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A Message to the New Administration and Congress

Better Healthcare for All Americans: A Proposed Agenda

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A Proposed Agenda**

Executive Summary

All Americans deserve better healthcare. Fortunately, there is consensus around what “better” means: lower costs, higher quality, greater efficiency, and an improved experience for patients and their families. A new presidential administration and Congress have the opportunity to make real progress toward achieving that vision, and there are several things we can do right now—quick fixes that build on the successes of the recent past and the robust spirit of innovation seen in every sector of healthcare. There’s no need for 30 more years of debate! These actions are achievable and transformative.

First, let’s **stabilize and improve private health insurance**.

There are sensible steps that can be taken — improving risk adjustment models, limiting special enrollment periods, reducing abuses of payment grace periods, enabling greater flexibility in plan design, no longer insisting on one-size-fits-all rules for different states and markets — to make health plan offerings robust and markets competitive. Allowing states to set their own standards will ensure a shopping experience that reflects the needs of geographies and populations.

Let’s also make health plan selection more consumer-friendly. People need clear, simple information on cost and benefits to make educated choices in an easily understood format. Accustomed to shopping online for everything from books to groceries, people expect an online health insurance purchasing experience that is just that easy.

Second, let’s **strengthen care coordination**, so that once people get health insurance, they can be treated by multiple providers and specialists in the locations and via the methods that make the most sense. These might include physicians and allied health professionals through telehealth and office visits. Surrounded by a community of care, patients will become more engaged, will take greater ownership of their health and consequently costs and utilization will go down.

Successful care coordination depends on various providers having all of the same information about a patient. Thus, their electronic health records must talk to one another. In the new healthcare age, hoarding and blocking patient data is no longer acceptable. Sharing, transparency, and collaboration are the order of the day, to the ultimate benefit of patients who are treated accurately and efficiently, and who may receive new treatments or cures derived from the insights gained from shared data.

Third, let’s **fine-tune the way in which federal government encourages innovation**. We also must create a healthcare system that rewards, rather than penalizes, innovation and that fully considers the health and societal benefits new medical innovations will yield. To create a fertile environment for creative payment models and greater patient engagement, the laws and regulations governing fraud and abuse must be updated. Integrated care and payment coordination depend on shared savings programs, bonus payments, patient incentives, and risk-sharing arrangements, many of which currently reside in a legal gray area. Legal reform is something we can do right now.

One example is the Center for Medicare & Medicaid Innovation which should be re-focused on demonstrations that have great potential impact but reasonable sample sizes. Just as with data, learning also should be shared. Just as with care coordination, multiple players should have input in order to pursue the most promising path. And just as consumers need clear, understandable healthcare choices, so do potential demonstration participants.

These improvements can be made in the short term. However, it’s also critical to take the long view in envisioning a healthcare system that can extend and improve our lives as never before. Some models and demonstrations may take years to show results, but those results may be so significant that their value is undeniable. Short-term thinking about the costs of new medications or potential cost savings can harm patients in the future. The Independent Payment Advisory Board is one example of this dangerous short-term thinking and should be repealed.

There is much to be optimistic about in American healthcare. We are in an unprecedented era of advancement in research, testing, and treatment. **As we move to realize a vision of truly personalized medicine, customized to every patient’s needs — including delivery method, care location, and cost — we must take concrete policy steps to fully unleash our innovative capabilities and achieve better healthcare for all Americans.**

Introduction

Congratulations! As a member of the new presidential administration or the 115th Congress, you have the opportunity to continue and accelerate the profound transformation of our healthcare system to benefit all Americans. We are on the threshold of an era in which people will live longer, healthier lives because they have access to new and more effective cures, therapies, and medical technologies; in which they will receive better care and better results due to the analysis and sharing of data; and in which they will benefit from a precise focus on protecting and maintaining health in a system that is efficient and sustainable. We have strong momentum, and healthcare progress is within our reach.

We did not arrive at this point overnight. Over the past few years, the ground has been laid for a fundamental change in the way we think about healthcare. Everywhere you look on the healthcare continuum—genomic science, drug development and medical technology innovation, health information technology, even how we deliver and pay for care—change is dramatic and meaningful. Even so, healthcare costs for a family of four now exceed \$25,000 per year. Without question, we must drive towards greater value. It is an exciting time: The status quo is being upended and previously unimaginable ideas are becoming our new reality.

But we're not there yet. To unleash the power of new American medical innovation and to realize the full potential of ways to deliver and pay for care, we must take action in both the legislative and regulatory arenas. If we can build on the successes of the past and commit to collaborating for the good of patients and their families, we can create a value-enhanced healthcare system that is affordable, accessible, and maintains health and well-being. This critical work begins in 2017, and it begins with you.

As you move into a position of public service and policymaking responsibility, we hope you will turn to this “Playbook” as a guide to the healthcare issues facing our country right now. Although these recommendations don't cover everything we can do to improve American healthcare, we believe they are our most essential action items, linking the innovative ideas already percolating in every sector of our healthcare system with the patients and consumers who can benefit tremendously from them.

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Who are we? The Healthcare Leadership Council (HLC) is an alliance of forward-thinking companies from every sector of American healthcare. Our members are hospitals, academic health centers, pharmaceutical companies, health insurance providers, medical device manufacturers, distributors, health information technology specialists, group purchasing organizations, pharmacies, healthcare workforce firms, and more. The ideas in these pages reflect the collaborative thinking of these visionary firms that touch the lives of patients in multiple ways.

Many of the ideas in this Playbook stem from an HLC initiative called the National Dialogue for Healthcare Innovation (NDHI). In addition to our own diverse members, we invited leading patient advocates, academic experts, employers, and representatives of federal health-related agencies to join us in a 2015 Summit on Healthcare Value and Innovation. Our goal was to agree on the barriers to health system efficiency and innovation, and to find solutions to take down those barriers.

Over the past year, these leaders have worked to narrow down the key areas that could make the greatest impact in terms of health system change and health delivery improvement. Those recommendations are incorporated in this Playbook, in addition to reforms that HLC's membership has agreed upon.

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Building an exciting future for healthcare requires a bipartisan dialogue on how to stabilize the nongroup health insurance market to provide affordable coverage for even more Americans, while avoiding a coverage gap during the revision period. Instead of imposing government price controls that freeze, and even undermine, innovation, let's figure out how to optimize the system to make it more affordable and give more patients access to new discoveries and care delivery methods that will extend and improve their lives.

In this Playbook, we recommend a forward-thinking, patient-focused policy agenda that zeroes in on three overarching goals:

Strengthen the Quality and Stability of the Health System

It is widely agreed that we must improve the efficiency and navigability of the nongroup health insurance market. We must modernize Medicare to protect its most vulnerable beneficiaries, and take full advantage of the strengths of the Medicare Advantage and Medicare Part D prescription drug benefit programs. We must improve the Center for Medicare and Medicaid Innovation (CMMI) to increase transparency, reduce burdensome participation requirements for pilot programs, and maintain the kind of limited scope for projects that reflects CMMI's originating spirit of innovation. We must adopt solutions that encourage Medicaid flexibility for states, recognizing that one size does not fit all, and reauthorize the Children's Health Insurance Program.

As our healthcare system transitions from a fee-for-service, volume-based orientation to a value-focused approach, all health sectors—payers, providers, and manufacturers—must collaborate to achieve both high-quality care and cost containment. Modernized federal fraud and abuse statutes are necessary to enabling these essential cross-sectoral partnerships to drive greater value.

And, without question, we must address those aspects of our healthcare system that threaten the ability to provide high-quality care, whether it is the current medical liability system, the Independent Payment Advisory Board (IPAB), or even healthcare payment formulas for the treatment of vulnerable populations.

Make Population Health an Imperative

We simply cannot accept a future in which chronic disease increases exponentially over the next several years, as the Centers for Disease Control and Prevention has predicted. We can avoid that destiny by investing in wellness practices that have been shown to improve health while reducing costs long-term. We can avoid it by improving healthcare payment and delivery to prioritize care coordination and patient engagement, especially by realizing the promise of telehealth. We can avoid it by enhancing the healthcare workforce to meet growing patient needs.

We also must recognize and respond to social and economic factors that affect the health of populations, such as inadequate housing, food insecurity, and un- or under-

employment. We must empower health organizations to reach beyond the clinical causes of poor health and take a holistic approach, so that we can decrease costs while helping those in need.

Drive Healthcare Value through Innovation

Our healthcare system generates millions of individual data transactions every hour. We can significantly improve healthcare practices, stimulate health research, and reduce medical errors by making optimal use of this accumulating mass of information. Right now, our ability to utilize and share valuable health data is only a fraction of what it can be. Policymakers need to speed the path toward systemwide interoperability, improve data transparency and patient access to information, and harmonize and modernize patient confidentiality laws.

Patients will benefit immeasurably—both in health and affordability—if we take sensible steps to streamline Food and Drug Administration (FDA) processes and speed new medicines and devices to market. They will benefit from a continuing federal commitment to precision medicine, which will bring about greater efficacy of biopharmaceutical therapies. And they will benefit from medical liability reform that permits incentives for their full participation in their own healthcare.

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HLC looks forward to working with you in improving our healthcare system, so we can take full advantage of the innovations emerging from every corner of every sector of American healthcare. Each of our member companies can demonstrate, from their own metric-supported successes, how the reforms recommended in this Playbook can improve patient care and strengthen financial sustainability and affordability.

As we enter this period of potentially seismic change, it is critical that we provide seamless care and coverage for patients and for all Americans. We must ensure that the healthcare system continues to function well and that government partners with the private sector to arrive at informed, collaborative solutions. If this sounds daunting, perhaps you will take inspiration from the words of Winston Churchill, who said, "To improve is to change. To be perfect is to change often." The art and science of quality healthcare involves the constant pursuit of perfection. In the pages to come, we offer specific steps to move toward that objective.



