Broad industry coalition unifies on health care improvement agenda

By Sarah Karlin

Deregulation tops the list of health system policy recommendations from an unusually diverse group of health care industry players including drug and medical device companies, payers, providers and patient groups.

The report calls for FDA reform, changes to federal anti-kickback and physician self-referral laws, as well as harmonization of state and national patient privacy laws and regulations. It seeks comprehensive and coordinated care for the chronically ill, as well as changes to Medicare's Medication Therapy Management program.

And it wants the long-sought nationwide health information interchangeability achieved by the end of 2018.

Produced by the Healthcare Leadership Council, a coalition of health care chief executives, in conjunction with public policy researchers at the University of Chicago, the report focuses on these six broad areas that the group argues would increase innovation while also boosting quality and value. The suggestions were also picked because they were seen as policies that could be embraced even in an election season.

"These steps aren't revolutionary, but they are transformative," Healthcare Leadership Council President Mary Grealy said in a statement. "Innovation is too often put on the back burner when we discuss health care policy, but it's critical to elevating health system value, to addressing quality and cost challenges."

While the Affordable Care Act extended health coverage to tens of millions of Americans, the coalition, which also includes academics and hospitals, say a comparable effort is needed to tackle cost, quality and value.

Some of the more specific proposals that fall under each of the six areas include asking CMS to permit collaboration between pharmaceutical companies and health plans on medication adherence. They also call for federal anti-kickback and Stark Law waivers for all accountable care organizations that meet certain conditions, even if they don't participate in the Medicare Shared Savings Program.

Proposed FDA reforms include asking for an expanded definition of valid scientific evidence to include well-documented case histories including registry data, studies published in peer-reviewed journals and data collected outside the U.S. This would give FDA more flexibility in reviewing new drugs and medical devices.

For medical devices, the report also calls for allowing companies to make certain changes to their products without having to get FDA approval.

Health policy experts said the report doesn't contain a lot of new ideas - but it does unify many interests.

"The section on the FDA reforms repeats out-dated non-evidence based arguments about how the FDA impedes innovation," Aaron Kesselheim of Harvard's School of Public Health said. "The section on reforming anti kick back and Stark laws is also a bit puzzling and seems to advocate for rolling back rules in this area, when we know … these rules are in place because allowing self-referrals leads to overuse of services."

Zack Cooper of Yale's School of Public Health said the report was fairly innocuous, though he said he didn't notice any game-changing ideas.

Many of the ideas like better comprehensive care planning and medication adherence are concepts everyone agrees on Cooper said, but the recommendations in the report don't dive into how to legislate or create policy that make this a reality. He also expressed some concern about rolling back ant-kickback laws.

Report: Healthcare Industry Needs to Accelerate Interoperability Efforts, Aim for December 2018 Deadline

February 18, 2016

by Heather Landi

The healthcare industry should aim to achieve health information interoperability sooner than the timeline outlined by the Office of the National Coordinator for Health Information Technology's (ONC) 10-year roadmap, more specifically, by December 31, 2018, according to the Healthcare Leadership Council (HLC).

That recommendation is part of a comprehensive [report](#) on the healthcare industry titled "Viable Solutions: Six Steps to Transform Healthcare Now" and is the result of HLC's National Dialogue for Healthcare Innovation (NDHI) initiative. The HLC report stated that in order to meet that deadline, which is three years away, the nation must achieve nationwide exchange of health information through interoperable certified electronic health records (EHRs) technologies.

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

"According to NDHI participants, this date of December 31, 2018 is achievable if driven by the private sector and the parameters and barriers noted above are sufficiently addressed," the report stated.

HLC is a coalition of chief executives from various disciplines in the healthcare industry, including payers, providers, manufacturers and health information technology firms, and its NDHI initiative is a platform through which various health industry sectors collaborate with patients, employers, academicians and government to examine, discuss and build consensus on how to address issues affecting the course of 21st century healthcare progress.

