# Addressing The Opioid Epidemic Through Regulatory Collaboration

Monday, March 7, 2022 | 1:00 - 5:00 p.m. ET Tuesday, March 8, 2022 | 8:00 a.m. - 12:30 p.m. ET

National Academy of Medicine (NAM) Keck Center, Room 100 500 5th St NW Washington, DC 20001

Hosted by the Opioid Regulatory Collaborative









## INTRODUCTION

The regulatory boards that license U.S. physicians, physician assistants, nurses and dentists have established the Opioid Regulatory Collaborative (ORC) in an effort to bring new resources and strategies to the nation's opioid epidemic response. Composed of leaders from the American Association of Dental Boards (AADB), the Federation of State Medical Boards (FSMB), the National Association of Boards of Pharmacy (NABP) and the National Council of State Boards of Nursing (NCSBN), the Collaborative aims to reduce opioid substance use disorder among the public as well as health care practitioners. The ORC builds on the work of the National Academy of Medicine's (NAM) Action Collaborative on Countering the U.S. Opioid Epidemic and will closely align its efforts with the NAM's Action Collaborative and other leading organizations as it moves forward. During its first formal summit meeting, scheduled for March 7-8 in Washington, D.C. at the National Academies Headquarters, keynote speakers and panelists will discuss current trends, pressing needs, and developments and strategies in the nation's effort to address this public health crisis. The meeting will also include opportunities for attendees from the four sponsoring organizations to network, share ideas and consider future action steps.

## **AGENDA**

### Monday, March 7, 2022

1:00 - 1:30 p.m.

#### Welcome and Opening Remarks (ORC Leadership)

**Humayun J. Chaudhry, DO, MACP**, President and Chief Executive Officer, Federation of State Medical Boards (FSMB)

**Lemrey "AI" Carter, MS, PharmD, RPh**, Executive Director/Secretary, National Association of Boards of Pharmacy (NABP)

**David C. Benton, RGN, PhD, FFNF, FRCN, FAAN**, Chief Executive Officer, National Council for State Boards of Nursing (NCSBN)

**Tonia Socha-Mower, MBA, EdD**, Executive Director, American Association of Dental Boards

#### **NAM Leadership**

**Remarks from Victor J. Dzau, MD**, President, National Academy of Medicine

1:30 - 2:15 p.m.

**Keynote Presentation** 

**Rahul Gupta, MD, MPH,** Director of U.S. National Drug Control Policy

2:15 - 2:30 p.m.

Break

2:30 - 3:45 p.m.

**Panel I: Education** 

#### Strategies to Advance Effective and Individualized Education

Panelists will discuss the current educational environment as it pertains to opioids and identify opportunities to better align educational efforts across professions to improve effectiveness and responsiveness. This session will explore how regulators can use federal and state standards, continuing education models, competency-based education strategies and other mechanisms to respond to the opioid crisis.

#### **Panelists**

**Doris Auth, PharmD,** Acting Deputy Director, Division of Mitigation Assessment and Medication Error Surveillance, Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA)

**Steve Singer, PhD**, Vice President of Education and Outreach, Accreditation Council for Continuing Medical Education (ACCME)

**Kathy Chappell, PhD, RN, FNAP, FAAN**, Senior Vice President, Accreditation, Certification, Measurement, and Institute for Credentialing, Research and Quality Management, American Nurses Credentialing Center (ANCC)

#### **Moderator**

**David C. Benton, RGN, PhD, FFNF, FRCN, FAAN**, Chief Executive Officer, National Council for State Boards of Nursing (NCSBN)

3:45 – 4:00 p.m.	Break
------------------	-------

4:00 - 5:00 p.m. Small-Group Breakout Session

Groups will be asked to discuss strategies to improve effectiveness of prescriber education, strategies for harmonization across disciplines and the role of regulators in licensee education and assessment.

