National Dialogue for Healthcare Innovation’s Opioid Crisis Solutions Summit: A Roadmap for Action
Overview

The growing crisis of opioid misuse, addiction, and overdose has had a devastating impact on communities across the United States. Between 1999 and 2016, more than 350,000 people died from an opioid-related overdose, with overdose deaths growing to more than 42,000 in 2016 alone.\(^1\)\(^2\) Although the epidemic was initially driven by increases in the prescribing of opioids through the 2000s, since 2010, overdose deaths have also been associated with rapid increases in heroin and illicitly-manufactured fentanyl.\(^3\) As a heterogeneous issue that affects communities across the United States, concrete action must be taken by public and private stakeholders to combat the rising rates of misuse, overdose, and addiction today.

Effective responses to this complex and evolving public health challenge require the participation of leadership at the state, local, and federal level, as well as healthcare systems and communities. Healthcare system leaders within the United States have a unique and important role to play. A comprehensive response to the opioid epidemic will require leveraging evidence-based approaches across the patient care continuum—including prevention, supporting safe opioid prescribing as a part of an integrated pain management approach, expanding access to evidence-based treatment for substance use disorders, and supporting individuals in recovery. However, pursuing these efforts in isolation is unlikely to be effective. Rather, they should be viewed as elements to support the development of a broader health system approach to promote the delivery of well-coordinated, high-quality, person-centered care that includes appropriate and effective management of pain. Advancing these comprehensive, person-focused approaches will require leaders from across the healthcare system to take new steps together, supported by regulatory and legislative reforms. For example, a new effective approach will break down current data silos, promote investment in research and evaluation, and develop innovative approaches for confronting current barriers to patient-centered care.

To provide holistic but practical solutions to address the multifaceted challenges underlying the opioid crisis, the Healthcare Leadership Council’s (HLC) National Dialogue for Healthcare Innovation (NDHI) organized the Opioid Crisis Solutions Summit on May 14, 2018 in Washington, DC. The Summit brought together thought

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\(^3\) Rudd RA, Aleshire N, Zibbell JE, Gladden RM. Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014. MMWR 2016, 64(50); 1378-82.
leadership from both public and private sectors beyond HLC’s own members from virtually all health disciplines, including leaders in healthcare, business, academia, government, patient groups, and addiction and recovery experts, to identify actionable and meaningful policy recommendations. Key priorities identified by Summit participants—including specific recommendations for lawmakers, regulators, and healthcare leaders—form the “Opioid Solutions Roadmap,” a collection of substantive actions that will reduce the toll of opioid-related misuse, addiction, and overdose while taking meaningful steps to improve patient care.

THE OPIOID EPIDEMIC IN THE UNITED STATES

- 11.8 million Americans ages 12 and over misused prescription pain medicine in 2016
- Every day more than 115 people in the United States die from an opioid-related overdose
- JAMA Study: 3 out of 4 heroin users started with prescription opioids
- In 2013, the total economic burden of prescription opioid overdose, abuse, and dependence in the United States was estimated at $78.5 billion

Over one-third, $28.9 billion of this, is due to increased health care and substance abuse treatment costs

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About the Process

The Healthcare Leadership Council is a coalition of chief executives from all sectors within the U.S. health system, representing hospitals, health plans, pharmaceutical companies, medical device manufacturers, biotechnology firms, health product distributors, laboratories, post-acute care providers, and academic health centers. HLC members are on the front lines of addressing this crisis in their communities, and believe that there is a need for a comprehensive, collaborative approach that leverages innovative, evidence-based efforts from both the public and private sectors.