In March 2015, under the auspices of NDHI, leaders of more than 70 healthcare organizations, including the U.S. Department of Health and Human Services (HHS), the Centers for Medicare & Medicaid Services (CMS) and the U.S. Food and Drug Administration (FDA), convened to identify the barriers impeding progress toward a high-value, innovation-driven healthcare system, according to HLC.

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

According to the report, the companies, organizations, and policy experts participating in the NDHI process agreed on six policy recommendations to improve U.S. healthcare:

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

In the area of health information interoperability, the NDHI initiative supports the establishment of a December 31, 2018 deadline for health information interoperability, "on or before which the nation must achieve nationwide exchange of health information through interoperable certified EHR technologies.

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

Following the summit and to continue work on these six steps, NDHI participants established three workgroups focusing on the following areas: patient engagement and adherence, data strategy and electronic health records (EHRs) interoperability and outdated and/or ineffective laws and regulations.

"The workgroups collaborated throughout 2015 to agree upon policy approaches that transcend the theoretical and are viewed as clearly achievable, whether through legislation, regulatory action, or proactive steps initiated by healthcare organizations. What emerged from this process is a blueprint that will be offered to executive and legislative branch policymakers and healthcare leaders," the report authors wrote.

In the area of interoperability, the HLC report notes that "while challenges still remain, the past decade has brought tremendous progress towards the adoption and meaningful use of health IT." And the report authors state that since the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009, there have been several major efforts by the public and private sectors to move toward an interoperable healthcare system.

"All stakeholders agree on the fundamental components of interoperability, but definitions of and timing for national interoperability differ, the report authors stated.

The HLC report notes the Office of the National Coordinator for Health Information Technology's (ONC) Interoperability Roadmap released in October outlines a vision for interoperability with a timeline and private/public sector opportunities for achieving the goals of interoperability. However, the ONC Interoperability Roadmap is a 10-year roadmap that lays out a plan to achieve nationwide interoperability by 2024.

The HLC report outlines a more ambitious goal with a national objective to achieve widespread exchange of health information through interoperable EHR technology nationwide on or before December 31, 2018, which is in parallel to the recommendation made in the Medicare Access and CHIP Reauthorization Act.

"NDHI believes that, by bringing together the ideas and technological expertise from both the public and private sectors, interoperability is an achievable goal that can and should be accelerated through innovation and partnership between government and the private sector," the report stated.

The HLC report also outlined a number of other recommendations for policymakers in the area of health information interoperability:

- Policymakers should encourage exchange of material and meaningful health data through the use of technologies and applications that enable bidirectional and real-time exchange of health data currently residing in EHR systems (e.g. open and secure API technology).
- Policymakers should use appropriate authority to certify only those EHR technology products that do not block or otherwise inhibit health information exchange. ONC 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, whenever and wherever 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.

The HLC stated that the recommendations in the report are intended to "drive health system transformation and a movement toward value and innovation."

"The consensus viewpoints contained in this report are also consistent with steps currently being taken by the federal government to guide a health system transition from fee-for-service to pay-for-value and toward more integrated, coordinated care. These recommendations should serve as a catalyst for further debate and decisive action," the report stated.

Coalition of Healthcare Leaders Urges 6 Key Reforms

Recommendations include increasing patient engagement, accelerating interoperability

by Shannon Firth
Contributing Writer

WASHINGTON -- Some basic health system reforms -- including better care planning, increased patient engagement, and improved interoperability -- can and should be implemented immediately, according to the Healthcare Leadership Council (HLC).

The council -- a diverse coalition of payers, providers, patient advocates, and vendors -- released a report outlining six "viable solutions" for improving the healthcare system Wednesday at a briefing here. The report, which was based on discussions of an HLC workgroup, was prepared for the council by the National Opinion Research Center (NORC) at the University of Chicago, a social science research group based in Bethesda, Md.

"The time for action is right now," Mary Grealy, president of the Healthcare Leadership Council, said at the briefing. Grealy stressed that the recommendations have strong bipartisan support and could be implemented even in an election year.

