privacy preferences.[cxxv]

For EHRs to deliver on the promise of better healthcare, they need to ensure that patient data are sent and received easily among providers across disparate systems. These shared records must be accurate and useable. Patient matching is critical to the successful sharing of patient records, but patient data matching is an ongoing obstacle to seamless information exchange between organizations.

The ONC recently performed an assessment of current industry capabilities and best practices for patient identification and matching with a focus on matching records among different organizations providing care to a specific individual. The Patient Identification and Matching Initiative focused on identifying

incremental steps to help ensure the accuracy of every patient's identity, and the availability of their information wherever and whenever care is needed.[cxxvi] In addition, the Care Connectivity Consortium (CCC) and the Sequoia Project believe patient privacy should be at the center of patient identity management strategies. Specifically, they want to help advance the ability of patients to protect the confidentiality and integrity of their data, and to help patients stay aware of and in control of their data. CCC spells out three principles to achieve these goals: (1) allow for anonymous or pseudonymous patient identities; (2) correct identification of patients so that their privacy preferences can be determined and honored; and (3) enable correct matching of patients to their records (whether anonymous or identifiable).

The potential benefits of successfully matching a patient to their health information across all care settings cannot be understated. It is critical to health information interoperability efforts, critical to provide a patient a comprehensive health record upon request, and critical to ensuring that health professionals have the information to safely and effectively treat patients. More effective patient matching could lower healthcare costs by preventing redundant tests and scans, and more effectively prevent adverse events caused by medication interactions. The private sector has taken steps forward to reach these goals, but federal legislators need to facilitate government cooperation in ensuring success in building this infrastructure nationally.

Harmonization of Federal Research Rules

Similarly, federal rules for human subjects research, combined with other privacy rules, create a complex and burdensome environment for research. For example, definitions between the HIPAA Privacy Rule and the Common Rule for human subjects research are not always consistent, creating ambiguity and confusion for researchers. There should be one harmonized privacy standard for research institutions so that research and innovation are not delayed. The federal government should streamline the internal review board (IRB) process, clarify researcher and IRB expectations with respect to the scope and intensity of IRB review, and focus IRB resources and attention on those studies warranting the most careful scrutiny.

Health Information Flow Recommendations

In summary, there are several core needs that currently stand as barriers to fully integrating the use of health information into a learning, interoperable health system:

- Create a single national definition for protected health information and privacy standard to protect patients while mitigating complications from state laws.
- Update and harmonize federal privacy rules with regard to new and innovative research to allow for simple, clear requirements for health organizations – many of whom conduct research and drive innovation while providing care.
- Support and cooperate with leading private sector organizations in their efforts to match the right patient to the right record with minimal time and effort.

In this dynamic environment of information sharing, stakeholders have growing concerns about open access to data and sharing data among and across providers because of the fear of breaching data confidentiality. Varying interpretations of HIPAA as well as different state privacy laws are also leading to confusion and a fear of violating the rules which is then resulting in restrictions to the movement and sharing of data. In addition, a growing number of data breaches are leading major health systems to be more cautious about sharing data. Building on these concerns, NDHI supports the need to review and simplify the complex web of laws regulating health information in light of the movement towards value based care and other information-based changes to the healthcare environment.

FDA Regulations

Manufacturers face unnecessary and redundant regulations from the FDA that delay access to breakthrough treatments and technologies. Various policies within the FDA's purview have facilitated delays in both the approval of and access to innovative medical technology and treatments. Encouraging policy change that streamlines FDA's responsibilities, while ensuring that companies are accountable, could reduce FDA's workload, allowing it to focus on higher-priority activities, and would represent a significant cost and time saving for the private sector and the federal government.

NDHI identified a series of unnecessary and redundant regulations from the FDA that delay access to innovative treatments and technologies. Addressing these barriers will help promote the development and availability of breakthrough treatments and technologies:

- **Reduce Regulatory Burdens on Multicenter Clinical Trials -** Eliminate the prohibition on using a single IRB of record for device trials, conforming the statute to the requirements for drug trials and the practice for other types of multicenter trials, and require FDA to develop guidance on the use of such single IRBs in device trials.

