



June 24, 2019

The Honorable Elijah Cummings
Chairman
House Oversight & Reform Committee
United States House
Washington, D.C. 20515

The Honorable Jim Jordan
Ranking Member
House Oversight & Reform Committee
United States House
Washington, D.C. 20515

Dear Chairman Cummings and Ranking Member Jordan:

On behalf of the Healthcare Leadership Council (HLC), we are pleased to submit this letter endorsing the importance of working to combat our nation's opioid crisis. We applaud Congress's bipartisan attention to an issue that is taking lives, devastating communities, and depleting the resources of our social services, healthcare and law enforcement infrastructure. HLC appreciates the House Oversight and Government Reform Committee's interest, including holding the recent hearing entitled, "Medical Experts: Inadequate Federal Approach to Opioid Treatment and the Need to Expand Care."

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, home care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patientcentered approach.

Last year, HLC convened over 70 organizations representing physicians, hospitals, insurers, drug and device manufacturers, distributors, pharmacies, employers and patients among others; collaborating over several months to build consensus on specific opioid-related recommended actions for Congress, federal regulators, and the healthcare industry. The group worked with the Duke-Margolis Health Policy Center, led by former Food and Drug Administration Commissioner and Centers for Medicare and Medicaid Services Administrator Mark McClellan, M.D., in developing a "Roadmap for Action." The "Roadmap for Action" gives clear guidance to healthcare leaders, lawmakers, and regulators on comprehensive approaches to stemming the crisis.

The Roadmap identifies five overarching priorities as essential to reversing trends in opioid abuse:

- Improving approaches to pain management;
- Preventing opioid misuse;
- Expanding access to substance use disorder treatment services;
- Increased use of care coordination through data; and
- Paying for care that is coordinated and high-quality.

HLC shares the witnesses' support of the "Comprehensive Addiction Resources Emergency (CARE) Act," H.R. 2569. The intention of H.R. 2569 to increase access to evidence-based treatment and wrap around services are among the recommendations the Roadmap calls for, as well as non-opioid, non-pharmacological, opioid-sparing pain management therapies; adoption of e-prescribing for all controlled substances by 2020; a system that provides real-time prescribing data on a national basis to aid healthcare decisionmaking; improved opioid stewardship and disposal; pharmacogenetic testing to assess an individual's risk for opioid misuse; expanded use of telehealth to facilitate access to care in rural and underserved communities; and the creation of an Opioid Learning Action Network through which healthcare leaders could share best practices and develop innovative care models.

We are pleased that Congress continues to build upon last year's efforts, and we stand ready to work with you in implementation of that legislation as well as additional efforts to address the opioid crisis like H.R. 2569. Should you have any questions, please do not hesitate to contact Debbie Witchey at (202) 449-3435 or dwitchey@hlc.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary R. Grealy". The signature is fluid and cursive, with the first name "Mary" being the most prominent.

Mary R. Grealy
President

Enclosure: "Roadmap for Action"

National Dialogue for Healthcare Innovation's Opioid Crisis Solutions Summit: **A Roadmap for Action**