The solutions presented by the council focused on six key areas:

- Improving comprehensive care planning
- Increasing patient engagement and medication adherence
- Making health information interoperable
- Revising federal anti-kickback and physician referral (Stark) Laws
- Updating FDA regulations
- Changing health information flow as it relates to patient privacy laws

Comprehensive Care

Susan DeVore, president and CEO of Premier based in Charlotte, N.C., and chair of the Healthcare Leadership Council, described how fragmented care impacted her own family.

Her mother, who had a bedsore, had been transferred from an assisted living facility to a hospital. Although a hospital is an inappropriate setting for a patient with a pressure ulcer, her mother was a Medicare beneficiary, and under Medicare's rules, patients must be admitted to a hospital for 3 days before they can be covered for a stay in a skilled nursing facility.

"We would have been willing to pay private pay, but the total bill for that was probably $40,000, they never solved the bed sore, and she died." DeVore told *MedPage Today* that her mother had other complicating factors.

"There are several rules like that, that cause behaviors that might not be in the best interest of the coordination of care of the patient," she added. In addition to supporting health systems' right to the appropriate facilities, the council also endorsed team-based care, building health literacy, and improving transitions from hospital to home-care settings.

Medication Compliance

Medication compliance is another issue that needs attention, according to the council. Medication therapy management (MTM), a program created alongside the Medicare Part D program, aims to educate beneficiaries on the proper use of their medicines and improve compliance rates. But Medicare's enhanced MTM model won't begin until 2017, and will run for another 5 years before being evaluated.

The council recommends expanding the model to all Medicare Part D beneficiaries and Medicare Advantage enrollees. "We think this whole area of chronic care is something that has to move forward faster," DeVore said.

Fraud and Abuse

The council also recommended changes to the federal anti-kickback statute and physician referral (Stark) laws, which it argued are "outdated" and "ineffective."

Christi Shaw, chief of Novartis's U.S. pharmaceutical division, described a private integrated medical center in California that gave beneficiaries with emphysema air conditioning units during a heat wave to prevent emergency room visits and hospitalizations. That idea worked, but most healthcare systems are legally prevented from offering to provide any item that might be considered a gift or an "inducement" to generate business.

If health systems want to think creatively and find ways to improve quality care and reduce costs, they need flexibility to do so, Shaw said.

To some degree the government has recognized these difficulties. Accountable care organizations (ACOs) in the Medicare Shared Savings program (MSSP) now operate under waivers from these laws to prevent participants from being liable for coordinating financial incentives among providers.

The Medicare Access and CHIP Reauthorization Act of 2015 even obligates the Secretary of Health and Human Services to review fraud prevention laws and the implications of waivers for alternative payment models. The findings of the HHS review are to be delivered to Congress by April 16, 2016.

Interoperability and Data Flow

In addition to comprehensive, coordinated care and collaboration, the council stressed the need for providers to be able to send and receive patient data free from technological or legal barriers.

[Andrew Baskin, MD](#), national director for clinical policy at Aetna, based in Hartford Conn., explained that patients' information is spread everywhere from doctor's offices to pharmacies, to labs, and to all-payer databases.

None of these facilities communicated with each other in "any meaningful way," he said.

But the solutions for achieving interoperability are out there. "This is not a technology issue. The technology exists for all health data to be exchanged today. What doesn't exist is common standards that we've all agreed upon," he said.

As reimbursement shifts towards alternative payment models, data flow among providers and other health systems becomes essential. The council has set a deadline for nationwide health information interoperability of Dec. 31, 2018.

It recommended collaboration with leading private-sector companies to resolve the obstacle of "patient matching" -- fitting the right patient to the right record in an appropriate amount of time, possibly through better algorithms or a unique identifier.

In addition to technological barriers hindering data flow, the council also discussed privacy issues. Its report recommends developing a "single national definition and privacy standard to protect patients while mitigating complications from state laws."

Health-Care Group Calls for IT, Fraud Law Changes This Year

By Sara Hansard

Feb. 17 — Accelerated progress toward a nationwide health information system, Food and Drug Administration reforms and changes to fraud and abuse laws were among the actions called for Feb. 17 by health industry and patient advocacy groups.