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SUMMARY

TAKE ACTION

Strengthen the Quality and Stability of the Health System

Work closely with private insurers to ensure stability and success of the nongroup health insurance market

Make it easier for Americans to buy private health insurance by allowing issuers to compete for customers as sellers of other consumer goods do: by offering distinct choices, clear costs, and sufficient information to make an educated selection

Avoid market disruption by curtailing Special Enrollment Periods, allowing insurers to refuse to re-enroll customers with unpaid premiums, and facilitating state flexibility in establishing network standards

Encourage consumers to develop health literacy to make informed health plan choices by highlighting and sharing best practices that already exist

Give states flexibility to utilize customized approaches to improve coverage for the Medicaid population

Extend funding for CHIP to ensure the safety net for the nation's most vulnerable remains intact

Streamline the administration of the Medicaid federal-state partnership and allow states the opportunity to innovate

Reform the federal fraud and abuse legal framework to support the multisector collaborations necessary to drive quality, coordinated care using value-based care models

Increase transparency and reduce misaligned incentives in CMMI demonstration programs

Repeal the blunt tool of the IPAB and instead focus on reducing costs through improved health, better care coordination, and innovations in medicines and delivery systems

Remove industry-specific taxes, which distort the market, and allow outcomes and value to drive healthcare decisionmaking

Modernize Medicare by adopting approaches proven successful in Medicare Advantage and Medicare Part D

Take steps to foster greater predictability and stability in the MA program to ensure accurate payments, increase transparency, and align incentives with beneficiary health needs

TAKE ACTION

Make Population Health an Imperative

Incentivize care for at-risk and vulnerable Americans by adjusting payment for social determinants of health

Invest in comprehensive, evidence-based wellness practices that help reduce costs and improve quality of life

Expand and implement Medicare Part D Enhanced Medication Therapy Management changes to better align financial interests while incentivizing innovation and investment

Enhance the Standard Medication Therapy Management model

Waive geographic and technological limitations on telehealth payment for all accountable care models, managed care, Medicare Advantage, and fee-for-service

Integrate and align programs for individuals dually eligible for both Medicare and Medicaid

Allow all healthcare professionals to practice to the full extent of their training and receive adequate payment for the service

Expand interstate licensure to allow a more flexible and mobile workforce

Make investments in health professional payment that will incentivize workforce growth

Increase federal funding for Graduate Medical Education



Drive Healthcare Value through Innovation

Prohibit data blocking and achieve systemwide interoperability by December 31, 2018

Harmonize laws protecting health information to facilitate patient and healthcare organization access across state lines

Modernize federal privacy rules for research to allow for simple, clear consent requirements that drive innovative research and cures

Support leading private-sector organizations in their efforts to seamlessly match the right patient to the right medical record

Use the Precision Medicine Initiative to break down barriers to research, and continue to facilitate private-sector involvement in leading this effort

Adopt recommendations to streamline and improve the FDA to help promote the development and availability of innovative treatments and technologies

Encourage federal agencies such as the FDA and CMS to maintain existing, successfully working, regulatory structures

Assess patient therapies and medications on their long-term value to the patient and health system, rather than focusing on immediate-term costs

Support the continued use of independent clinical comparative effectiveness research to inform patients of the most effective treatments

Enact meaningful medical liability reform that allows for safe harbors that reward following clinical best practices and facilitates a learning healthcare system

Strengthen the Quality and Stability of the Health System

Americans deserve a healthcare system they can count on. “Coverage gaps” and “doughnut holes” may be trendy lexicon, but they can be terrifying for people with chronic disease or life-threatening illnesses. As we continue to craft a healthcare system that provides high-quality, high-value care for all, stability and sustainability are the ultimate end goals. Visionary health policy is key to achieving those goals.

Policymakers have a responsibility to ensure access to care for all Americans, including the most vulnerable, at times and in places that work best for patients and their families. You can do that through creative benefit design for Medicare as well as demanding transparency and accuracy from CMS. You can also make sure that consumers have a robust individual insurance market in which to shop for private coverage; that they have the education and information to make wise choices; and that geography does not limit their options.

Enlist and encourage the participation of players in the private-sector healthcare market by continuing to insist on value-based payment systems with meaningful incentives and systems that are transparent and predictable. Give them a rich, fertile environment in which to innovate, rather than one that makes experimentation onerous or even illegal. Together, we can catalyze major change that will benefit all Americans and their families.

STABILIZE AND REFORM THE NONGROUP HEALTH INSURANCE MARKET

We need an affordable, sustainable health insurance market that features choice and flexibility to meet individual consumer needs. We must find the balance between affordability and desirable coverage. Innovative plans that use available healthcare dollars to cover uninsured Americans will improve accessibility and increase financial stability. Market-based reforms that give consumers greater control and responsibility over their own healthcare decision-making and incentivize healthy choices will also lead to lower

costs, improved health outcomes, and greater long-term sustainability of the health system.

Ensure Market Flexibility and Affordability in the Long Term

As Congress and the Administration consider a replacement for the ACA, the nongroup health insurance market requires immediate steps to ensure stable health insurance coverage while long-term changes are considered. In the long run, the health insurance market should be reformed to make private health insurance more affordable and accessible. We must ensure that people can purchase health insurance regardless of pre-existing health conditions if they maintain continuous coverage. We should provide advanceable, refundable tax credits for low-income individuals to help purchase health insurance that best meets their needs. To make health insurance sustainable, the pool of insured individuals must include those who are healthy as well as those who have greater demand for healthcare services. Improved risk adjustment to account for higher cost enrollees will provide balanced incentives for health insurers to enroll all customers.

We need innovative product designs that attract new consumers and offer them affordable options, as opposed to one-size-fits-all standardized benefits packages. We must ensure that nonstandard plan options are presented to shoppers in a way that is clear and does not penalize innovative plan design.

More people will select health insurance if the process to review choices and make selections is easier. Certified private insurance market websites (similar to Kayak or Travelocity) could compete for enrollees. Ease of use and choice will be key to their success: the quality of user experience and decision support tools, including out-of-pocket cost calculators; smart plan-finder tools to prioritize and quickly highlight best-fit options; searchable provider networks and drug formularies; and clear cost information for common services will earn them customers. Consumers could choose to enroll through these private markets or directly through an insurer.

Take Immediate Action to Ensure Stabilization

Urgent near-term interventions are needed to stabilize the current nongroup marketplace and prevent its collapse while longer-term reforms are debated and implemented. These key steps are needed now, and should be in place by early 2017 to enable plan-year 2018 preparations. The near-term transition steps include:

- Maintaining current premium and cost-sharing subsidies for consumers.
- Stabilizing the nongroup market by providing sufficient funding for high-risk individuals.
- Restoring greater regulatory oversight to the states by returning regulatory approval authority for nongroup products.
- Easing burdensome federal regulations that drive costs and dissuade issuers from participating in the nongroup market.

Special Enrollment Periods

A one-time open enrollment period should resemble Medicare's open enrollment program. Special Enrollment Periods (SEPs), which are circumstances under which consumers can sign up at times outside the yearly open enrollment period, should be limited in number because multiple enrollment periods cause costs to rise. Consumers who enroll under an SEP are more than twice as likely to drop coverage after a short time. They incur higher claims costs during the first three months of enrollment, which indicates they may be waiting to purchase insurance until they have a need for health services and coverage.

In addition, under the current SEP process, exchanges handle validation and enrollment without consulting with insurance issuers. HHS requires all issuers to accept the SEP enrollment decisions of the exchanges. Most of the exchanges allow enrollees to attest to SEP qualifying events without requiring any proof. This permits abuse of the SEPs, worsening the risk pool and resulting in higher premiums for the individuals who enroll at the appropriate time. HHS must begin validating SEPs prior to enrollment by requesting and reviewing documentation to verify that an applicant qualifies for coverage.

Managing short-term enrollments is challenging. Pre-enrollment verification will not prevent individuals from enrolling for short periods, but it will go far in helping to minimize potential abuses and ensure that only those who are truly eligible for exceptions can enroll during SEPs. While HLC supports the pre-enrollment verification pilot program, we urge implementation of pre-enrollment verification broadly.

Grace Periods

The current three-month grace period for nonpayment of premiums has resulted in a growing number of consumers not paying their premiums for a full year. Issuers should be permitted to require payment of outstanding premiums before customers can re-enroll.

Network Flexibility

The varying geographies and demographics across states and markets make it impossible to apply uniform network standards nationally. The attempt to do so results in requirements that are, at times, impossible to implement.

CMS should defer to the states regarding network standards. Where a state does not choose to implement network adequacy standards, the National Association of Insurance Commissioners (NAIC) Health Benefit Plan Network Access and Adequacy Act should be the guide. This model was crafted by engaging numerous stakeholders to find a balance between issuers' needs and consumers' need for a robust health insurance market. Rather than applying unbending approaches, such as numerical time and distance standards that may not meet the unique needs of a state's or market's population, CMS should emulate the flexibility inherent in the NAIC model.

Develop Best Practices to Improve Health Benefit Literacy

Better health literacy equips consumers to select and use the best health coverage option for them. The private sector has led the way in developing health literacy programs that provide consumers with information on their health benefits in an easily understandable way. Indeed, 30 members of America's Health Insurance Plans have initiated literacy programs. HHS's Office of Disease Prevention and Health Promotion National Action Plan to Improve Health Literacy emphasizes the importance of engaging all stakeholders in a multisector effort to improve health literacy. The National Academies of Science, Engineering, and Medicine Health Literacy Roundtable brings leaders from academia, industry, government, foundations, and associations together with representatives of patient and consumer interests to improve health literacy. Consumers should have best practices to guide them when choosing a plan on the public market.

Take Action:

- Work closely with private insurers to ensure stability and success of the nongroup health insurance market
- Make it easier for Americans to buy private health insurance by allowing issuers to compete for customers as sellers of other consumer goods do: by offering distinct choices, clear costs, and sufficient information to make an educated selection
- Avoid market disruption by curtailing Special Enrollment Periods, allowing insurers to refuse to re-enroll customers with unpaid premiums, and facilitating state flexibility in establishing network standards
- Encourage consumers to develop health literacy to make informed health plan choices by highlighting and sharing best practices that already exist

PROMOTE MEDICAID INNOVATION AND ACCESSIBILITY

State Medicaid programs can serve as a platform for innovation and systemwide care improvement. By focusing on a few key areas, we can help to bring higher quality care and better value to Medicaid beneficiaries:

Encourage Medicaid Flexibility for States and Reauthorize the Children's Health Insurance Program

It is essential that states be given flexibility in providing health insurance to low-income individuals and increase their access to healthcare services. Ideally, this would happen through enhanced access to private plans administering Medicaid managed care. The federal government should be flexible in enabling states to pursue creative mechanisms to provide Medicaid coverage by allowing strategies that incentivize healthy behaviors and more engagement in care management.

With that in mind, subsidies through Medicaid and CHIP should be provided to individuals who cannot afford their share of the premium for their employer sponsored health insurance. Premium assistance is a policy option to help more low-income Americans gain access to the quality healthcare that comes with having coverage in the private market. States can reduce the cost of safety net programs by taking advantage of contributions that employers are willing to make toward workers' health coverage. HLC supports coverage options for low-income individuals that ensure their needs are met through the best avenue possible. Most states have found that Medicaid managed care tools promote coordinated care, manage chronic and complex conditions, encourage healthy living, and provide non-medical services such as transportation.

The Children's Health Insurance Program (CHIP) has proven to be a monumental success for America's uninsured children, with 8.4 million enrolled in 2015. Since its inception, the program has reduced the number of uninsured low-income children and extended coverage to parents and guardians; it has a 90 percent coverage rate for children today. Due to these successful, positive outcomes, funding for CHIP should be extended to ensure the safety net for the nation's most vulnerable remains intact.