Many HLC member organizations from multiple health sectors are already implementing innovative strategies to address the opioid crisis. To understand approaches being utilized across the health system today, HLC’s “Inroads Against Addiction: How the Healthcare System is Battling the Opioid Crisis,” serves as a compendium of “gold star” best practices that may be expanded to help more communities. Building upon this work, the Opioid Crisis Solutions Summit brought together a diverse group of healthcare stakeholders, government leaders, and other experts to develop a concrete set of recommendations that identify best practices, prioritize solutions, and identify policy reforms necessary to collaboratively address the opioid crisis. Prior to the Summit, in order to solicit input from this broad range of healthcare leaders, workgroups were formed to focus on targeted areas of need: 1) Best-in-Class Care Management; 2) Therapeutic Innovation; and 3) Technology and Data Analytics. These workgroups, chaired by healthcare leaders within HLC membership, worked over the months leading up to the Summit to develop, prioritize, and refine recommendations for the roadmap. Each workgroup’s draft recommendations were then presented at the Summit, where they were discussed by participating healthcare leaders with the goal of reaching a consensus and a shared commitment on the path forward for healthcare leaders, lawmakers, and regulators.

OPIOID SOLUTIONS ROADMAP: KEY THEMES AND PRIORITIES
OPIOID CRISIS SOLUTIONS SUMMIT KEY PRIORITIES

There is no single solution for the complex challenges associated with opioid misuse and addiction. Actions need to be taken at multiple points along the patient care continuum, with the necessity for legislation, regulation, and industry-initiated steps to remove barriers to improved care, essential flow and use of data, and the development of innovative therapeutic tools. The Opioid Crisis Solutions Summit, and the workgroup activity leading up to it, coalesced around five key priority areas for action, with more specific proposed recommendations for healthcare leaders, policymakers, and regulators in the sections that follow.

Priority Area #1:
Improve Healthcare System Approaches to Pain Management
While maintaining access to appropriate pain management for chronic pain, hospice, and palliative care patients, much more can be done to expand access and awareness of non-opioid, opioid-sparing, or non-pharmacological approaches.

Priority Area #2:
Improve Healthcare System Approaches to Prevent Opioid Misuse
From improved supply chain security and disposal practices to tailored prescribing guidelines, healthcare system leaders can employ a number of innovative strategies to improve opioid stewardship and prevent misuse.

Priority Area #3:
Expand Access to Evidence-Based Substance Use Disorder Treatment and Behavioral Health Services
Access to appropriate levels of care for patients with substance use disorders (SUD) is imperative. Addressing existing barriers to treatment and investing in education for the patient and provider and support for substance use disorder treatment programs are essential public-private priorities.

Priority Area #4:
Promote Improved Care Coordination Through Data Access and Analytics
Optimizing the use of data and digital technologies, whether through e-prescribing or enabling real-time clinician access to prescribing and dispensing data, is critical in combating the opioid crisis.

Priority Area #5:
Develop Sustainable Payment Systems that Support Coordination and Quality Care
Innovative payment frameworks should encourage patient-centered, team-based coordinated care that utilizes the services of primary care, pharmacists, nurse practitioners, certified peer recovery specialists, licensed addiction treatment professionals, behavioral health specialists, and others in the healthcare continuum to achieve optimal outcomes for SUD patients.
Putting Priorities into Action: Recommendations for Healthcare Leaders, Policymakers, and Regulators

How can healthcare leaders, lawmakers, and regulators have the greatest impact in bringing care management solutions to the opioid crisis? What commitments can healthcare leaders make today?

RECOMMENDATIONS FOR HEALTHCARE LEADERS

1. Develop a plan for improving access to a range of evidence-based, non-opioid, opioid-sparing, and non-pharmacological pain management therapies. This plan may include:
   a. Development of research and evaluation strategies to build an evidence base for integrated models incorporating non-opioid, opioid-sparing, and non-pharmacological pain management therapies.
   b. Recommendations for coverage and benefit design for non-opioid, opioid-sparing, and non-pharmacological pain management therapies.
   c. Development, evaluation, and adoption of voluntary value-based models for integrated pain management as well as SUD treatment that promote integrated approaches and incentivize evidence-based practices and robust long-term outcomes.
   d. Identification of best practices and scaling of innovative care delivery models.
   e. Education, support, and promotion of strategies that will reduce barriers to holistic pain management, including treatment availability and financial barriers.
   f. Data collection and long-term evidence generation to inform future efforts.

2. Healthcare leaders should prioritize closing the SUD treatment gap by working to increase access to appropriate in-person or telehealth SUD treatment and recovery services in every community that they serve. Specific efforts could include organizational commitments to reducing care fragmentation, providing or incentivizing medication-assisted treatment (MAT) training in underserved areas, and investing in peer and recovery support workforce and services.