The Healthcare Leadership Council (HLC), which includes providers, insurers, drug and device manufacturers as well as patient groups, said a firm date of Dec. 31, 2018, should be set to achieve health information interoperability with the private sector leading efforts to enable health-care organizations to share data with one another. The group held a briefing on Capitol Hill to announce its recommendations, which it said in a release should win bipartisan support "and can gain traction even in an election year permeated with partisan politics."

The group also called for implementation by Medicare, insurers and health-care providers of best practices to improve care for chronically ill patients, as well as standardization of national privacy laws and improved access to patient data for medical research.

The recommendations bring together sectors of health care that often are at odds with each other to push for changes the individual groups support. Even with the fierce partisan atmosphere in Washington, bipartisan agreements are possible, such as the 2015 agreement between Congress and administration to get rid of the Medicare sustainable growth rate formula used to pay doctors.

Reduce FDA Administrative Burdens

The recommendations included a series of changes to improve the efficacy of the FDA, in part by reducing administrative burdens and bringing treatments and technologies to the market more rapidly.

In addition, the federal government should "reform outdated physician self-referral and anti-kickback statutes, as well as expand Medicare payment waiver policies, to enable better coordination while protecting against fraud and abuse," the release said.

The group also said the Centers for Medicare & Medicaid Services should improve its Enhanced Medication Therapy Management Model. "Misaligned incentives have prevented the medication therapy management (MTM) program, part of the Medicare Part D prescription drug program, from achieving significant benefits," the report said.

In September 2015, the CMS announced its intent to form a Part D Enhanced MTM Model to better align prescription drug plan sponsor and government financial interests while creating incentives for robust investment and innovation, and the model should be "optimized," it said.

"These steps aren't revolutionary but they are transformative," HLC President Mary Grealy said in a statement. "Innovation is too often put on the back burner when we discuss healthcare policy, but it's critical to elevating health system value, to addressing quality and cost challenges. There are viable, practical, common-sense solutions that can and should be implemented to help make our healthcare system more patient-centered and effective."

The HLC has begun meeting with congressional leaders about the recommendations and will continue the conversations in the weeks ahead, Grealy said.

The group's report and recommendations were produced in partnership with NORC, an independent public policy research organization at the University of Chicago.

Group Recommends Faster Paths to Health IT Interoperability

By Frank Irving on February 18, 2016

Interoperability requirements or incentives should be technology-neutral and focused on outcomes, says HLC report.

Health IT interoperability is a key area for elevating health system value identified by a coalition of industry stakeholdersHealth IT interoperability is a key area for elevating health system value identified by a coalition of industry stakeholders. The Healthcare Leadership Council (HLC) published a set of recommendations on Feb. 17, taking into consideration care planning, medication management, IT interoperability, legal barriers, information flow improvements and Food and Drug Administration reforms.

The report — informed by HLC's National Dialogue for Healthcare Innovation (NDHI), a platform for health industry collaboration — offers a blueprint for policymakers to drive health system transformation.

The companies and organizations involved in the NDHI initiative support establishment of a Dec. 31, 2018 deadline for achieving nationwide exchange of health information through interoperable certified EHR technologies.

"A system built on accessible information and secure, meaningful data sharing will elevate healthcare delivery, advance quality and cost-efficiency, and enable new strides in medical research," the HLC document states.

Accordingly, all NDHI members agree on the following points:

- Policymakers should encourage use of technologies and applications that enable bidirectional and real-time exchange of health data currently residing in in EHR systems.
- Only those EHR technology products that do not block or otherwise inhibit health information exchange should be certified.
- The federal government should work with the private sector to build on current and emerging best practices in patient identification and matching. The aim in this area would be "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," the report states.

- Interoperability requirements or incentives should be "technology-neutral" and focused on outcomes rather than on adoption or use of specified technologies. The report emphasizes that future policies should not "stifle innovations in health system connectivity."

Beyond those areas, NDHI advocated for more ambitious goals, including the national objective for achieving widespread health information exchange by the end of 2018. Additionally, the group said consumers should have easy and secure access to their electronic health information and be able to direct it to any desired location — with assurance that it will be "effectively and safely used to their benefit."