- **Reduce FDA Premarket Submission Rule -** Reduce the review burden on FDA and companies by allowing companies to make certain changes to devices without a premarket submission if their quality system has been certified as capable of evaluating such changes.

- **Recognition of Standards –** Timely review of a request for recognition of a standard established by an internationally or nationally recognized standards organization would improve regulatory efficiency. Through greater use of standards and more transparency in this area, FDA review will be more efficient and the time to bring medical technology from the bench to the bedside will be reduced.

- **Valid Scientific Evidence** – Expanding valid scientific evidence to include evidence described in well-documented case histories, including registry data, studies published in peer-reviewed journals, and data collected in countries outside the U.S. would allow greater flexibility in the FDA review of medical devices and improve access to new therapies for patients (Cures Section 2222).

- **Training and Implementation of Least Burdensome** – Training related to the meaning and implementation of the least burdensome provisions would increase efficiency and consistency for the FDA and manufacturers, allowing greater innovation for patients. Improved understanding and use of

the least burdensome provisions would minimize the time involved in bringing new treatments to patients, while maintaining FDA's high standards for safety and efficacy (Cures Section 2223).

- **Increase flexibility to share scientific and healthcare economic information with population health decision-makers** –Biopharmaceutical manufacturers can and should partner with payers and providers in efforts to communicate about and optimize the clinical benefits of prescribed treatments. The push for value-based payment is accelerating demands by payers and providers for a growing range of information about the clinical and economic outcomes of their products. Biopharmaceutical companies routinely develop data describing the cost-effectiveness of various treatment options, data based on post-market use of these medicines, as well as safety and efficacy information. Application of these data can enhance patient care and the efficiency of the healthcare system, but companies are not currently permitted to share such information proactively with healthcare professionals or payers.

Table 6 in Appendix A provides more detailed descriptions of these issues.

Conclusions

NDHI recognizes that these FDA regulatory barriers are all addressed in some way through the House 21st Century Cures effort. The bill would provide additional resources to the NIH and to the FDA and benefits patients, researchers, and clinicians by supporting new opportunities for breakthrough treatments and cures. The bill is also designed to remove unnecessary regulatory burdens with an emphasis on patient centered research and care and break down barriers among healthcare silos to promote innovation and communication among researchers, scientists, and innovators. Finally, the bill includes an accelerated pathway for FDA approval and Medicare and Medicaid coverage for products that represent significant improvements in treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions that would stimulate development of new diagnostics and treatments and assure prompt availability of those treatments to patients. NDHI will continue to address and support these issues in the Senate and through other opportunities as they arise.

Conclusion

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.

Through the Healthcare Leadership Council's National Dialogue for Healthcare Innovation 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 recommendations in this paper are intended to drive health system transformation and a movement toward value and innovation. The consensus viewpoints contained in this report are also consistent with steps currently being taken by the federal government to guide a health system transition from fee-for-service to pay-for-value and toward more integrated, coordinated care. These recommendations should serve as a catalyst for further debate and decisive action.

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[xcvii] 42 U.S.C. § 1320a-7b(b) (2015).

[xcviii] 42 U.S.C. § 1395nn(a) (2015).

[xcix] Pub. Law 114-10, 129 Stat. 87 ("MACRA") (Apr 16, 2015).

[c] MACRA, § 101(e)(7).

[ci] MACRA, § 512(b) (i.e., "Gainsharing Report").

[cii] Social Security Act 1128A(b)(1)

[ciii] MACRA, § 512(a)

[civ] CMS, "Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016," 80 Fed. Reg. 41686 (July 15, 2015).

[cv] 80 Fed. Reg. at 41909-30.

[cvi] CMS, "Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016" 80 Fed. Reg. 70886 (November 16, 2015). Comment period ends at 5 pm (EST) on December 29, 2015.

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cxiv OIG, 78 Fed. Reg. at 79216; CMS, 78 Fed. Reg. at 78765.

cxv OIG, 78 Fed. Reg. at 79216; CMS, 78 Fed. Reg. at 78766.