3. Pledge to adopt electronic prescribing (E-Prescribing) for all controlled substances by 2020.

4. Building on work already done by groups such as the National Quality Forum (NQF) and the Pharmacy Quality Alliance (PQA), the healthcare community should come together to address a lack of standardization on quality measures for SUD treatment and management of chronic pain by harmonizing and tying incentives to national quality measures. Such quality measures should include opioid and treatment services utilization, as well as patient- and provider-reported outcomes related to pain management, function, and quality of life.

5. Leverage the expertise of primary care, pharmacists, nurse practitioners, physician assistants, nurses, behavioral health counselors, licensed addiction treatment professionals, certified peer recover specialists, physical therapists, and other providers in coordinated care management approaches through recognition and payment of services, as well as integration into care teams and opioid stewardship models.
6. Pursue opportunities, including public and private partnerships, to develop **technologies and models that expand access to quality care** for underserved populations. Expanding the use of technology-enabled health information technology (health IT) strategies such as telehealth can help facilitate access to care for rural or underserved communities (e.g., addressing a lack of SUD providers in rural areas) or ensure individual care continuity (e.g., providing appropriate access to opioids for post-operative patients).

7. Develop consensus **best practices for improving opioid stewardship** in healthcare settings, promoting **supply chain security** to address diversion in healthcare settings, and facilitating **safe disposal of medications** in home and community settings.

8. Healthcare leaders should **draw from previous strategies** such as the Surgeon General’s Report on Alcohol, Health, and Drugs *Facing Addiction in America*, National Quality Forum’s *Opioid Stewardship Playbook*, Shatterproof’s *National Principles of Care*, and those of Facing Addiction with the National Council on Alcoholism and Drug Dependence (NCADD), to identify potential treatment and payment practices that can be piloted, evaluated, and improved on an ongoing basis. Healthcare leaders should convene an **Opioid Learning Action Network** to discuss innovative models, share experiences and lessons learned from implementation of best practices, and develop strategies for scaling innovations. Featured topics could include:

   a. Identifying and scaling **innovative care models** for chronic pain management, opioid stewardship, and SUD treatment.

   b. Evaluating current **opioid stewardship** initiatives to improve evidence-based care, as well as expanding efforts to **track and evaluate healthcare system progress** in addressing the opioid epidemic.

   c. Developing **value-based payment and payment innovation models** for pain management and SUD treatment that align the financial interests of insurers and care institutions with patient outcomes.

9. Evaluate the impact of Centers for Disease Control and Prevention (CDC) *Guideline for Prescribing Opioids for Chronic Pain* on patient care and continue to develop **tailored prescribing guidance or shared decision-making tools** appropriate for specific indications, procedures, practice settings, or type of surgery.

10. Develop, evaluate, and adopt emerging technologies and care approaches that **promote personalized care**. In particular, data-based approaches to support improved individualized care, including **pharmacogenetic testing**, may hold promise in assessing an individual’s risk for opioid misuse or other adverse events, provided personal data are protected from privacy and security violations. **Mobile apps**, such as those that may expand therapeutic options and support long-term recovery, may be used to develop more personalized approaches to ongoing care. Innovative approaches that deliver patient-centered care should be encouraged, with adequate safeguards against discrimination or stigma.
11. Develop innovative technology and data analytic solutions to encourage the creation, adoption, and evaluation of emerging strategies that will address gaps in information access and care. Below are specific recommendations:

   a. Evaluate current state, health system, and payer interventions to determine their impact on patient care. Further evaluate the use of patient “risk scores,” predictive analysis, and other tools being developed to support improved provider decision-making and patient-centered care.

   b. Encourage the use of technology-assisted education and communication to promote awareness of opioid stewardship best practices and improved care. Patient or provider education can be assisted by innovative apps, social media, or other educational resources intended to improve patient understanding of the risks and benefits of opioid therapies, communicate best practices for prescribing guidelines, link to patient resources for how to store or dispose of opioids, and other purposes.

   c. Drive adoption of clinical decision-making support, including shared decision-making tools.