"By bringing together the ideas and technological expertise from both the public and private sectors, interoperability is an achievable goal that can and should be accelerated through innovation and partnership between government and the private sector," the document states.

The report also points out that diverse state laws create barriers to the implementation of health information exchanges within and across state borders. "Healthcare organizations have long advocated for the harmonization of national and state privacy and security requirements in order to simplify compliance and facilitate greater information sharing, and promote patient access," the report states. "We believe that a broader harmonization that would clearly incorporate the Health Insurance Portability and Accountability Act governing standards would benefit the healthcare system without creating any material adverse impact on individuals."

Additionally, the report calls for more government cooperation with the private sector in building a national infrastructure in support of matching patients to their health information across all care settings.

"Positive health system transformation does not require a wholesale remaking of health delivery structures, but rather the enabling and acceleration of patient-centered innovation," the report concludes.

Industry leaders propose 6 healthcare reforms

By **Heather Caspi** | February 18, 2016

Dive Brief:

- Stakeholders collaborating under the Healthcare Leadership Council (HLC) have released a set of six recommended steps to improve U.S. healthcare, ranging from Food and Drug Administration (FDA) reforms, updates to fraud and abuse laws, and increased efforts toward a nationwide health information system.
- Those involved suggest the reforms are capable of achieving bipartisan support, even given that it's an election year fraught with partisan politics.
- To develop the recommendations, HLC's National Dialogue for Healthcare Innovation brought together senior leaders from all healthcare sectors and engaged patient groups and key industry voices, the group says, and produced the final report in collboration with policy research organization National Opinion Research Center.

Dive Insight:

The group describes its recommendations as common-sense solutions that can help make the U.S. healthcare system more patient-centered and effective. "These steps aren't revolutionary, but they are transformative," HLC president Mary R. Grealy said in a prepared statement.

The recommendations include:

- Sett a deadline of December 31, 2018, for achieving interoperability between healthcare organizations for data sharing;
- Improve the efficacy of the FDA by reducing the agency's administrative burdens and speeding the review of innovative treatments and technologies;
- Implement best practices across the industry to improve care for chronically ill patients;
- Reform outdated physician self-referral and anti-kickback statutes and expanding Medicare payment waiver policies, to improve care coordination and protection against fraud and abuse;
- Standardize state and federal privacy laws and improving access to data for research; and
- Improve CMS' Enhanced Medication Therapy Management Model to help the program follow through on improving patients' health

The HLC reports it has already started discussing the recommendations with congressional leaders.

Recommended Reading

The National Dialogue for Healthcare Innovation (NDHI): Report: Six Steps to Transform Healthcare Now

INDUSTRY, PATIENT STAKEHOLDERS SUGGEST ANTI-KICKBACK, CMS, FDA REFORMS

18 February 2016

The Healthcare Leadership Council brought recommendations to improve the healthcare system -- including improvements to Medicare's medication therapy management program, changes to the anti-kickback and physician self-referral laws, and FDA reforms -- to Capitol Hill Wednesday (Feb. 17), and HLC President Mary Grealy said the group is already talking to Senate and House lawmakers about the suggestions.

The recommendations were based on discussions by companies, patient advocacy organizations, federal government officials and academic health policy experts participating in HLC's National Dialogue for Healthcare Innovation initiative. Participants included AARP, the Advanced Medical Technology Association, America's Health Insurance Plans, Aetna, FDA, CMS, HHS, Pharmaceutical Research and Manufacturers of America, among many others.

The companies and organizations identified six areas in which certain changes could improve the healthcare system: improved care coordination to address chronic disease; improvements in the federal medication therapy management program; accelerated health information interoperability, driven by private sector innovation; FDA reforms to speed medicines and technologies to patients; changes to laws and regulations that are impeding multi-sector collaboration; and improved access to patient data for quality healthcare.

The report released by the group Wednesday states that the federal anti-kickback statute and the physician self-referral law "in their current form may inhibit current priority initiatives -- such as medical homes, bundled payments and accountable care organizations (ACOs) -- that are designed to promote value and care coordination among providers by aligning financial incentives for improved outcomes."