NATIONAL DIALOGUE FOR
Healthcare Innovation



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

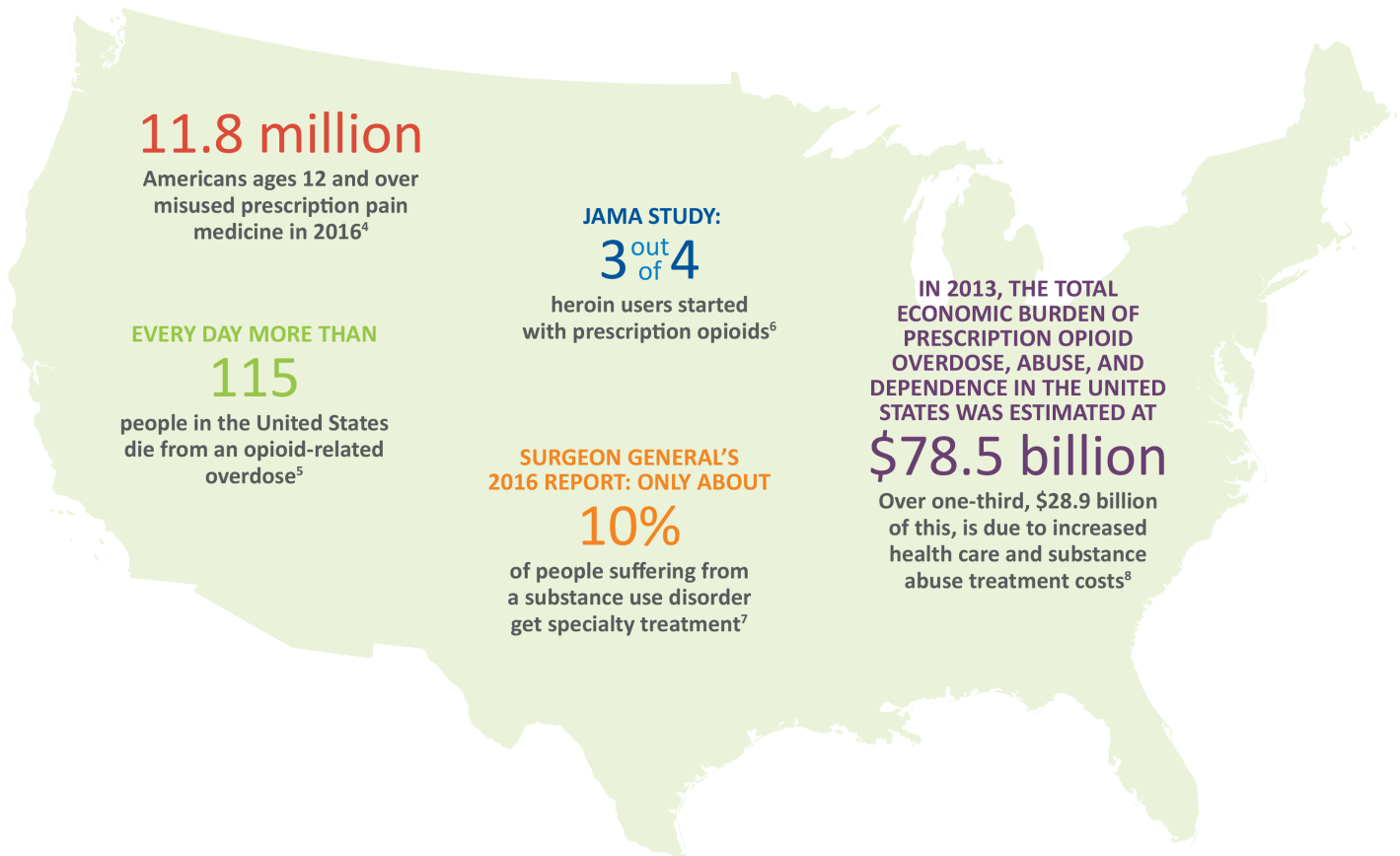
¹ Wide-ranging online data for epidemiological research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2017. Available at <http://wonder.cdc.gov>.

² Hedegaard H, Warner M, Miniño AM. Drug overdose deaths in the United States, 1999–2016. NCHS Data Brief, no 294. Hyattsville, MD: National Center for Health Statistics. 2017. Retrieved from <https://www.cdc.gov/nchs/products/databriefs/db294.htm>

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



⁴ Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health. Rockville, MD: Center for Behavioral Health Statistics and Quality, SAMHSA. Retrieved from <https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.pdf>.

⁵ Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2017. Available at <http://wonder.cdc.gov>.

⁶ Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. (2014). The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years. *JAMA Psychiatry*, 71(7); 821-826. Retrieved from <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/1874575>.

⁷ Facing Addiction in America: The Surgeon General’s Report on Alcohol, Drugs, and Health. (2016). U.S. Department of Health and Human Services. Available at <https://addiction.surgeongeneral.gov/key-findings/early-intervention>.