Reduce Excessive and Counterproductive Regulations

In recent years, state Medicaid directors have highlighted some of the challenges in the way the Medicaid federal-state partnership is administered. They cite burdensome and repetitive reporting requirements and extensive delays in approving any proposed changes as some of the barriers to delivering better care more efficiently. States would like to remove those barriers and have more autonomy in executing

their Medicaid programs. The federal government's goal is to ensure that funds are being used in the best way possible and that those in need of Medicaid in different states are being treated equitably.

Those two goals are not mutually exclusive. CMS should continue to facilitate new care delivery models for Medicaid beneficiaries. It is critical that we make other changes within CMS to ensure that promising proposals to improve quality of care and reduce costs will be widely disseminated and adopted.

Take Action:

- Give states flexibility to utilize customized approaches to improve coverage for the Medicaid population
- Extend funding for CHIP to ensure the safety net for the nation's most vulnerable remains intact
- Streamline the administration of the Medicaid federal-state partnership and allow states the opportunity to innovate

SUPPORT IMPLEMENTATION OF VALUE-BASED CARE

Policymakers must encourage the development of alternative healthcare payment systems that attain greater cost efficiencies and include streamlined and nimble quality measures to ensure that cost-reduction efforts do not result in poorer health outcomes or restrict patient access to the most effective treatments and therapies. CMS must bring greater predictability, transparency, and consistency to its work on payment and delivery reforms as it continues to move forward with implementation of MACRA.

CMS has taken important steps forward with the Merit-Based Incentive Payment System and in clarifying the requirements for qualifying alternative payment models under MACRA. However, more is needed. Addressing physician self-referral and anti-kickback laws and regulations is essential to the multisector collaboration, patient engagement, and cost containment innovations that can make healthcare more cost-efficient while elevating quality.

Reform "Stark" and Anti-Kickback Fraud and Abuse Laws

When the Federal Anti-Kickback Statute (1972) and the Physician Self-Referral ("Stark") Law (1988) were enacted, the healthcare system provided few or no financial

incentives to providers or patients to improve health or care delivery. Reimbursement models generally rewarded volume, based on the number of services provided, rather than health promotion and maintenance. These models naturally promote overutilization, which in turn increases costs. Through these two pieces of legislation, Congress sought to restrict financial arrangements that could lead to overutilization, inappropriately influence provider decision-making, and compromise patient care. Both laws are quite broad, prohibiting financial relationships and arrangements that are permitted in other industries; the safe harbors and exceptions, though numerous, are extremely narrow in scope.

As we continue to move toward quality-driven, value-based care delivery and payment models, challenges arise if these innovative models conflict with the outdated federal fraud and abuse legal framework. The new models encourage integration and care and payment coordination between and among providers and other industry stakeholders using financial incentives, such as shared savings, bonus payments, or risk-sharing arrangements. The legal framework must allow care delivery and payment models that encourage broader collaboration among stakeholders to accelerate ongoing improvements in care quality and patient safety, while reducing the rate of cost growth.

Ensure Consistency among Waivers for Programs to Improve Patient Health

The federal government has issued waivers that protect certain arrangements from further scrutiny under the fraud and abuse legal framework, but the waivers are limited and only benefit a small group of stakeholders participating in Medicare-approved programs. CMS should apply waivers for patient incentives under the Medicare Shared Savings Program to all CMMI demonstrations.

The current waiver gives ACOs the flexibility to encourage preventive care and patient compliance with treatment regimens without facing civil monetary penalties due to beneficiary inducements. ACA 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 approach helps reduce the concerns of potential participants in CMMI demonstrations, prospective, bright-line waivers could increase their confidence and participation. Additionally, CMS should ensure that exemptions (such as the ability to waive copays) apply to ACOs outside of CMMI demonstrations, which operate with the same patient-serving incentives as those participating in CMMI programs.

Many other federal statutes and regulations potentially complicate these new models, including the Civil Monetary

Penalties (CMP) law's beneficiary inducement and gainsharing provisions; the civil and criminal False Claims Acts; HIPAA; antitrust and tax law; and state laws that overlap with, mirror, or relate to these federal laws. Primary and immediate efforts in this area should focus on the Federal Anti-Kickback Statute and the Physician Self-Referral ("Stark") Law as they are enforced by HHS, through its Office of Inspector General (OIG) and CMS.

It is particularly important to note the relationship between the Federal Anti-Kickback Statute and the 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). Industry stakeholders are often unable to engage in patient-serving arrangements due to concerns that they could implicate the Anti-Kickback Statute and/or the CMP law. For example, routinely waiving patient copayments to encourage patient engagement could be interpreted to implicate both the CMP law's beneficiary inducement provisions as well as the Anti-Kickback Statute, which prohibits a copayment waiver because it constitutes something of value provided to a patient. As such, when considering potential changes to the Anti-Kickback Statute, related changes to the CMP law may be needed to ensure consistency in interpretation and application of both. (*Appendix A includes detailed fraud and abuse policy recommendations*).

It is also 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. MACRA calls 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 "Stark" in the 2016 Medicare 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 2016 Medicare Physician Fee Schedule included the first major changes to the physician self-referral rule since 2009. CMS has stated that the "Stark" updates were meant to accommodate healthcare delivery system/payment reform, reduce burdens, facilitate compliance, clarify certain applications of the law, and issue new exceptions. CMS and the next administration must build on this work by considering the broader reforms discussed here.

Focus the Center for Medicare & Medicaid Innovation on Small, High-Impact Demonstrations

The Center for Medicare & Medicaid Innovation (CMMI) was created under the ACA to test new payment and delivery methods. Since its inception, CMMI has administered new models that aim to enhance beneficiary care, improve health outcomes, and provide assistance to populations with special health needs. However, the approach to model testing must be more predictable, rigorous, and transparent. CMMI should be required to engage stakeholders in model development; and limit the size and scope of tests in true demonstration programs.

Increase Transparency of CMMI Decision-Making

Testing a variety of healthcare delivery strategies helps to determine best approaches to reform, and allows a mechanism for faster nationwide adoption of those approaches that improve value. Some CMMI demonstrations, however, have moved beyond the intended scope established by Congress, and could impede patient access to and the delivery of quality care. As CMMI contemplates additional payment and delivery system reforms, its staff must engage in transparent, comprehensive collaboration with stakeholders throughout the demonstration process. CMMI should be required to consult with affected stakeholders as part of the model development process, prior to issuing any new proposed payment models.

Healthcare stakeholders are already adjusting to rapidly evolving payment and coverage rules under the ACA and, soon, the Medicare Access and Child Health Insurance Program Reauthorization Act of 2015 (MACRA). Therefore, effective two-way communication is particularly important. Stakeholders typically have limited opportunity for input before CMMI launches new payment demonstrations; or have limited opportunities to participate. CMS must invite and invest this participation and input; and must share the lessons learned and best practices from completed demonstration projects in a timely way. More information about both successful and unsuccessful CMMI pilots could help to inform private-sector efforts to improve value and enhance the patient experience.

Reduce Burdensome Requirements and Misaligned Incentives

Some organizations have chosen not to participate in demonstration projects because the requirements are onerous, incentives are not appropriately aligned, or data from CMS is insufficient to make educated decisions about participation. CMMI pilots should allow participants the flexibility to determine the tools that will promote innovation, while ensuring regulatory consistency among federal

programs to avoid unnecessary complications. By considering the challenges for healthcare organizations participating in many of the demonstrations, including whether there are properly aligned incentives for participation, CMS will promote better patient outcomes and further its goal of transforming healthcare.

CMS also must improve the technology platform used to upload quality data submissions in a timely and accurate manner. The current system is resource-intensive and can be misleading in how status reports and feedback are provided. CMS must improve these systems, apply a reasonable standard of flexibility, and stay focused on the overall aim of the demonstrations to transform healthcare delivery.

Ensure Appropriate Scope of Projects in Alignment with CMMI Statutory Mission

In addition to potential patient access and treatment disruption concerns, several recent CMMI demonstrations also raise questions about the scope and mandatory participation requirements of these demonstrations. Under the ACA, CMMI was charged with implementing payment and delivery demonstrations in a targeted, patient-centered, and transparent way that accounts for the unique needs of beneficiaries. CMMI is statutorily required to ensure that its initiatives target “deficits in care,” and can only expand the scope and duration of a demonstration after careful assessment of its impact on quality of care, patient access, and spending. The scope of certain recent CMMI initiatives appears to conflict with the narrow, targeted “demonstrations” envisioned by the ACA. CMMI model tests should be small and time-limited in order to test and evaluate innovative payment policies, while minimizing potential negative unintended consequences for beneficiaries.

Take Action:

- Reform the federal fraud and abuse legal framework to support the multisector collaborations necessary to drive quality, coordinated care using value-based care models
- Increase transparency and reduce misaligned incentives in CMMI demonstration programs

REMOVE BARRIERS TO HEALTHCARE SYSTEM IMPROVEMENT

While a healthcare provider's first priority should be to the patient, increasingly that becomes difficult due to overly burdensome and conflicting laws and regulations. A number of changes should be made to existing laws and regulations to ensure providers can focus on their patients to ensure access to affordable and high-quality healthcare.

Repeal the Independent Payment Advisory Board

The Independent Payment Advisory Board, a provision of the Affordable Care Act, poses an imminent threat to patient access to healthcare. IPAB undermines and usurps Congressional authority over the Medicare program. Because Congress has not appointed IPAB members, HHS would make recommendations, thus transferring authority over the program from the legislative branch to the executive branch. The law requires IPAB to achieve scoreable savings within one year. Thus, instead of pursuing long-term reforms that may not achieve immediate savings, IPAB is more likely to consider short-term savings in the form of arbitrary and significant payment cuts for healthcare providers. This was, in fact, the conclusion of the Congressional Budget Office, which stated that IPAB is most likely to focus on payment rates or methodologies for services provided by nonexempt providers.

This would be devastating for patients, restricting access to care and innovative therapies. IPAB-generated payment reductions would only increase the access difficulties faced by too many Medicare beneficiaries. Further, payment reductions to Medicare providers will almost certainly result in a shifting of health costs to employers and consumers in the private sector.

Although it is necessary to bring greater cost efficiency to the Medicare program while improving the quality of care delivered to Medicare beneficiaries, IPAB will achieve neither of these objectives. It will only weaken, not strengthen, a program critical to the health and well-being of current and future beneficiaries.

Remove Taxes and Fees that Distort Costs and Complicate Healthcare

There also are a number of burdensome taxes and fees imposed on the health industry that should be repealed, which distort the market and can inhibit the efficient delivery of care. Taxes such as the health insurance provider's fee and the medical device tax are the product of legislative efforts to offset the costs of the ACA. These fees and taxes serve to complicate an already complex payment system and result

in higher costs for the consumer. While the desire to offset costs is understandable, industry-specific taxes are not the best way to fund important efforts to expand healthcare access. Instead of artificially increasing costs for some healthcare products and services, the government should allow patient outcomes and value to drive decisionmaking in healthcare.