The regulatory and legislative options to modify the two laws were chosen by the group based on the willingness of Congress, CMS or the HHS Office of Inspector General to address them, the potential to alleviate barriers to developing and implementing new models of care delivery and whether meaningful action may be taken in the next six to 12 months.

The regulatory options include creating waivers for all ACOs that meet certain conditions, whether those ACOs are participating in the Medicare Shared Savings Program or not.

Another suggestion includes extending existing exceptions for donation and financial support of electronic health record (EHR) software, related technologies and training beyond 2021.

A legislative option would require the HHS secretary to review the anti-kickback statute, the physician self-referral law and the civil monetary penalty law and assess whether these laws create unnecessary barriers to integrated care delivery and payment models, whether these laws are effective in limiting

fraudulent behavior and 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 cost.

The companies, organizations and policy experts further said that misaligned incentives have prevented the medication therapy management program from achieving significant benefits. They suggest accelerated implementation of the Enhanced MTM Model -- which currently would not start until 2017, run for five years and then be evaluated. "This means a potential delay of seven to 10 years before the model's benefits can be extended to all Medicare beneficiaries," says the report.

The group says the design of the model should be expanded to offer benefits to all Part D members, including those in Medicare Advantage plans, to better align the financial interests of government and prescription drug plan sponsors.

Furthermore, NDHI says, CMS should reconsider its stance on collaboration between pharmaceutical manufacturers and health plans, adding that such collaboration can encourage appropriate interactions that will result in improved medication adherence.

Non-adherence is identified by the report as an issue in patients with chronic disease which could be costing the healthcare system as much as $300 billion annually. The group says that improved care coordination and adherence can have a dramatic effect on population health while significantly reducing health system costs.

NDHI participants, using diabetes as a case study, developed three principles to inform comprehensive care plans and serve as the rationale for government reimbursement activities: comprehensive care planning must address the population's multiple co-morbidities and complex care needs; chronic disease programs must address these illnesses across the entire continuum of care; and comprehensive care planning must be cognizant of issues related to the individual and community-level context.

The NDHI also calls for a harmonized privacy standard for research institutions so that research and innovation are not delayed, and says the federal government should streamline the internal review board process, clarify researcher and IRB expectations and focus IRB resources and attention on those studies warranting the most careful scrutiny. The group says that federal rules for human subjects research, combined with other privacy rules, create a complex environment for research, citing inconsistencies between the HIPAA Privacy Rule and the Common Rule.

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

NDHI says there should be a national objective to achieve interoperable EHR technology nationwide by December 2018 --which follows the recommendation in the Medicare Access and CHIP Reauthorization Act -- and that consumers should have easy and secure access to their electronic health information.

Members of NDHI agreed to build upon recommendations already presented to Congress and the White House to achieve an interoperable health IT infrastructure. The group said policymakers should encourage the use of technologies and applications that enable bidirectional and real-time exchange of health data currently residing in EHR systems, and use appropriate authority to certify only those EHR technology products that do not block or otherwise inhibit health information exchange.

The federal government, in collaboration with the private sector, should build on current and emerging best practices in patient identification and matching, and any interoperability requirements or incentives should be "technology neutral" and focused on outcomes, the report says.

NDHI additionally identified regulatory barriers within [FDA](#) that "delay access to breakthrough treatments," which the group says are all addressed in the House-passed 21st Century Cures Act. The group says it will continue to address and support these issues in the Senate.

The stakeholders call for eliminating the restriction on using a single IRB of record for device trials, and requiring [FDA](#) to develop guidance on the use of such single IRBs. Allowing companies to make certain changes to devices without premarket submission if their quality system has been certified as capable of evaluating such changes is also suggested.

Timely review of a request for recognition of a standard established by an internationally or nationally recognized standards organization would improve regulatory efficiency, says NDHI, adding that [FDA](#) review would be more efficient through greater use of standards

NDHI pushes for expanding valid scientific evidence to include well-documented case histories, including registry data, studies published in peer-reviewed journals, and data collected in countries outside the United States, saying this would allow greater flexibility in the [FDA](#) review of medical devices and improve access to new therapies for patients.