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Appendix A

Table 6. Issues with FDA Regulations

Issue	Summary
Reduce Regulatory Burdens on Multicenter Clinical Trials - Eliminate the prohibition on using a single IRB of record for device trials, conforming the statute to the requirements for drug trials and the practice for other types of multicenter trials, and would require FDA to develop guidance on the use of such single IRBs in device trials (Cures Sections 2261 and 2262)[cxxviicxxviii]	■ Five problem areas: - HIPAA has overburdened IRBs, confused prospective research participants, and slowed research and increased its cost - Local review of multicenter studies delays research and does not improve protocols or consent forms - Reporting off-site adverse events to local IRBs is wasteful of the resources of sponsors, investigators, and local IRBs and does not add to participant safety - Uncertainties about key terms in the regulations governing pediatric research lead to marked differences in the ways that local IRBs review research involving children ■ Lack of consensus on when IRB review is required for quality improvement efforts is slowing progress ■ FDA and OHRP support the use of central IRBs for multicenter trials ■ In July 2011, DHHS invited comments on their proposal to change the Common Rule to include mandated centralized review for multicenter trials ■ Local IRBs vary in their willingness to defer to centralized IRB review
Recognition of **Standards** *Reduce* **FDA Premarket Submission Rule -** Reduce the review burden on FDA and companies by allowing companies to make certain changes to devices without a premarket submission if their quality system has been certified as capable of evaluating such changes (Cures Section 2201)[cxxix]	■ Center for Devices and Radiological Health (CDRH) believes that conformance with recognized consensus standards can support a reasonable assurance of safety and/or effectiveness for many applicable aspects of medical devices ■ Information submitted on conformance with such standards should have a direct bearing on safety and effectiveness determinations made during the review of IDEs, HDEs, PMAs, and PDPs ■ In 510(k)s, information on conformance with recognized consensus standards may help establish the substantial equivalence of a new device to a legally marketed predicate device ■ if any premarket submission contains a declaration of conformity to the recognized consensus standards, this declaration should, in many cases, eliminate the need to review the actual test data for those aspects of the device addressed by the standards ■ Conformance with recognized consensus standards may not always be a sufficient basis for regulatory decision, for example, a specific device may raise a safety or effectiveness issue not addressed by any recognized consensus standard, or a specific FDA regulation may require additional information beyond what conformity to the recognized consensus standards provides

Issue	Summary
Valid Scientific Evidence – Expanding valid scientific evidence to include evidence described in well-documented case histories, including registry data, studies published in peer-reviewed journals, and data collected in countries outside the United States would allow greater flexibility in the FDA review of medical devices and improve access to new therapies for patients. (Cures Section 2222)[cxxx]	■ FDA relies upon only valid scientific evidence to determine whether there is reasonable assurance that the device is safe and effective ■ FDA defines valid scientific evidence as evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use ■ Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness
Training and Implementation of Least Burdensome Requirement for Premarket Review of Devices– Training related to the meaning and implementation of the least burdensome provisions would increase efficiency and consistency for the FDA and manufacturers, allowing greater innovation for patients. Improved understanding and use of the least burdensome provisions would minimize the time involved in bringing new treatments to patients, while maintaining FDA's high standards for safety and efficacy. (Cures Section 2223)	■ Senators Richard Burr (R-NC) and Al Franken (D-MN) introduced the FDA Device Accountability Act ■ The Act would eliminate unnecessary burdens that are slowing down FDA's consideration of new, innovative medical devices ■ The Act: (i) extends application of the "least burdensome" requirement to premarket application (PMA) reviews and to all significant decisions, and adds training, review and auditing of FDA's application of the requirement; (ii) explicitly permits non-local or centralized IRBs for device clinical trials; and (iii) requires FDA to update its existing regulatory guidance to clarify the criteria for waiving CLIA requirements, specifically certain considerations for in vitro diagnostics.
Section 114 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) **Increase flexibility to share scientific and healthcare economic information with population health decision-makers** – Biopharmaceutical manufacturers can and should partner with payers and providers in efforts to communicate about and optimize the clinical benefits of prescribed treatments. The push for value-based payment is accelerating demands by payers and providers for a growing range of information about the clinical and economic outcomes of their products. Biopharmaceutical companies routinely develop data describing the cost-effectiveness of various treatment options, data based on post-market use of these medicines, as well as safety and efficacy information. Application of these data can enhance patient care and the efficiency of the healthcare system, but companies are not currently permitted to share such information proactively with healthcare professionals or payers.[cxxxi], [cxxxii]	■ Mandates the application of "competent and reliable scientific evidence" standard to FDA review of Healthcare Economic Information (HCEI) in prescription drug promotion if it is "provided to a formulary committee, or other similar entity" and "directly relates" to an approved indication ■ Changes standard of evidence for the dissemination of only HCEI to experts who make health plan coverage decisions for formulary decision making, did not change the substantial evidence requirement that applies to effectiveness claims in all other types of prescription drug labeling and promotion ■ Not intended to be used to communicate with the public, patient, or individual providers