Take Action:

- Repeal the blunt tool of the IPAB and instead focus on reducing costs through improved health, better care coordination, and innovations in medicines and delivery systems
- Remove industry-specific taxes, which distort the market, and allow outcomes and value to drive healthcare decisionmaking

IMPROVE EXISTING FEDERAL DELIVERY AND COVERAGE PROGRAMS

Modernize and Strengthen Medicare

Medicare has played a vital role in American healthcare since it began providing benefits to seniors and individuals with disabilities more than 50 years ago. However, the complicated structure of separate coverage for hospital benefits, physician benefits, prescription drug benefits, and supplemental insurance protection (for those who can afford it) makes the system even more complex and difficult to navigate. Medicare also does not provide catastrophic coverage to protect against high out-of-pocket costs. Beneficiaries deserve a modern Medicare insurance program that will provide better, more comprehensive care (see *Appendix B for Medicare Reform Principles*).

Improve Care for Medicare's Most Vulnerable Beneficiaries

Supplemental benefits that address patients' socioeconomic challenges along with their medical conditions have been shown to lead to better health outcomes. CMS should test models that improve care coordination and lower costs for vulnerable populations. These models should include beneficiaries with chronic conditions, lower incomes, or other limitations.

Further, Medicare Advantage (MA) plans should be allowed to offer a wider array of supplemental benefits—medical services or non-medical, social services that improve the overall health of individuals with chronic disease. For example, by providing broader community services such as transportation to medical appointments, more expensive care may be avoided and patient health may improve.

Patients who are cared for in their homes by family members and aides have better health outcomes and lower healthcare costs. Although Medicare has included such services as family respite, certain home-aide assistance, and home care as part of the Medicare benefit package, it has recently reduced them, increasing costs and worsening outcomes. We must reinstitute the benefits that support a family-based model of care. At a minimum, these benefits should be reinstated for Special Needs Plans (SNPs), which could include these benefits as part of their Model of Care (MOC). The MOC would then be reviewed by the National Commission for Quality Assurance (NCQA). If approved by NCQA, then an SNP would be permitted to offer these important benefits.

Maintain Medicare Advantage Stability and Predictability

Since 2004, the number of beneficiaries enrolled in private MA plans has more than tripled. In recent years, more Medicare beneficiaries have chosen the MA program when they become eligible for Medicare coverage; now, almost one-third of Medicare beneficiaries participate in MA. These private MA plans appeal to new beneficiaries because they seem more like their previous employer-sponsored health insurance, which typically provided catastrophic coverage and better care coordination. Health plan participants are best served by a stable and predictable partner in the federal government.

As CMS moves forward with changes to risk adjustment and the MA star ratings program, the agency should foster

more stability in the MA program, especially in the technical changes that are made each year as part of the Advance Notice. These steps must ensure accurate payments, be transparent, and create incentives to treat the sickest patients.

CMS could use star ratings to drive changes to make Medicare Advantage more predictable and stable. For example, to promote value-based payment arrangements in MA, CMS should set star rating quality performance standards at the beginning of the measurement period, rather than at the end (i.e., make the system prospective, rather than retrospective). The agency also should take steps to mitigate significant year-over-year swings, so plans can work with their providers to meet targets and continue to increase quality for patients systematically. CMS should work with Congress to eliminate the MA benchmark cap for high-quality plans so they can retain their full quality bonus payment funds; these could be used to fund additional benefits, services, and other investments that can help beneficiaries.

Appropriate regulation and oversight are critical to ensure fair, robust, and consumer-centric competition in a new Medicare market. We must avoid regulation that is unnecessarily burdensome or that imposes unnecessary expenses.

Take Action:

- **Modernize Medicare by adopting approaches proven successful in Medicare Advantage and Medicare Part D**
- **Take steps to foster greater predictability and stability in the MA program to ensure accurate payments, increase transparency, and align incentives with beneficiary health needs**

Make Population Health an Imperative

Chronic diseases are responsible for seven of ten deaths each year, and treating people with chronic diseases accounts for 86 percent of our nation's healthcare costs, according to the Centers for Disease Control and Prevention. By putting patients at the center of how we pay for and deliver care, we can arrive at value-driven, quality healthcare. Consumers who take more responsibility for planning and deciding on their own healthcare can drive change throughout the healthcare system. Evidence-based wellness and prevention practices can help them stay out of the healthcare system altogether.

Once patients do engage with the healthcare system, treatment of their chronic disease requires care coordination among multiple health professionals and providers; and delivery via a means that patients can manage. It's critical that we ensure equally coordinated and integrated care to the country's most vulnerable, making the system easier for "dual-eligibles" to navigate. An empowered, well-trained healthcare workforce, sufficient in numbers to meet demand, is the linchpin on which delivery of this care hinges.

PROMOTE AND INVEST IN EVIDENCE-BASED WELLNESS PRACTICES

We can reduce the incidence of chronic disease by investing in interventions that help people to change their behaviors and that have been proven to reduce costs and improve quality of life. We can reduce the burden of chronic disease through creation and better use of evidence-based wellness practices and changes to existing systems in all settings, including school, worksite, clinical, and community. Patients should be able to expect a comprehensive approach to wellness and prevention that includes a range of treatments and interventions, from vaccines for newborns to community-based prevention programs.

Wellness is a goal for everyone, both those who are still healthy and those already burdened with disease. It can be addressed at various stages, from prevention, to treatment, to interventions that mitigate the progression of disease or additional complications and enhance patients' ability to manage their own health and well-being.

Increase Healthcare Value by Preventing and Managing Chronic Disease

Preventive services can potentially save two million lives and nearly \$4 billion annually, according to estimates. We can prevent more episodes of chronic disease through better public- and private-sector development of evidence-based wellness practices (see *Appendix C for HLC's Wellness Principles*). Individuals should be motivated and rewarded for adopting those practices too. Currently, the U.S. Department of Health and Human Services (HHS) does not allow reimbursement for programs that reward people for achieving a specific goal or outcome. Don't we all need—and respond to—that kind of encouragement? Providing and paying for prevention and wellness services promotes patients' engagement in their own health and will help to reduce the financial burden of chronic disease on both families and government programs.

Ensure Appropriate Payment for Treatment of At-Risk, Vulnerable Individuals

It's important to factor in the socioeconomic status (SES) of a population when considering payment and performance metrics. Sociodemographic factors such as income, education, language proficiency, social support, living conditions, and available community resources can promote or inhibit a patient's adherence to the treatment plan recommended by a medical professional. The current system, which does not account for these factors, creates an uneven playing field for performance measurement and subsequent performance-based payment. Further, adjusted performance measures are critical for patients, payers, providers, and others to make fair comparative evaluations about quality and value.

Similarly, common approaches to risk-adjusting data must be developed to ensure consumer decision-making is based on accurate comparisons. The impact of multiple factors,

such as socioeconomic status, on clinical outcomes is well documented. Adjusting for these factors is necessary if data are to be used accurately for comparisons. As we think about the best way to account for SES (both for risk adjustment and the awarding of stars), we must engage stakeholders in a robust comment opportunity leading to a formal rulemaking process.

CMS should provide additional transparency around Medicare risk adjustment model updates by incorporating a formal notice and 60-day comment process, and releasing needed information that would enable stakeholders to assess the impact of the proposed changes. The risk adjustment model must be refined further to make it more accurate and appropriate. Additionally, CMS should allow greater time to assess the proposal, especially given the magnitude of the proposed changes and the operational implications of implementation.

Take Action:

- Incentivize care for at-risk and vulnerable Americans by adjusting payment for social determinants of health
- Invest in comprehensive, evidence-based wellness practices that help reduce costs and improve quality of life

PROVIDE AND PAY FOR CARE COORDINATION THAT INCREASES PATIENT ENGAGEMENT

Comprehensive care planning for chronic disease requires a holistic, patient-centered approach that spans the continuum of care and includes caregivers and community-level partners. Accountable care organizations (ACOs) are one way to do this. ACOs closely connect groups of providers who are willing and able to take responsibility for improving the overall health status, care efficiency, and experience for a defined population of healthcare consumers. But we need more incentives focused on health outcomes and increased collaboration between patients and health professionals, to provide ACOs and other alternative solutions with the fertile policy environment to improve the health of the populations served. HLC has identified three Care Planning Principles (see *Appendix D*) that, along with key components and practices, should be included in comprehensive care plans to best address chronic disease. These components can also inform reimbursement and quality measure development.

Encourage Patient Engagement through Medication Adherence

To mitigate, treat, and hopefully cure their chronic conditions, patients must take their medications and follow their healthcare provider's instructions... but many don't. They may fail to keep appointments, to make recommended dietary or lifestyle changes, or to follow other treatments and recommendations. These lapses can lead to poorer outcomes, more serious disease—even death. They can also lead to higher costs due to complications, hospitalizations, and invasive procedures that could have been prevented.

We can't derive the greatest value for our healthcare dollar unless and until patients are full participants in their care, and adherence plays a crucial part. We can help patients adhere by developing common principles to be incorporated into any patient's care plan; and by improving and streamlining federal Medication Therapy Management (MTM) programs. Using innovative therapies, policies, and practices to support improved patient adherence that maximizes quality outcomes will enhance healthcare value.

Medication Therapy Management Models: Standard vs. Enhanced

Medicare's Medication Therapy Management (MTM) program can be a useful tool in increasing patient medication adherence. The Medicare Modernization Act (MMA), which created the Part D prescription drug benefit, requires that every Part D plan offer an MTM program as a quality improvement feature. However, the existing program has not achieved significant benefits.

In September 2015, the Centers for Medicare and Medicaid Services (CMS) announced its intent to form a Part D Enhanced MTM Model. The Enhanced model is designed to test changes that would better align the financial interests of prescription drug plan sponsors and government. It seeks to create incentives for robust investment and innovation in better MTM targeting and interventions. This effort should be applauded—but more can and should be done to optimize the program (see *Appendix E* for specific recommendations).

Because not all plans participate in the Enhanced MTM demo, CMS must also improve the Standard MTM model. This can be done by establishing predetermined standard eligibility criteria for the Standard MTM program; taking into account the population served and the plan type used when CMS evaluates the MTM program; and by not unfairly disadvantaging plans that include more beneficiaries in the Standard MTM program.

Strengthen the Role of Telehealth in Care Coordination

Telemedicine and remote patient monitoring can supplement in-person healthcare visits, and have been shown to improve healthcare access and quality while lowering costs. They help to meet patient demand, deliver care to patients who cannot be seen by a clinician in person, and help providers care for patients within models in which they take on increased risk. Some 29 states and the District of Columbia require health insurers to cover telehealth visits, while similar laws are pending in six states. Some insurers are moving on their own to cover telehealth services because they see them as a way toward cost-effective, high-quality care.