Other suggestions include training [FDA](#) staff to improve their understanding of the least burdensome requirements, so that the time to bring new treatments to patients is minimized, and a push to increase flexibility for biopharmaceutical manufacturers, payers and providers to share scientific and healthcare economic information in order to optimize the clinical benefits of prescribed treatments. -- Erin Durkin

FierceHealthcare

6 policy reforms to improve U.S. healthcare

Representatives from Premier, Aetna and other organizations collaborate on Healthcare Leadership Council initiative
February 17, 2016 | By Leslie Small

Leaders from across the industry have identified six "common-sense solutions" to improve the U.S. healthcare system, touching on subjects including data interoperability, Medicare payment policies and care of chronically ill patients, according to a report released Wednesday.

Working on behalf of the Healthcare Leadership Council's (HLC) National Dialogue for Healthcare Innovation initiative, the group of industry leaders included Premier Inc. President and CEO Susan DeVore Andrew Baskin, M.D., Aetna's national medical director for quality performance; and Christi Shaw, Novartis Pharmaceutical Corporation's president and head of U.S. General Medicines.

In developing the six steps, the industry leaders sought to identify reforms that they believed could draw support from both parties even in a politically charged election year, according to a statement emailed to *FierceHealthcare*.

"These steps aren't revolutionary, but they are transformative," said HLC President Mary R. Grealy. "There are viable, practical, common-sense solutions that can and should be implemented to help make our healthcare system more patient-centered and effective."

Here's an overview of the six steps:

- Set a "firm date"--Dec. 31, 2018--to achieve health information interoperability everywhere in the U.S., with the private sector leading the way to help healthcare organizations share data. This parallels the goal set forth by the Medicare Access and CHIP Reauthorization Act (MACRA), the report notes.
- Implement reforms to improve the Food and Drug Administration, including easing administrative burdens imposed on the agency and taking steps to more quickly deliver innovative treatments and technologies to patients.
- Implement "best practices" for Medicare, insurers and healthcare providers to improve all aspects of care for chronically ill patients. Specifically, the report outlines

a set of comprehensive care planning principles using diabetes patients as an example.

- Reform outdated physician self-referral and anti-kickback statutes, and expand Medicare payment waiver policies in order to encourage care coordination while preventing fraud and abuse. [Congress has already set its sights on making changes to the Stark law governing physician self-referral following MACRA's passage](#).
- Standardize the nation's privacy laws on the state and federal levels, and improve access to patient data for research. For example, the report notes that "one particularly burdensome barrier to nationwide health information exchange is the many diverse state laws across the country regulating health information alongside HIPAA." The Office of the National Coordinator for Health IT, has [argued HIPAA does not impede interoperability](#).
- Improve the Centers for Medicare & Medicaid Services' [Enhanced Medication Therapy Management (MTM) Model](#), including allowing participating plans to help develop the quality indicators that comprise the uniform set of MTM data elements, and employing a public comment process that allows a full range of stakeholders to provide input into the final measure set.

The HLC has already started to meet with lawmakers to discuss the group's policy recommendations, Grealy said in a statement.

To learn more:
- read the [report](#) (.pdf)

Healthcare Leadership Council: 6 steps for lawmakers, providers to immediately improve healthcare

Written by Shannon Barnet | February 17, 2016

At a Capitol Hill briefing Wednesday, the Healthcare Leadership Council recommended six steps the White House, Congress and the healthcare industry can take to immediately improve the country's healthcare system.

The recommendations originate from the Healthcare Leadership Council's National Dialogue for Healthcare Innovation initiative, which involves patient advocacy leaders, healthcare providers, insurers, drug company representatives and other industry experts.

During the briefing, the council called for the following six actions:

1. Set a firm date of Dec. 31, 2018, to achieve nationwide health information interoperability.

2. Develop reforms to further enhance the efficacy of the U.S. Food and Drug Administration by reducing the administrative burdens imposed on the agency.