Appendix A Citations

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Appendix B

The Healthcare Leadership Council Would Like to Thank the Following Organizations for Engaging in the 2015 National Dialogue for Healthcare Innovation Process:

AARP
Academy of Nutrition and Dietetics
AdvaMed
Aetna
Alliance for Aging Research
American Association of Diabetes Educators
American Diabetes Association
American Medical Association
American Public Health Association
America's Health Insurance Plans
AmerisourceBergen
Amgen
AMN Healthcare
Anthem
Ascension
athenahealth
BaylorScott & White Health
Bio-Reference Laboratories
Bipartisan Policy Center
BlueCross BlueShield of Tennessee
Boehringer Ingelheim USA
Business Roundtable
C.R. Bard
Cancer Support Community
CAPG
Cardinal Health
Center of Health Engagement
Centers for Medicare & Medicaid Services
Change Healthcare
Cleveland Clinic
Costs of Care
Dartmouth University Geisel School of Medicine
Diabetes Hands Foundation

An Initiative of the

ECRI Institute
Edwards Lifesciences
Eli Lilly and Company
FasterCures
Federation of State Medical Boards
Food and Drug Administration
Franciscan Missionaries of Our Lady Health System, Inc.
GlaxoSmithKline
Golden Living
Health Care Service Corporation
Health Management Associates
Healthcare Incentives Improvement Institute
HealthCare Institute of New Jersey
Healthcare Leadership Council
Indiana University Health
Johnson & Johnson
Leapfrog Group
Leidos
Lewis Sullivan Institute for Healthcare Innovation Patient Experience Council
Mallinckrodt (formerly Ikaria)
Marshfield Clinic Health System
Mayo Clinic
McKesson Corporation
McKinsey & Co.
MedCare Investment Funds
Medtronic
MemorialCare Health System
Merck
Milken Institute School of Public Health George Washington University
National Association of Medicaid Directors
National Business Coalition on Health
National Coalition on Health Care
National Minority Quality Forum
National Pharmaceutical Council
Nestlé Health Science
Network for Excellence in Health Innovation
NewYork-Presbyterian Hosptial
NORC at the University of Chicago
NorthShore University HealthSystem
Novartis Pharmaceuticals
Novo Nordisk
Owens & Minor
Patient-Centered Primary Care Collaborative
Pfizer
Pharmaceutical Care Management Association
Pharmaceutical Research and Manufacturers of America
Premier healthcare alliance
Prescriptions for a Healthy America

PricewaterhouseCoopers
RAND Health
Sanofi US
SCAN Health Plan
Select Medical
Society for Women's Health Research
Stryker
Surescripts
Takeda Pharmaceuticals U.S.A.
Teladoc
Texas Health Resources
The AIDS Institute
The Commonwealth Fund
U.S. Chamber of Commerce
U.S. Department of Health and Human Services
University of Pennsylvania, Perelman School of Medicine
Vizient
VNAA
Walgreens
Weight Watchers International
YMCA-USA
ZS Associates
360 Degree Insights LLC

An Initiative of the