However, multiple restrictions have prevented broader telehealth expansion under Medicare. These include limitations on geography (currently limited to rural areas and Alaska and Hawaii), originating site (where the patient is at the time of service), site of service (where the doctor is), and type of eligible provider. Medicare also restricts telehealth to live video that substitutes for an in-person visit and does not extend to asynchronous store-and-forward technology, except in a limited number of federal demonstration projects. While CMS has already elected to waive the originating site and geographic limitations as part of its Next Generation Accountable Care Organization (ACO) model, it has not yet done so for the other ACO models or Medicare Advantage (MA).

Payment for telehealth services should always connect to the type of service being provided, not the setting in which it is conducted, so providers are able to choose the means that is most effective for each patient. Telehealth should be included as part of the basic MA benefit package and not limited to the amount of supplemental benefit funds available. It also should be used in all ACOs and in the Merit-Based Incentive Payment System program.

Integrate and Coordinate Care for Medicare/Medicaid “Dual-Eligibles”

Over nine million Americans make up the dual-eligible population: those beneficiaries enrolled in both the Medicare and Medicaid programs. Two-thirds are low-income elderly, and one-third is under 65 and disabled. Medicare primarily pays for acute and hospital care and prescription drugs, while Medicaid generally helps to pay for Medicare premiums, cost sharing, and long-term care, as well as other nonmedical services such as transportation. Approximately 54 percent of dual-eligible beneficiaries have cognitive impairments and, therefore, often have greater healthcare needs and more difficulty navigating the healthcare system.

A lack of alignment and cohesiveness between the programs can lead to fragmented or episodic care for Medicare-

Medicaid enrollees. For example, the two programs have different enrollment periods, notifications, and appeals processes, which is often confusing to patients. It is important that both Medicare and state Medicaid IT systems track dual-eligible beneficiaries so that they remain enrolled in programs that serve them best and preserve their benefits.

Well-coordinated and integrated care is even more crucial for the dual-eligible population. Integrated care can provide the dual-eligible patient with a more satisfying healthcare experience and better health outcomes. Modern technologies, such as telehealth, are more cost-effective and scalable than in the past, and they should be utilized for enhanced coordination of care.

Take Action:

- Expand and implement Medicare Part D Enhanced Medication Therapy Management changes to better align financial interests while incentivizing innovation and investment
- Enhance the Standard Medication Therapy Management model
- Waive geographic and technological limitations on telehealth payment for all accountable care models, Medicare Advantage, and fee-for-service
- Integrate and align programs for individuals dually eligible for both Medicare and Medicaid

ENHANCE THE HEALTHCARE WORKFORCE

Our population is growing, and a larger proportion of people in this country are older, turning 65 at a rate of 11,000 per day—increasing the demand for healthcare services. Seniors represent 14.5 percent of our population, yet funding to educate future doctors has been frozen since 1996. Experts predict a significant shortage of physicians in coming decades. The healthcare workforce is not limited to doctors; nurses, nurse practitioners, physician assistants, pharmacists, dentists, and many other professionals also provide healthcare. Enhancing the healthcare workforce can help us to meet the growing need driven by population increases, aging, and consumer demand. For example, pharmacists, currently an underutilized resource, can play a more prominent role in the provision of healthcare services—especially for patients with chronic conditions. They coordinate and manage medications, monitor chronic diseases, and educate patients, among other responsibilities.

There are steps we can take to ensure a sufficient number and quality of healthcare professionals to care for the nation's growing, aging population. All health professionals should be able to exercise all of their capabilities within a healthcare team. In some cases, policies limit the ability of health professionals to practice to the full extent of their training. These must be changed.

Healthcare professionals also must be able to move around, in order to serve areas with the greatest or changing needs. If we expand interstate licensure, so that providers licensed in one state can also work in another, we can partially alleviate projected shortages in multiple healthcare specialties and geographic areas.

Federal support for a strong healthcare workforce is absolutely necessary to meet rising patient demand. Particularly, Medicare and Medicaid reimbursement must remain at adequate levels to incentivize physicians and other health professionals to continue practicing and treating rising numbers of seniors. While there is broad consensus that the workforce should be strengthened, the funding to increase the number of physicians or dramatically change payment

structures has proven difficult to find. Federal support is needed for training medical residents and the allied health professionals who work with them in primary care, behavioral health, psychiatry, dentistry, and geriatrics (see *Appendix F for specific recommendations*).

Take Action:

- Allow all healthcare professionals to practice to the full extent of their training
- Expand interstate licensure to allow a more flexible and mobile workforce
- Make investments in health professional payment that will incentivize workforce growth
- Increase federal funding for Graduate Medical Education

Drive Healthcare Value through Innovation

We can drive exponential improvements in healthcare by using and maximizing the information and tools that are available to us. Patients will be better served through expanded access to federal health data, widespread adoption of health information technology, and the use of interoperable health information systems. We can use data not only to accelerate progress in medical care, but to make the healthcare system more efficient and increase its value. Consumers should have convenient access to their own electronic health information.

We need to take these steps sooner rather than later. As the private sector drives the development of technologies and applications that enable real-time exchange of meaningful health data, federal and state authorities must develop policies that better enable the interstate electronic exchange of individual health information.

ACCELERATE DATA INTEROPERABILITY AND EXPAND DATA ACCESSIBILITY

When people visit a hospital or healthcare provider, they need to know that everyone treating them is on the same page—literally. Consistent, real-time information is key to preventing conflicting or redundant healthcare decisions and to ensuring that patients receive the best possible care. Health organizations cannot be “silos” of information, jealously guarding what they have, but rather sharing it freely in an interoperating health system. This shared data improves care and accelerates progress in medicines, technologies, and research.

People and providers want interoperable nationwide health information. During HLC’s National Dialogue for Healthcare Innovation, participants joined together to recommend concrete steps to improve patient access, an end to data blocking, and a firm deadline for achieving interoperability success. The Office of the National Coordinator for Health Information Technology continues to convene experts and helps to drive the conversation on next steps through its interoperability roadmap and other efforts.

Prohibit Data Blocking and Achieve Systemwide Interoperability by 2019

It’s important to recognize the distinction between *intraoperability* (the exchange of data within a closed vendor or provider network) and *interoperability* (exchange across heterogeneous systems or environments). Interoperability efforts must not only prohibit data blocking, but must also include efforts to link both clinical data and administrative/claims data. They should comprise providers, payers, pharmacies—any organization involved in the delivery of care, and all of whom will be able to make more informed decisions. Further, patients will be empowered to be more active in the medical decision-making process.

Leaders in every healthcare field foresee an interoperable health IT infrastructure that benefits consumers and improves health system quality and cost efficiency. We hope that our Interoperability Principles (see *Appendix G*) can help to guide the work of Congress, the administration, and other organizations working to create the health system of the future.

Improve Patient Access to Data and Promote Responsible Transparency

As taxpayer-funded entities, government health agencies must ensure maximum public benefit from data collected through their operations. Although HHS has taken steps to reduce time lag and improve compatibility of the data it releases, there is still significant room for improvement. If the government eliminates agency data “silos” and allows regular access to data at minimal cost to organizations that are subject to consumer protection laws, those organizations can develop novel ways to fight disease, improve the quality of care, reduce costs, and accelerate innovation—all to the direct benefit of patients.

Government data releases must be conducted responsibly, with sufficient information to make its context clear. Cost data, for example, should always include corresponding quality data to allow for a true assessment of the value of products and services. This quality information must include metrics validated by healthcare experts in the private sector, as well as in government. Proprietary information should never be made public unless expressly permitted by the generating organizations.

Consumers want to understand healthcare prices so that they can make informed decisions. However, “input prices” are not helpful in making these decisions. Consumers need prices at the point of service—the actual charge for an operation, a treatment, or a medication. Any cost data that is released should feature sufficient context and clarity to ensure that consumers are empowered to make judgments based on value.

Modernize Health Information Confidentiality Rules

Data can and must be used to enable evidence-based care and predict future needs of our complex healthcare delivery system. It can be used to better understand how to optimize the practice of medicine, the delivery of healthcare, and new approaches to wellness and prevention of illness. It is fundamental to designing, implementing, and evaluating innovative approaches to value-based delivery system reform, as well as medical breakthroughs. At the same time, access must be balanced with the public’s concern about the confidentiality and use of health information.

HLC leads a broad group of organizations, collectively known as the Confidentiality Coalition, that works to help policymakers strike the right balance between the protection of confidential health information and the information-sharing needed to provide the very best quality of care. The coalition is active with Congress and the administration on policies related to data exchange, privacy, data security, and cybersecurity. Regulatory clarity is key to health information flow and protection; patients and providers will be better served by a uniform national standard, based on the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, rather than the inconsistent and conflicting state laws that currently supersede federal regulation. A uniform national standard would help us to avoid a patchwork of laws at the state level. HIPAA-covered entities and their business partners should be governed by HIPAA/HITECH notification requirements (see *Appendix H for Coalition principles*).

Harmonize State and Federal Health Information Exchange Laws

State laws vary widely in how they regulate health information exchange and exist alongside the federal HIPAA statute. This creates enormous complexity and makes it difficult to implement health information exchanges within and across state borders.

Healthcare organizations want consistent national and state privacy and security requirements to simplify compliance, facilitate greater information sharing, and promote patient access. A broader harmonization that clearly incorporates HIPAA governing standards would benefit the healthcare system without creating adverse impact on individuals. For example, in order to address the growing national opioid epidemic, harmonization and alignment of federal Patient Record Confidentiality regulations (42 CFR Part 2) with HIPAA would improve healthcare outcomes

for people with substance use disorders, while continuing to protect their personal health information.

The federal government is working to outline a path toward harmonization of conflicting, confusing, and burdensome state privacy laws; this provides new hope for efforts to simplify the protection of health information. We must educate states on existing federal standards and begin a dialogue on this important problem. There is both precedent and will for an accelerated national timetable with stakeholder leadership and specific action items around harmonization of state and federal privacy laws.

Modernize Federal Rules Regarding Information Used in Research

Many patients in this country are waiting for treatments and cures, but federal rules for human subject research, combined with other privacy rules, create a complex and burdensome environment for researchers. For example, definitions in the HIPAA Privacy Rule and the Common Rule for human subject research are not always consistent, creating ambiguity and confusion for researchers. One harmonized privacy standard for research institutions would ensure 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; focus IRB resources and attention on those studies warranting the most careful scrutiny; and ensure that patient consent policy is achievable for the research community.

Remove Barriers to Accurate Patient Matching

Without accurate information 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 duplicated; unnecessary testing or improper treatment may be ordered; and patient confidence may be eroded. The inability to accurately match data is a serious threat to patient safety.

Barriers to data sharing may also cause providers to face costly clinical workflow inefficiencies and potential inaccuracies, including misidentifying patient records, ordering duplicate tests, and failing to protect patient privacy preferences. But it’s tough to strike a balance between secure and legal sharing of information with the need to consistently and accurately match patient data.