3. Have Medicare, insurers and healthcare providers implement best practices to improve care for chronically ill patients.

4. Reform outdated physician self-referral and anti-kickback statutes, and expand Medicare payment waiver policies to boost care coordination while preventing fraud and abuse.

5. Standardize the country's privacy laws across Congress, the White House and the states to improve access to patient data for quality healthcare and medical research.

6. Demand CMS improve the Enhanced Medication Therapy Management Model to help the program achieve its goal of improving patients' health.

"These steps aren't revolutionary, but they are transformative," said HLC president Mary R. Grealy. "Innovation is too often put on the back burner when we discuss healthcare policy, but it's critical to elevating health system value, to addressing quality and cost challenges. There are viable, practical, common-sense solutions that can and should be implemented to help make our healthcare system more patient-centered and effective."

According to Ms. Grealy, the HLC has already begun meeting with top Congressional leaders to address these recommendations, and will continue these discussions in the weeks ahead.

Healthcare IT News

FDA reform, privacy law standards needed in next healthcare overhaul, group says

The Healthcare Leadership Council also lists interoperability among six reforms that are essential for the sector.

By Jessica Davis

The Healthcare Leadership Council has identified six healthcare reforms that should be implemented by the White House, Congress and the healthcare industry to reform healthcare; it was announced last week at a Capitol Hill briefing and in a report highlighting the changes.

For starters, nationwide health information interoperability in the private sector should be achieved by December 31, 2018, the group said.

The group also targeted the Food and Drug Administration, saying reforms that focus on reducing administrative burdens placed on the organization should be enacted so the FDA can better bring innovative treatments and technology to patients.

"These steps aren't revolutionary, but they're transformative," said HLC President Mary R. Grealy, in a statement. "Innovation is too often put on the backburner when we discuss healthcare policy, but it's critical to elevating health system value and to address quality and cost challenges."

The Centers for Medicare and Medicaid Services also needs to improve the Enhanced Medication Therapy Management Model to reach its goal of improving patient health and should implement best practices for Medicare, insurers and healthcare providers to improve care for the chronically ill, the group said.

The federal government should reform outdated physician self-referral and anti-kickback statutes and expand Medicare payment waiver policies to protect against fraud and abuse, while improving care coordination.

Cybersecurity also needs focus, the group said, pointing to Congress and the states to standardize privacy laws and increase access to patient data.

The recommendations are compiled from the HLC's National Dialogue for Healthcare Innovation initiative – a collaboration of patient advocacy leaders, drug company representatives, patient advocacy leaders, patient groups and other industry experts that convened over the course of a few months.

David Barrett, CEO of Lahey Clinic and Bill Hawkins, chairman and CEO of Medtronic, co-chaired the group.

 "There's a widespread understanding that, for all of our healthcare system's considerable strengths, we need to make strides in providing high-quality care at sustainable costs," Susan DeVore, president and CEO of Premier, Inc. and HLC chair, said in a statement. "The six steps on which we have reached agreement will move us significantly in that direction."

HLC has begun meetings with congressional leaders about the recommendations and will continue the conversations in the coming weeks. The compiled recommendations were produced by a partnership with NORC, the independent public policy research organization at the University of Chicago.

FASTER, SOONER, NOW: The Healthcare Leadership Council — a group gathering all sorts of healthcare organizations — has a message on interoperability: faster, sooner, now. (Well, December 31, 2018.) The message comes as a part of a comprehensive [report](#) on healthcare.

Your correspondent spoke with Andy Baskin, an Aetna exec, and Susan DeVore, Premier Healthcare Alliance's CEO, Wednesday, and they were quite keen to emphasize that they felt ONC's ten-year interoperability roadmap was appreciated…but a bit slow. They'd like the sector and its governmental counterparts to pick up the speed, particularly by encouraging more standards and rooting out the data blockages.

Joel White, of Health IT Now, was in strong agreement, writing, "For too long the government has tried to micromanage innovation and interoperability via the meaningful use program, and it hasn't worked. The … report rightly points out that government regulation won't get us to where we need to be."