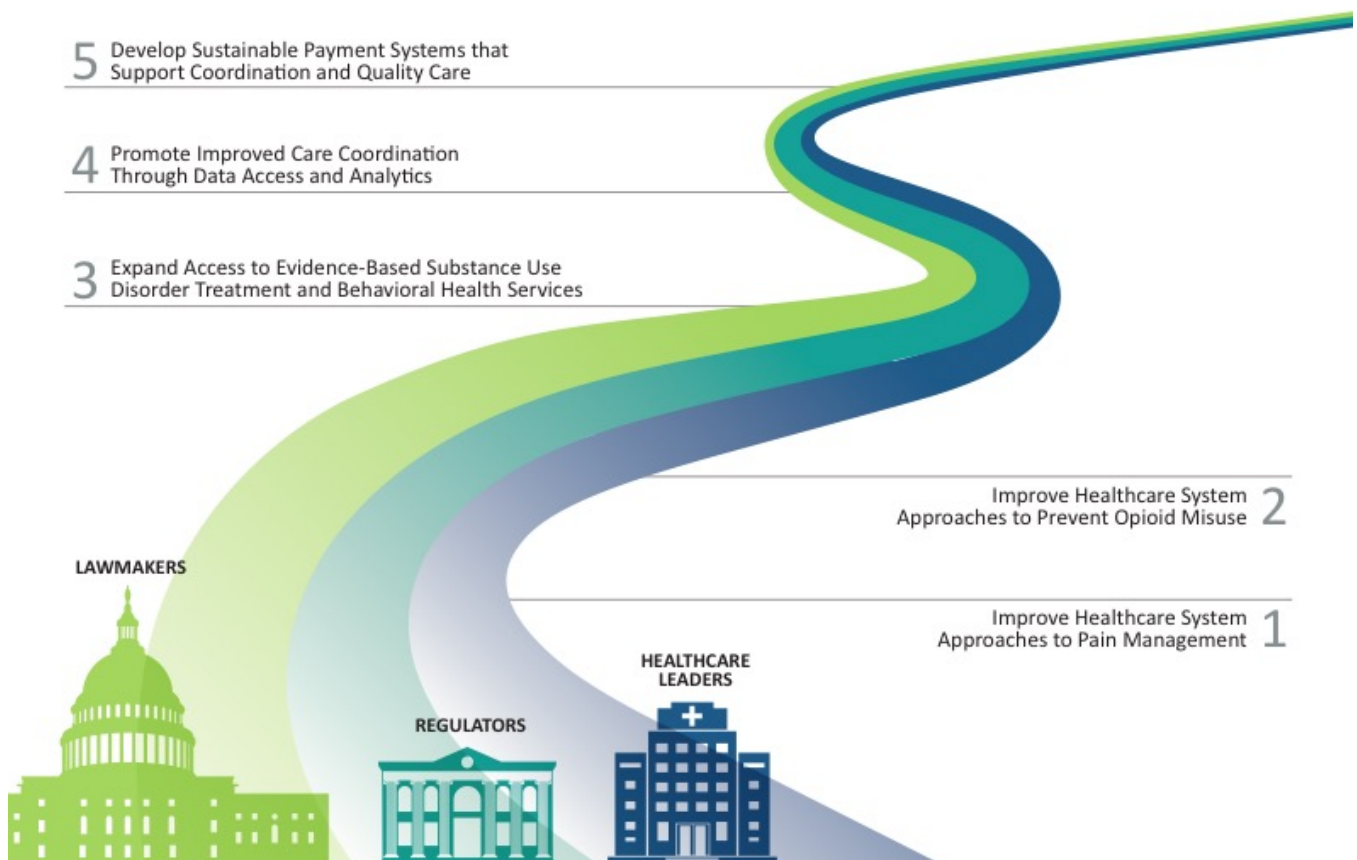
⁸ Florence CS, Zhou C, Luo F, Xu L. (2016). The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. *Med Care*, 54(10); 901-906. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/27623005>.

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.

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.





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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	Premier healthcare alliance
National Association of ACOs	RetireSafe
National Association of Chain Drug Stores	SCAN Health Plan
National Association of Community Health Centers	Shatterproof: Stronger Than Addiction
National Certification Commission for Acupuncture and Oriental Medicine	Stryker
National Pharmaceutical Council	Surescripts
National Quality Forum	Teladoc, Inc.
New York-Presbyterian Hospital	The Joint Commission
Outdoor Behavioral Healthcare Council	The Kennedy Forum
Pacific Dental Services	U.S. Chamber of Commerce
Park Ridge Health (Adventist Health System)	WEconnect
Pfizer	West Virginia University School of Public Health
Pharmaceutical Research and Manufacturers of America	



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