Successfully matching patients to their health information across all care settings is critical to health information interoperability efforts, to providing patients with a comprehensive health record upon request, and to ensuring that health professionals have the information to safely and effectively treat patients. The private sector has taken steps to reach these goals, but federal legislators need to facilitate government cooperation in building this infrastructure nationwide.

Take Action:

- Prohibit data blocking and achieve systemwide interoperability by December 31, 2018
- Harmonize laws protecting health information to facilitate patient and healthcare organization access across state lines
- Modernize federal privacy rules for research to allow for simple, clear consent requirements that drive innovative research and cures
- Support leading private-sector organizations in their efforts to seamlessly match the right patient to the right medical record

SUPPORT RESEARCH, COVERAGE, AND ACCESSIBILITY OF NEW THERAPIES**Maintain Federal Commitment to Precision Medicine**

The next administration must maintain leadership of the Obama administration's Precision Medicine Initiative. With an eye toward greater long-term affordability gained through more effective, targeted treatments and cures, there is an opportunity to achieve significant progress in the development and use of personalized medicine.

Improve Food and Drug Administration Effectiveness in Continuing to Improve Review Timeframes

Manufacturers are constantly developing innovative medical treatments and technologies, but it can happen faster if we review and reform Food and Drug Administration (FDA) policies. We must enact policy changes that streamline FDA's responsibilities, while ensuring that companies continue to be accountable. This could reduce FDA's workload, allowing it to focus on higher-priority activities and saving significant cost and time both for the private sector and the federal government (see *Appendix I for specific recommendations*).

Use the Most Efficient Regulatory Structure

Maintaining the rapid pace of medical innovation requires efficient, effective regulatory approaches and structures. When certain cutting-edge advancements such as Laboratory Developed Tests and Next-Generation Genetic Sequencing are already being appropriately regulated, it would be a mistake to make unnecessary or duplicative changes to that oversight. If existing regulatory agencies like CMS maintain responsibility for enforcing measures such as the Clinical Laboratory Improvement Amendments, we can maintain that rapid pace

of medical innovation and preserve FDA resources to focus on accelerating important innovations in drugs and devices.

Realize the Promise of New Treatments

The 21st century has brought giant leaps forward in the development of new therapies and medications. We must be careful not to assess their potential solely in terms of cost, which admittedly can be significant in some cases due to major investments in research. Therapies and medications must be assessed also on their value, potentially alleviating symptoms, shortening the duration or intensity of an illness, rendering future interventions or surgeries unnecessary—even delaying or preventing deaths that may have previously seemed certain. Isolated consideration of the immediate-term costs of individual treatments is shortsighted and not in the best interest of patients.

Take Action:

- Use the Precision Medicine Initiative to break down barriers to research, and continue to facilitate private-sector involvement in leading this effort
- Adopt recommendations to streamline and improve the FDA to help promote the development and availability of innovative treatments and technologies
- Encourage federal agencies such as the FDA and CMS to maintain existing, successfully working, regulatory structures
- Assess patient therapies and medications on their long-term value to the patient and health system, rather than focusing on immediate-term costs

FACILITATE A LEARNING HEALTH SYSTEM

It has been said that the definition of foolishness is attempting to solve the same problem the same way. The ability to experiment, make mistakes, and learn from those mistakes is critical to creating a healthcare system that takes lessons from its failures as well as its successes. Fear of punitive consequences can stifle experimentation and risk-taking, potentially robbing patients of beneficial medications and treatments. Sensible medical liability reform, buttressed by requirements for evidence and best practices, will create an environment that fosters, rather than inhibits, the creative problem-solving patients need and deserve. Clinical

effectiveness research provides the guardrails within which that creativity is unleashed. Only if we generate valuable learning that informs the next generation of outside-the-box thinkers will human medical and scientific advancement continue.

Utilize Comparative Clinical Effectiveness Research

Clinical comparative effectiveness research is an important component of a health system that pays for value. It is a useful tool in advancing patient interests in efficient, high-quality healthcare. Independent, transparent, clinical comparative effectiveness research should aim to help clinicians deliver better healthcare and be patient-centered. It should be prioritized on the basis of diseases and conditions with the greatest prevalence, including those that impose the greatest clinical and aggregate economic burdens on patients and society. It should also allow for individual differences among patients and evolve with changes in the healthcare system (see Appendix J for HLC principles on comparative effectiveness research).

Enact Sensible Medical Liability Reform Measures

Better patient care and safety in the information age hinges on new tools, including the use of evidence-based best practices and electronic health records (EHRs). Some EHR systems incorporate clinical practice guidelines to inform clinical decision-making. Other methods also promote adherence to best practices and evidence-based medicine.

Integration of continuous quality improvement measures relies on the human element. People must promptly identify, report, and correct technical glitches in IT systems. They must follow best practices in their medical specialty. But the threat of liability litigation incentivizes silence and higher utilization, which hinders ongoing quality improvement. The administration should establish reasonable protections for healthcare providers who follow best practices, while retaining the ability of patients who suffer injury caused by an adverse event to recover damages. The bipartisan solution around which consensus is evolving is liability *safe harbors*. This approach:

- gives providers who rely on evidence-based medicine or a certified EHR system whose technical defect led to an adverse event greater legal fairness should a lawsuit ensue; and
- affords conscientious providers additional safeguards, such as a rebuttable presumption, a tighter statute of limitations, evidentiary and procedural refinements, and a higher bar for punitive damages.

Systemic health quality improvement is a universally shared goal. The convergence of health information technology (HIT) and evidence-based medicine requires new approaches

in order to revolutionize the healthcare delivery system. This includes incentives that foster rapid, ongoing systemic quality improvement, such as safe harbors. Achieving this goal depends on factors such as practitioners following evidence-based best practices, and “meaningful users” of HIT supplying information when systems malfunction.

Take Action:

- Support the continued use of independent clinical comparative effectiveness research to inform patients of the most effective treatments
- Enact meaningful medical liability reform that allows for safe harbors that reward following clinical best practices and facilitates a learning healthcare system

CONCLUSION

We have an exciting period of opportunity before us. Important advances have been made in the past few years—both in the public and private sectors—that are changing the way we think about healthcare and the healthcare system. Together, we must build a system that helps people live longer, healthier lives by leveraging new cures, therapies, and medical technologies. We must build a system in which patient data can be used with unprecedented precision to maintain and improve health and well-being. Prevention, collaboration, communication, and transparency are required to drive healthcare value through innovation.

To fully unleash the potential of this innovation, we must move away from the tired, unproductive health policy debates of the past and move forward with initiatives that put patients at the center of care and bring them real value.

Appendix A — Medicare Fraud & Abuse Policy Recommendations



HLC has adopted Medicare Fraud & Abuse Policy Recommendations based on our expectation of the willingness of Congress, the Center for Medicare Services, or the Office of the Inspector General to address the potential impact of the change and whether meaningful action may be taken in the next year.

- Create Anti-Kickback Statute and “Stark” law waivers for all accountable care organizations that meet certain conditions, whether or not those ACOs are participating in the Medicare Shared Savings Plan.
- 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 that a 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 the definition of “fair market value” to account for new payment models that incentivize performance (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. 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.
- Expand the parameters of the MACRA-mandated and alternative payment model report (due by April 16, 2017) and mandate a new report that broadens the MACRA-mandated gainsharing report (issued by CMS in 2016) to include recommendations. These reports could be expanded to require the HHS Secretary to review and assess the Anti-Kickback Statute, the Physician Self-Referral (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; the Secretary also should consult with the Department of Justice, the Internal Revenue Service, and the Federal Trade Commission. 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, the “Stark” law, and the CMP law to protect arrangements among all participants 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 to adapt the Anti-Kickback Statute, the “Stark” law, and the CMP law to the current healthcare environment. 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.

Appendix B — Medicare Reform Principles

HLC has adopted Medicare Reform Principles to inform policymakers on how to implement Medicare reforms that achieve greater care quality, value, and program sustainability.

- **Fostering value through consumer choice should be a motivating force behind reform.** Structural reform of Medicare should allow beneficiaries to have a choice of health plans and options from which to choose. Medicare reform should foster a market that encourages the development of healthcare delivery models, coverage options, and products that stem from an innovative, competitive environment, and the protection of Medicare’s earned benefits.
- **Empowering and protecting beneficiaries must be a central component to reform.** Medicare beneficiaries should be empowered to choose among multiple affordable health plans, which provide catastrophic coverage and offer, at a minimum, the same benefits and actuarial value as traditional Medicare. It is also important that the government provide sliding-scale financial assistance to beneficiaries based on their income levels. Beneficiaries should always have access to needed treatments and providers.
- **Medicare reform should incorporate a system where an “apples-to-apples” comparison of health plans, including traditional Medicare, is available to all beneficiaries.** Beneficiaries should be able to access understandable health coverage information, whether it is online, over the phone, in writing, or delivered verbally in face-to-face meetings. Whether they choose traditional Medicare or a private plan, they should be able to easily weigh total costs, benefits, and quality in order to choose a plan that best fits their needs.
- **Medicare reform should look to the successful competitive market-based features included in existing federal programs that provide better access to coordinated care.** The ability to coordinate care and support better care transitions results in better-managed patients and better outcomes. Programs such as Medicare Part C (Medicare Advantage), the Medicare Part D Prescription Drug Benefit, and the ACA, for example, all have features that encourage affordability, choice, quality, and innovation. The best elements of these models should be adopted as part of Medicare reform.
- **Payments to health plans and providers should reflect accurate mechanisms to assure fairness for all beneficiaries and providers.** Medicare beneficiaries differ in many ways, from basics like age and gender, to more nuanced characteristics such as prior use of healthcare services and socioeconomic status. Payment to health plans and providers should be quality-based and risk-adjusted to reflect these important personal characteristics, so all stakeholders are treated fairly and there remains ample choice and competition in the market, especially for high-risk beneficiaries.
- **Effective oversight is important to ensure the success of a modernized Medicare program.** Appropriate regulation is critical to ensure fair, robust, and consumer-centric competition in a new Medicare market. By contrast, regulation that is unnecessarily burdensome or that imposes unnecessary expenses should be avoided.
- **If we do not act thoughtfully now, consequences will be severe.** The longer we wait to reform Medicare in a meaningful way, the more likely we risk encountering a budget environment that will implement drastic, arbitrary spending cuts and/or tax hikes to all stakeholders who participate in the Medicare program. This “death by a thousand cuts” will hinder beneficiaries’ access to healthcare services and products, negatively impact healthcare quality, and limit innovation. In addition to potentially reduced services for Medicare beneficiaries, policymakers could be faced with delaying eligibility or other proposals that could harm beneficiaries.