RECOMMENDATIONS FOR LAWMAKERS

1. While specific legislative and regulatory solutions should be developed in consultation with healthcare stakeholders, Congress should support efforts to create access to real-time prescribing data within the clinician workflow on a national basis. Such a solution could utilize new or existing legal and regulatory authorities, and should have the following overall goals:

   a. Enable actionable, real-time information that will integrate seamlessly into clinician workflows with the goal of providing prescribers and dispensers the critical data necessary to inform clinical decision-making.

   b. Build upon existing data systems and pathways.

   c. Meet national standards to ensure that patient prescription history data, risk assessments, or clinical algorithms are applied consistently.

   d. Address current barriers in state-to-state prescription drug monitoring program data interoperability.

2. Amend 42 CFR Part 2 to align with the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of healthcare treatment, payment, and operations (TPO). Allowing confidential sharing of information on SUD diagnosis history can help improve patient safety, quality, and care coordination and ensure that the privacy of patients undergoing SUD treatment is protected.

3. Incentivize increased access to evidence-based, comprehensive SUD treatment (including MAT and psychosocial counseling) and overcoming of barriers to care. Specific priorities include expanding population-specific models of care and improving patient navigation of the treatment system, as well as expanding access to treatment within home and community settings, peer recovery support, and community recovery services. Congress should also facilitate partnerships with healthcare leaders to support increased access to care and ensure that federal programs enhance coverage for medications approved by the U.S. Food and Drug Administration (FDA) for treatment of opioid use disorder (OUD).
4. Support research, funding, and expanded access to innovative and evidence-based therapies, technologies, and approaches for integrated pain management as well as SUD treatment. Integrated pain management approaches should emphasize the prevention of opioid-related harms, and should reduce stigma and barriers to appropriate treatment for vulnerable and underserved populations. Specific priorities include:
   
a. Supporting research needs outlined in the National Pain Strategy such as the development of methods and metrics to monitor and improve the management of pain, as well as the development of appropriate, patient-centered integrated pain management practices based on a biopsychosocial model.
   
b. Investing in efforts to advance research and development of new medications and technologies to treat opioid addiction that may produce safer or more effective treatments for outcomes that matter to patients.
   
c. Supporting public-private partnerships that can expedite the arrival of innovative, non-opioid, opioid-sparing, and non-pharmacological pain management therapies to market, with an emphasis on personalized approaches based on patients' individual genetics and needs.
   
d. Supporting research on novel diagnostic approaches for determining individual risks for opioid-related harm, including genetic risk factors, to improve individualized patient-centered approaches.
   
e. Supporting research efforts and clinical initiatives to develop a better evidentiary base for understanding the risks, benefits, and appropriateness of long-term opioid therapy or other pain management therapies for specific patient populations and conditions.

5. Work with healthcare stakeholders to build a base of evidence to support non-opioid, opioid-sparing, and non-pharmacologic treatments for pain and direct Medicare to reimburse for therapies that are shown to manage chronic and acute pain while minimizing the risk of opioid addiction. Ensure that all federally-supported programs promote awareness of evidence-based, integrated pain management approaches and reduce barriers to access for patients.

6. Require E-Prescribing for all controlled substances where practicable, which will allow prescriptions to be transmitted securely, limit tampering, and reduce fraud. Congress should also work with regulators and stakeholders to address current barriers to implementation.

7. Congressional leaders should emphasize prevention as a primary strategy for addressing the opioid epidemic. As Congress considers legislation establishing opioid quantity limits and other prevention strategies, lawmakers should:
   
a. Avoid “one-size-fits-all” solutions that create barriers to appropriate pain treatment, including appropriate chronic pain management, hospice, and palliative care.
   
b. Incorporate the expertise and experience of health system stakeholders and patients into any legislative effort.
   
c. Promote provider and patient awareness of responsible opioid stewardship.
8. Improve **oversight of fraudulent treatment practices** that exploit patients and healthcare resources by providing low-quality care and engaging in predatory and fraudulent business practices. The development of quality measures for SUD treatment services, in collaboration with clinical stakeholders, would assist with identification of fraudulent practices and support evidence-based care.