5:00 p.m. Adjourn Day One

5:30 - 6:30 p.m. Reception - Grand Foyer of the Grand Hyatt Hotel

6:30 - 8:00 p.m. Dinner - Constitution Room of the Grand Hyatt Hotel

Grand Hyatt Washington, 1000 H Street NW, Washington, DC 20001

## **AGENDA**

## Tuesday, March 8, 2022

8:00 - 8:05 a.m. Welcome and Recap of Day One

8:05 – 9:00 a.m. Keynote Presentation

**Josh M. Sharfstein, MD**, Vice Dean for Public Health Practice and Community Engagement, John Hopkins Bloomberg School of Public Health

9:00 - 9:15 a.m. Break

9:15 - 10:15 a.m. Panel II: Prevention

Risk Reduction and Accountability: What's Working Today and What Do We Need for the Future?

Panelists will discuss structural factors and how regulatory levers can be used to improve prevention efforts. Topics will range from prescription drug monitoring programs (PDMPs) to online pharmacies. An emphasis will be placed on identifying opportunities to harmonize existing policies and how best to define regulatory accountability for individual professions and interprofessional teams.

#### **Panelists**

**Libby Baney, JD**, Partner, Faegre Drinker Consulting, and Senior Advisor, Alliance for Safe Online Pharmacies (ASOP)

**Christopher M. Jones, PharmD, DrPH, MPH, CAPT**, U.S. Public Health Service, Acting Director, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention

**Danna Droz, JD, RPh**, Prescription Monitoring Program Senior Manager, National Association of Boards of Pharmacy

#### **Moderator**

**Lemrey "AI" Carter, MS, PharmD, RPh**, Executive Director/ Secretary, National Association of Boards of Pharmacy (NABP)

10:15 - 10:30 a.m.

Break

10:30 - 11:30 a.m.

**Panel III: Treatment** 

Protecting Patients and Practitioners: New Trends in Opioid Addiction Treatment

Panelists will discuss current treatment options and strategies, including new developments related to the COVID-19 pandemic and telehealth and virtual care services. This session will identify potential focus areas for new regulatory strategies and development.

#### **Panelists**

**Jake Nichols, PharmD, MBA**, Co-Founder, President and Chief Executive Officer, Renovo Health

**Melissa Weimer, DO, MCR, FASAM**, Associate Professor of Medicine and Medical Director of the Addiction Medicine Consult Service, Program in Addiction Medicine, Yale School of Medicine

**Neeraj Gandotra, MD**, Chief Medical Officer, U.S. Substance Abuse and Mental Health Services Administration

#### **Moderator**

**Tonia Socha-Mower, MBA, EdD**, Executive Director, American Association of Dental Boards

11:30 - 11:45 a.m.

**Break** 

11:45 a.m.

**Next Steps and Closing Remarks** 

12:30 p.m.

**Adjourn** 

**Doris Auth, PharmD** 

Acting Deputy Director, Division of Mitigation Assessment and Medication Error Surveillance, Center for Drug Evaluation and Research (CDER) U.S. Food and Drug Administration (FDA)

Doris Auth is currently the acting Deputy Director for the Division of Mitigation Assessment and Medication Error Surveillance. She joined the FDA in January 2011 as a Risk Management Analyst in the Division of Risk Management and was the team leader of the REMS Assessment team from 2012-2016 before becoming the Associate Director of DRM, and Division Director in 2020. Prior to joining the FDA, Doris worked as a clinical pharmacist in California, Hawaii, Washington D.C. and Virginia in both hospitals and long-term care. Her last position before joining the agency was as a research pharmacist where she oversaw primarily studies of antibiotics and psychiatric drugs. Doris has a Bachelor of Science in Pharmacy from the University of Pittsburgh and a Doctor of Pharmacy from the University of Maryland and completed a pharmacy residency at the National Institutes of Health Clinical Center.



In her role at Faegre Drinker Consulting, Ms. Baney develops legal and policy solutions for health and life sciences companies and nonprofits, advising and advocating

on issues related to patient safety online, prescription drug distribution and anti-counterfeiting, opioid epidemic response and related compliance matters. Among other clients, Ms. Baney represents the Alliance for Safe Online Pharmacies (ASOP Global), the ASOP Global Foundation, the American Telemedicine Association and the National Association of Boards of Pharmacy (NABP).