- **The sustainability of Medicare for future generations is at stake.** We have reached the point at which policymakers can no longer avoid addressing the serious economic challenge presented by Medicare's inability to keep pace with incoming beneficiaries' healthcare needs. As 11,000 Baby Boomers turn 65 every day, 11,000 new beneficiaries become eligible for Medicare. These beneficiaries will consume more than three dollars in healthcare services for every dollar they paid in Medicare payroll taxes during their working years. Furthermore, while we had 19 active workers supporting each beneficiary through payroll taxes in 1965, today that ratio is less than 4 to 1.

Appendix C — Wellness Principles

HLC has adopted Wellness Principles to guide development of policies and operations in the area of wellness, prevention, and chronic disease management. The HLC Wellness Principles can help guide the investment of federal dollars through grants, Medicare, Medicaid, and other federal programs; innovative employer and health provider-based initiatives; effective community-based programs; evidence-informed policy systems and environmental change strategies; vaccines; and other interventions that seek to promote wellness.

- **To address the multifaceted causes and effects of chronic disease, payment incentives must be re-aligned and burdensome regulations and other barriers to innovation must be removed.** Regulatory actions and policies such as the federal Essential Health Benefits package should be constructed in ways that support, not hinder, wellness. Government should not create barriers to disease prevention. While recognizing the need for guidelines and standards, the private sector should continue to invest in new, innovative ideas to help decrease the burden of chronic disease and meet the health needs of varied populations. Such ideas may exist outside the traditional healthcare delivery system model. The ACA provisions allowing premium adjustments for employees who adopt healthy behaviors and employer wellness incentives are significant positive developments in this area.
- **Wellness initiatives should be focused on evidence-based wellness and disease prevention behaviors and chronic disease management approaches that can achieve broad reach, high impact, and sustainable change.** There is a large body of evidence already in place supporting the implementation of many different health interventions that will reduce the burden of chronic disease.
- **Workplace wellness programs can increase the health of entire communities by improving the health of workers and, by extension, their families.** HLC supports efforts that make it easier to develop, implement, and sustain employee wellness initiatives such as tax incentives and reduced premiums for employees who participate in wellness programs. There are workable solutions for both small employers and larger organizations. Small organizations, in particular, benefit from community-wide interventions that affect their employees' environment outside of work.
- **The federal government, by investing significant resources in promoting wellness and prevention, can make a substantial improvement in the overall health status of the U.S. population.** The scale of chronic disease in America requires federal investment in addition to existing private efforts. When invested wisely, federal dollars are a valuable tool to help improve the health of Americans and control healthcare spending. The expertise and experience of HLC member companies and organizations lead to recommendations on criteria for measuring and reporting outcomes of proposed interventions. This information can help guide members of Congress and the federal government as they appropriate federal dollars. Federal funding should be used to build upon successful, evidence-based initiatives developed and employed by the private sector, combining private-sector innovation with public-sector population reach.

Additionally, the federal government should use its reimbursement authority and existing mechanisms to alter the payment landscape to encourage and support wellness and prevention. Providing, financing, and incentivizing prevention and care coordination services for Medicare and Medicaid beneficiaries—and relying upon already-successful private-sector programs to shape those services—can help drive consumer engagement. Federal policymakers should emphasize wellness through the various levers at their disposal, such as the Essential Health Benefits package requirements and CMMI; existing wellness offices in each federal agency; the Federal Employee Health Benefits Plan; Medicare and Medicaid coverage decisions; and tax incentives.

- **Prevention efforts and healthy behaviors cannot be broadly achieved through a single, traditional delivery system model.** Wellness and prevention measures must be coordinated and linked to primary care, must be accessible in schools, worksites and community settings, may include trained health educators and communications technology, and may be based outside the traditional, licensed healthcare delivery system. HLC member companies and organizations have helped patients manage their care outside the clinical setting using advances in technology that connect patients to the healthcare system and reinforce clinically appropriate messages. To meet the needs of a growing patient population, it is essential to address the shortage of primary care physicians with allied health professionals and other trained members of the community where appropriate. Such innovative workforce deployment will extend the reach of the existing healthcare infrastructure and provide a lower-cost way to deliver certain kinds of care. Furthermore, successful wellness initiatives work best when individuals live in communities that can support their healthy lifestyle decisions. Therefore, government policy will be critical to ensuring that the infrastructure exists to support public and private wellness initiatives within communities.
- **Taking into account the downstream effects of behavior change which may be beyond the traditional ten year budget analysis window for prevention and wellness initiatives will allow for their cost savings to be appropriately estimated in federal budget projections.** It is critical that the healthcare and policy communities be willing to accept that expected positive outcomes and ROI may not be fully realized in the early stages of any evidence-based wellness initiative. Programs and methods designed to improve wellness need to be allowed to mature to determine the initiative's success if initial metrics do not show immediate results. Evaluation needs to incorporate broad savings, including non-healthcare specific savings, from healthy behaviors.

Appendix D — Care Planning Principles



HLC, under the auspices of the National Dialogue for Healthcare Innovation, has adopted Care Planning Principles that, if enacted, would improve the care of patients with chronic disease by promoting better care coordination. Comprehensive care planning for chronic disease requires a holistic, patient-centered approach that spans the continuum of care. These three principles and their components underscore HLC's vision to ensure patient adherence and maximize quality outcomes across chronic disease challenges.

- **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 chronic disease. The notion of “team-based care” should be integrated as a standard component in care planning.
 - Care plans should incorporate evidence-based care coordination strategies that address underlying patient co-morbidities (e.g., depression). Addressing missed treatment goals may require evaluation of barriers such as disease-related distress or depression. Comprehensive care plans, by definition, should address the full range of each individual patient's health problems.
 - Comprehensive care planning should include the use of care coordinators to address the multitude of daily issues facing persons with chronic disease. 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 chronic disease must include interdisciplinary teams that can meet the holistic needs of patients and families, 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 to access care; and providing health education. An increasingly multidisciplinary approach to patient care can improve 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.
 - Comprehensive care planning should be supported by improved communication and data sharing among providers on the interdisciplinary care team, including the primary care provider, specialist, nurse, dietitian, mental health provider, exercise physiologist, other team members and specialists, and hospital-based providers, as well as non-licensed, community-based health providers. One strategy for strengthening 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. The use of patient-centered health information technologies is one way to ensure communication between patients and providers in care planning and empower patients to express their values, needs, and preferences regarding 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 care for other important treatment indicators. For example, remote patient monitoring technology extends care outside of conventional clinical settings to the home. This can improve access to care and decrease healthcare delivery costs.
- **Principle 2: Chronic disease programs must address chronic disease across the entire continuum of care.**
 - 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.

- 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 to 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.
- Comprehensive care planning must focus on care transitions for patients with chronic disease. Numerous ongoing projects are testing evidence-based models for patient transitions from hospitals into their communities. The identification of evidence-based strategies for transitions, including patient-engagement activities post-discharge, will be crucial for comprehensive care planning for patients with chronic disease.
- Care planning should also include end-of-life planning and discussions. Such conversations must 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.

▪ **Principle 3: Comprehensive care planning must take individual and community context into account.** 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 individual patients and the context in which they live.

- Care plans must empower and equip patients and their caregivers with the tools they need to play an active role in managing chronic disease. To best help patients when they return home it is essential for care plans to mobilize and incorporate outpatient resources that help support patient engagement and adherence. Registered dietitians and others also play a role in providing patients with the tools needed to manage their disease. This type of education has been shown to improve quality of life for patients. Aging and Disability Resource Centers (ADRCs) are one example of a community offering that may benefit elderly people living with chronic disease. ADRCs have five core functions: information, referral, and awareness; options counseling, advice, and assistance; streamlined eligibility determination for public programs; person-centered transitions; and quality assurance and continuous improvement.

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 plans. Currently, the only tools health plans can utilize 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 flexible enough to permit providers to develop individualized care plans that tailor tools to support specific patient needs. Further, some plans want to provide services that do not fall within the definition of medical necessity: 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).

- Chronic care plans should use health literacy assessments as a tool to inform appropriate interventions for individual patients. By using data to identify which patients are most likely to become non-adherent, physicians can target resources and time to the most at-risk patients. Further, care plans should adopt best-evidence practices in reaching low-literacy patients. Chronic care plans should also 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).

Appendix E — Medication Therapy Management Recommendations



HLC, under the auspices of the NDHI, made recommendations to improve the new “enhanced MTM model” for MTM and underscore the areas where HLC believes the model is making positive strides to improve the Medicare program.

POSITIVE FEATURES	AREAS FOR IMPROVEMENT
GENERAL	
<p>Emphasis on regulatory flexibility will allow targeting of high-risk beneficiaries and provide appropriate level and intensity of services (allows Prescription Drug Plans [PDP] to stratify services by beneficiary risk; allows different levels and types of MTM services).</p> <p>Waivers will allow various providers to offer interventions of a type that are not usually furnished in traditional MTM programs.</p>	<p>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.</p> <p>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 sponsors and government financial interests, and optimize therapeutic outcomes.</p> <p>Restriction of the model over the five year demonstration creates unfair competitive disadvantage for plan sponsors outside the designated regions. Additionally, all PDP 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).</p>
SPECIFIC	
<p>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.”</p>	<p>CMS should invest in research to determine whether these payment incentives will offset participating plan sponsors’ increased resources in the Enhanced MTM model.</p>

POSITIVE FEATURES	AREAS FOR IMPROVEMENT
<p>Quality Measures “CMS will develop new MTM-related data and metric collection requirements for both monitoring and evaluation purposes.”</p>	<p>CMS should provide participating plans with the opportunity to participate in developing the quality indicators that comprise the uniform set of MTM data elements.</p> <p>CMS should rely on measures that have been developed through an intensive, transparent development and evaluation process such as those employed by national quality organizations like the Pharmacy Quality Alliance and the National Quality Forum.</p> <p>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.</p> <p>CMS should employ a public comment process that allows a full range of stakeholders to provide input into the final measure set, performance standards (for purposes of determining performance-based payments), and evaluation methods.</p> <p>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.</p> <p>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).</p> <p>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.</p>
<p>Lessons Learned</p>	<p>CMS should be more explicit about how plans’ proprietary information can be appropriately protected.</p> <p>Lessons learned should be shared with plans outside of the model’s geographic limitations.</p> <p>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.</p>
<p>Stakeholder Collaboration</p>	<p>CMS should reconsider its stance regarding manufacturer and health plan collaborations to allow for appropriate interactions that will result in improved medication adherence.</p>

Appendix F — Workforce Principles

HLC has adopted Workforce Principles to guide strategies and activities in addressing healthcare workforce challenges. These principles may also guide other stakeholders as they advocate for policies that strengthen and support the healthcare workforce. There are *two overarching themes*:

- **Build the Future Healthcare System.** As the healthcare system changes, so too must the healthcare workforce. Public and private efforts to develop and strengthen the healthcare workforce must be constructed in a way that encourages the healthcare delivery system to lower costs and improve outcomes. Workforce policies geared toward the goals of the future rather than the current system will produce a shift toward improved quality in healthcare and create a workforce ready to address critical needs.
- **Promote Quality and Value.** The existing workforce must also transform to reflect the changing healthcare landscape. Efforts to improve and strengthen the healthcare workforce must move the system from volume-based, episodic care to value-driven, team-based, quality care that incorporates prevention and other important health determinants. We must realign the current workforce to better promote quality and value.