9. Encourage the **integration of pharmacists into care teams** by recognizing and allowing for reimbursement under Medicare Part B of pharmacist-provided services within the full scope of practice under state law.

10. Require the Centers for Medicare and Medicaid Services (CMS) to provide a secure electronic transmittal infrastructure that **would facilitate electronic prior authorization** in Medicare Advantage and Part D and move towards greater standardization and efficiency in the prior authorization process.

**RECOMMENDATIONS FOR REGULATORS**

1. The Department of Health and Human Services (HHS), in collaboration with clinical stakeholders, should emphasize prevention of opioid misuse by **developing educational resources** for patients and families, as well as **shared decision-making tools** to improve informed patient consent prior to prescribing opioid analgesics for the management of pain.

2. Federal and state regulations, and reimbursement policies, should be revised to support the **expanded use of telemedicine**, as well as in-home and community-based SUD treatment and recovery support in order to increase access for medically-underserved populations.

3. CMS should **review and modify all reimbursement policies** to ensure that they do not create barriers for multi-modal pain treatment (including non-opioid, opioid-sparing, and non-pharmacologic therapies), as well as evidence-based SUD treatment. Where appropriate, CMS should provide guidance to state Medicaid programs for covering these services.

4. Federal interagency leaders should leverage the expertise of health system stakeholders to identify and develop strategies to **address legal, regulatory, and practical barriers** for access to evidence-based SUD treatment, including barriers to MAT, improved behavioral health coordination, reduction of regional variations in provider availability, and patient navigation of the broader continuum of SUD levels of care.

5. Federal agencies, such as the CDC, CMS, and FDA, should **promote clinician and patient education and awareness of appropriate and evidence-based pharmacologic and non-pharmacologic pain management therapies** through guidance to providers and tools such as the CDC's Checklist for Prescribing Opioids for Chronic Pain, CMS's Medicare & You handbook, and the FDA's Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics.

6. CMS should expand upon its existing **Opioid Misuse Strategy** to develop and leverage existing models for **value-based payment for integrated pain management and comprehensive SUD treatment** that incentivize evidence-based practices and quality care. Demonstration projects should be voluntary and prioritize cost-effective, team-based approaches to implementing treatment goals created in collaboration with the patient.
7. States should authorize third-party payers, including pharmacy benefit managers (PBMs), commercial insurers, Medicare, and Medicaid, to allow access to prescription drug monitoring program (PDMP) data for enrolled patients in order to help improve patient care and manage costs. Data agreements for sharing PDMP data with third-party payers should ensure protections for patient privacy, data security, and protection against PDMP data being used for inappropriate purposes.

8. Federal regulators should recognize provider status for pharmacists in Medicare Part B for the full scope of practice under state law. States can also assist with the integration of pharmacists, nurse practitioners, licensed addiction treatment professionals, certified peer recovery specialists, and physician assistants into care teams and opioid stewardship models through recognition and payment for pain management and SUD services.

9. As recommended by the President’s Commission on Combatting Drug Addiction and the Opioid Crisis, HHS should implement guidelines and reimbursement policies that foster Recovery Support Services.

10. The Drug Enforcement Administration (DEA), in collaboration with stakeholders, should develop clear guidance on the safe, practical, and cost-effective disposal of controlled substances in medical care settings to help improve supply chain security.

11. The DEA should help drive innovation and provider adoption of electronic prescriptions for controlled substances (EPCS) by modernizing current regulatory requirements for EPCS that contribute to extra cost, burden, and lack of EHR integration for healthcare providers.

12. State regulators, in partnership with the Federation of State Medical Boards, should help facilitate increased adoption of prescriber education by harmonizing education requirements and allowing for greater portability across state lines.