Principles:

- **Ensure a Sufficient Healthcare Workforce**
 - All sectors of American healthcare are or will be affected by a shortage of specialists, physicians, nurses, skilled scientists, pharmacists, and/or allied health workers who provide the expertise and capacity to treat an increasingly diverse, aging, and chronic disease-ridden population. This has effects throughout the healthcare system, including on access and cost.
 - In particular, the physician workforce is hampered by policies and payment systems that have resulted in a shortage of physicians in certain disciplines and geographic areas, as well as financially strained academic medical centers serving the sickest and most vulnerable patients. Graduate medical education, which is funded under the Medicare program, has not been increased for more than 15 years. Misaligned payment systems discourage health professionals from pursuing careers in key specialties or geographic areas, while an aging population combined with increased access to insurance coverage through healthcare reform has increased demand.
 - The healthcare workforce pipeline for all sectors of healthcare begins with STEM (science, technology, engineering, and math) education. More STEM education is needed at all levels to train and retain the workers needed to fill more traditional healthcare jobs, as well as geneticists, engineers, and specialists who are able to interpret the large amounts of data produced in healthcare. A shortage in graduates with STEM education has made it difficult for some healthcare companies to hire qualified workers for high-paying positions in the United States. A well-educated, qualified workforce is essential to research, innovation, and patient care.
 - An emphasis on STEM education should be integrated into federal policies. The federal government has many areas of influence that should be used to promote STEM skills, including immigration policies; policies to drive innovation; federal and state spending priorities; and education policies affecting elementary, secondary, and postsecondary students.
 - We need dramatic reform of how physicians are trained and paid. Payment policies should be sufficient to cover the full cost of direct and indirect medical education in the clinical setting, be better aligned to meet geographic needs, and be more efficiently allocated to meet evolving patient demand. Payment should be sufficient to bring enough workers into the system.

- **Support Nonphysician Providers**

- Nonphysician providers such as nurse practitioners, nurse assistants, community-based providers, pharmacists, and trained health educators are an integral part of the healthcare delivery system. Health services provided by nonphysician providers are an important way for the current healthcare system to be more productive and efficient, because the services they provide are often involve lower cost to the patient and supplement the care given in a traditional healthcare setting. Additionally, these varied providers are critical players in team-based care.
- In order to meet the needs of a growing and aging population, we need dramatic reform of how the healthcare workforce incorporates nonphysician providers. Nonphysician providers should be allowed to deliver the care that they are trained to provide as members of health teams. Reimbursement and regulatory gaps or barriers should be addressed so this type of care is accessible to more patients.

- **Promote and Enhance Tools that Support a More Efficient Healthcare Workforce**

- In order to make the workforce as efficient, effective, and patient-centric as possible, providers from all sectors must utilize tools to reach, treat, and engage patients. Telehealth is an important component of these tools. Telehealth acts as a force-multiplier, extending the ability of the current healthcare workforce to meet patient needs (e.g., in underserved areas). It can elevate quality by reaching individuals more effectively (e.g., locating noncompliant patients or providing interpretation services for those with language barriers). Further, telehealth supports improved workforce training and development (e.g., using telehealth to train or retrain workers and allowing workers to interact with each other via telehealth).
- Telehealth legislation and regulation should be flexible enough so that new and innovative technologies do not face disincentives from outdated frameworks. Additionally, HLC supports re-examining restrictive reimbursement and regulatory barriers that make it challenging to use telehealth across state lines and for qualified nonphysicians to be paid for care provided in a telehealth setting.

Appendix G — Interoperability Principles



HLC, under the auspices of the National Dialogue for Healthcare Innovation, has adopted Interoperability Principles that reflect HLC's vision for data flow that enables a 21st-century healthcare system.

- **Policymakers should encourage exchange of material and meaningful health data** through the use of technologies and applications that enable two-way, 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 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.
- **We must strive 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 MACRA).
- **Consumers should 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.

Appendix H — Confidentiality Coalition Privacy Principles

HLC and the Confidentiality Coalition, which HLC chairs, developed Privacy Principles to reflect the private sector’s vision for policies and practices that safeguard the privacy of patients and healthcare consumers, while enabling the essential flow of information that is critical to the timely and effective delivery of healthcare, improvements in quality and safety, and the development of new lifesaving and life-enhancing medical interventions.

- Confidentiality of patient medical information is of the utmost importance in the delivery of medical care. All care providers have a responsibility to take necessary steps to maintain the trust of the American patient as we strive to improve healthcare quality.
- Patients’ private medical information should be protected from others outside the healthcare delivery system and should be supplied only in circumstances necessary for the provision of safe, high-quality care and improved health outcomes.
- The framework established by the HIPAA Privacy Rule should be maintained. This rule established a uniform framework for the acceptable uses and disclosures of individually-identifiable health information within healthcare delivery and payment systems.
- The Privacy Rule requires that healthcare providers and health plans use the minimum necessary amount of personal health information to treat patients and pay for care by relying on patients’ “implied consent” for treatment, payment of claims, and other essential healthcare operations. This model has served patients well by ensuring quick and appropriate access to medical care, especially in emergency situations where the patient may be unable to give written consent.
- Personal health information must be secured and protected from misuses and disclosures outside of HIPAA’s acceptable uses for treatment, payment, and healthcare operations. Strict enforcement of violations is essential to protect individuals’ privacy.
- Providers should have as complete a patient history as is necessary to treat patients. Having access to a complete and timely medical record that matches the correct individual allows providers to remain confident that they are well-informed in the clinical decision-making process.
- A privacy framework should be consistent nationally so that providers, health plans, and researchers working across state lines may exchange information efficiently and effectively in order to provide treatment, extend coverage, and advance medical knowledge, whether through a national health information network or another means of exchanging health information.
- The timely and accurate flow of de-identified data is crucial to achieving the quality-improving benefits of a national health information exchange while protecting consumer privacy. Federal privacy policy should continue the HIPAA regulations for the de-identification and/or aggregation of data to allow access to properly de-identified information. This allows researchers, public health officials, and others to assess quality of care, investigate threats to public health, respond quickly in emergency situations, and collect information vital to improving healthcare safety and quality.
- To the extent not already provided under HIPAA, privacy rules should apply to all individuals and organizations that create, compile, store, transmit, or use personal health information. A similar expectation of acceptable uses and disclosures for non-HIPAA-covered health information is important in order to maintain patient trust in all healthcare organizations.



The Confidentiality Coalition is a broad group of organizations working to ensure that we as a nation find the right balance between the protection of confidential health information and the efficient and interoperable systems needed to provide the very best quality of care. www.confidentialitycoalition.org

Appendix I — U.S. Food and Drug Administration Recommendations



HLC, under the auspices of the National Dialogue for Healthcare Innovation, adopted recommendations in 2016 to streamline and improve the U.S. Food and Drug Administration (FDA). While recent progress has been made on several of these recommendations, HLC will remain involved during implementation to promote the development and availability of breakthrough treatments and technologies.

- **Reduce Regulatory Burdens on Multicenter Clinical Trials.** Eliminate the prohibition on using a single internal review board (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 the 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.** Regulatory efficiency would be improved by the timely review of a request for recognition of a standard established by an internationally or nationally recognized standards organization. Through greater use of standards and more transparency in this area, FDA review will be more efficient and medical technology can be transferred from the bench to the bedside more quickly.
- **Expand Types of 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 speed access to new therapies for patients.
- **Provide Training on “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 provisions would minimize the time involved in bringing new treatments to patients, while maintaining FDA’s high standards for safety and efficacy.
- **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.

Appendix J — Clinical Comparative Effectiveness Principles

HLC has adopted Clinical Comparative Effectiveness Principles to aid policymakers as they evaluate comparative effectiveness research.

- **Public-private clinical comparative effectiveness research must remain independent and its processes transparent.** Researchers require a stable and adequate funding stream and need to be insulated from politics. A transparent process is also necessary to ensure that consensus-based standard-setting and the development of research methodology and protocols are broadly accepted in clinical practice.
- **Clinical comparative effectiveness research should prioritize research on the basis of diseases and conditions with the greatest prevalence, including those that impose the greatest clinical and economic burdens on patients and society.**
- **Clinical comparative effectiveness research should be publicly available and broadly disseminated to multiple stakeholders.** The information should be produced and distributed in a variety of formats and mediums that consider the specific needs of those with various educational, technical, and cultural backgrounds.
- **Systematized clinical comparative effectiveness research should aim to help clinicians deliver better health care and be patient-centered.** Comparative effectiveness assessments should involve, whenever possible, considerations about quality of life, functional status, economic productivity, and other factors beyond medical efficacy that are important to patients, their caregivers, and society. However, no single comparative effectiveness assessment should be the primary criterion in decisions or recommendations related to insurance coverage, payment policy, or financing of care.
- **Clinical comparative effectiveness research should examine the entire health system from a comprehensive perspective.** It should not be limited to a specific healthcare sector and should examine all types of interventions for a condition, including procedures, diagnostic tests, preventive screenings, drugs, devices, and other medical care. The research should also examine health benefit and delivery designs and care management, as well as other factors that affect health, such as lifestyle and nutritional choices. The goal should be to identify effective, efficient interventions that achieve better value and health outcomes over time.
- **Clinical comparative effectiveness research should allow for individual differences among patients.** As medicine becomes more individualized, assessments should recognize that various interventions may work for specific subgroups of the population but not for others, based on genetic variability and other factors. Thus, research must be flexibly designed to target smaller populations with certain characteristics.
- **Clinical comparative effectiveness research must evolve with changes in healthcare.** Healthcare constantly evolves as new technologies and practice innovations offer patients and clinicians more options. Comparative information should support the generation of new insights on clinical effectiveness, facilitate access to important new interventions, and create incentives for innovation that will improve the standard of care and support a value-based system. By promoting a learning healthcare system that updates research in a timely manner with real-world data, comparative effectiveness research can avoid, rather than promote, a one-size-fits-all approach to healthcare.

The Healthcare Leadership Council

The Healthcare Leadership Council (HLC) is a coalition of chief executives from all disciplines within American healthcare, who care about a shared vision for the future. We provide the only forum of its kind, convening industry leaders to collaborate on policies, plans, and programs that will bring positive change to the healthcare system. Since HLC was founded in 1988, our purpose has been to bring together key stakeholders and decision makers from across the healthcare industry to create a healthcare system that is accessible, affordable, and patient-centered; that prizes innovation; and that delivers value to all. If you share this vision, please visit www.hlc.org to join us.

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