13. To promote the development, appropriate use, and access to new therapies with the potential to mitigate the risks of opioid-related harms, FDA should issue guidance and work with stakeholders to promote clarity regarding design needs, labeling considerations, and pre- and post-market evidentiary requirements for:
   a. Opioid formulations labeled as abuse-deterrent/tamper-resistant, with additional data and evidence needed to support the impact of abuse-deterrent/tamper-resistant formulations on opioid misuse and public health.
   b. Packaging, storage, and disposal solutions to enhance opioid safety and improve opioid stewardship.
   c. Opioid-sparing claims for non-opioid, non-pharmacological, and non-oral therapies.

14. In order to address current gaps in access to SUD treatment, federal regulators should allow residents operating under a physician’s supervision to prescribe buprenorphine instead of requiring a separate DEA registration. States should also incentivize increased provider training and examine current regulations and scope of practice laws to allow pharmacists, nurse practitioners, physician assistants, behavioral health counselors, licensed addiction treatment professionals, case managers, certified peer recovery specialists, and other providers to be better integrated into care management teams as appropriate, particularly for medically-underserved areas with a lack of MAT providers.
15. State and federal regulators should develop private-public partnerships that encourage the **development and demonstration of technology and data solutions** to address current gaps in SUD treatment access and delivery. For example, current standards for network adequacy could be used to **rapidly identify treatment resource availability** and improve transitions of care.

**Conclusion and Next Steps**

This roadmap of recommended solutions is the product of a unique and important collaboration, bringing together organizations throughout the healthcare continuum that have the expertise and influence to effectively address a challenge of extraordinary magnitude and daunting complexity. This document is a call to action, not only for lawmakers and regulators, but also for all sectors of American healthcare. While public policy has a vital role to play in removing barriers to advancements in care and empowering accelerated therapeutic innovation, private sector leadership is critical on every aspect of this issue, from improvements in pain management to data-driven proactive interventions to strengthened opioid stewardship. By building upon ongoing initiatives that are already yielding promising results, healthcare leaders can and will make a difference in stemming a crisis that has already claimed too many lives and damaged too many families and communities. The organizations that participated in this process are committed to advocating for and implementing the aforementioned recommendations, and doing so without delay.
Summit Participants

AdvaMed
American Association of Neurological Surgeons
American Association of Nurse Practitioners
American Nurses Association
American Physical Therapy Association
American Psychiatric Association
American Public Health Association
American Society of Addiction Medicine
American Society of Health System Pharmacists
America's Essential Hospitals
America's Health Insurance Plans
AmerisourceBergen
AMN Healthcare
Anthem
Ascension
Association for Behavioral Health and Wellness
Aware Recovery Care
Better Medicare Alliance
Biotechnology Innovation Organization
Bipartisan Policy Center
Blue Cross Blue Shield Association
BlueCross BlueShield of Tennessee
Cardinal Health
Chronic Pain Research Alliance
City of Hope
Cleveland Clinic
Collaborative for Effective Prescription Opioid Policies
Congress of Neurological Surgeons
ConnectiveRx™
Duke-Margolis Center for Health Policy
Faces & Voices of Recovery
Facing Addiction with NCADD
Federation of American Hospitals
Franciscan Missionaries of Our Lady Health System
Health IT NOW
Healthcare Distribution Alliance
Healthcare Leadership Council
Hearst Health
Hospice and Palliative Nurses Association
Innovative Health Solutions
IQVIA
Leidos
Lily's Place
Mallinckrodt Pharmaceuticals
Marshfield Clinic Health System
Mayo Clinic
McKesson Corporation
Medtronic
Mental Health America
National Academy of Medicine
National Alliance on Mental Illness
National Association for Behavioral Healthcare
National Association of ACOs
National Association of Chain Drug Stores
National Association of Community Health Centers
National Certification Commission for Acupuncture and Oriental Medicine
National Pharmaceutical Council
National Quality Forum
New York-Presbyterian Hospital
Outdoor Behavioral Healthcare Council
Pacific Dental Services
Park Ridge Health (Adventist Health System)
Pfizer
Pharmaceutical Research and Manufacturers of America
Premier healthcare alliance
RetireSafe
SCAN Health Plan
Shatterproof: Stronger Than Addiction
Stryker
Surescripts
Teladoc, Inc.
The Joint Commission
The Kennedy Forum
U.S. Chamber of Commerce
WEconnect
West Virginia University School of Public Health