David C. Benton, RGN, PhD, FFNF, FRCN, FAAN
Chief Executive Officer, National Council for State Boards of Nursing

David Benton has served as Chief Executive Officer of the National Council of State Boards of Nursing (NCSBN) since 2015. Previously, he worked at the International Council of Nurses in Geneva, beginning as the Council's consultant on nursing and

health policy specializing in regulation, licensing and education, and later becoming CEO. He qualified as a general and mental health nurse at the then Highland College of Nursing and Midwifery in Inverness, Scotland. David has held senior roles for twenty-five years across a range of organizations, including working as Executive Director of Nursing at a health Authority in London; as a senior civil servant in Northern and Yorkshire Region; as Chief Executive of a Nurse Regulatory body in Scotland and as Nurse Director of a University Trust Health System. He was awarded the inaugural Nursing Standard Leadership award in 1993; the Fellowship of the Florence Nightingale Foundation in 2001; and the Fellowship of the Royal College of Nursing in 2003 for his contribution to health and nursing policy. He is also a Fellow of the American Academy of Nursing and a visiting professor of nursing policy at the University of Dundee in Scotland.



Lemrey "Al" Carter, MS, PharmD, RPh

Executive Director/Secretary, National Association of Boards of Pharmacy
In his role at the National Association of Boards of Pharmacy® (NABP®), Dr. Carter
leads an international organization whose membership includes the state boards of
pharmacy in all 50 United States, the District of Columbia, Guam, Puerto Rico, the

Virgin Islands, the Bahamas, and all 10 provincial pharmacy regulatory agencies in Canada. Dr. Carter currently serves as a Governor of the Pharmacy Technician Certification Board (PTCB) Board of Directors and Chair of the PTCB Certification Council, and is a former member and Chair of the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy. In addition to serving on the Board, he was appointed by the Illinois House of Representatives to serve two terms on the Illinois Collaborative Pharmaceutical Task Force. Previously, Dr. Carter oversaw pharmacy operations and professional affairs in the community pharmacy setting, responsible for the day-to-day operations and pharmacy regulatory oversight of more than 9,200 pharmacies in the United States as well as oversight, management, and execution of all commercial, Medicare Parts B and D, and state Medicaid plans. He has served on numerous committees and task forces for pharmacy organizations, including as Chair of the 2019 NABP Overview Task Force on Requirements for Pharmacy Technician Education, Practice Responsibilities, and Competence Assessment.

Kathy Chappell, PhD, RN, FNAP, FAAN

Senior Vice President, Accreditation, Certification, Measurement, and Institute for Credentialing, Research and Quality Management, American Nurses Credentialing Center

Dr. Chappell is the Senior Vice President of Accreditation, Certification, Measurement, the Institute for Credentialing Research and Quality Management, and Advanced Practice Initiatives at the American Nurses Credentialing Center (ANCC). She is responsible for certification of individual registered nurses (RNs) and advanced practice registered nurses (APRNs); and development of board certification examinations. Dr. Chappell is responsible for the accreditation of organizations that provide continuing nursing education and interprofessional continuing education and for accreditation of residency and fellowship programs for RNs and APRNs. She directs the Institute for Credentialing Research, analyzing outcomes related to credentialing, and the quality management department. She also leads the Advanced Practice Initiatives department. She is a Fellow in the American Academy of Nursing and a Distinguished Scholar and Fellow in the National Academies of Practice.



Humayun J. Chaudhry, DO, MACP, MACOI

President and Chief Executive Officer, Federation of State Medical Boards

Dr. Chaudhry leads the Federation of State Medical Boards (FSMB), representing the 70 state and territorial medical and osteopathic boards that license and regulate physicians, physician assistants and other health professionals in the United States.

The FSMB co-owns the United States Medical Licensing Examination and operates the Federation Credentials Verification Service. Dr. Chaudhry is a Master of the American College of Physicians, a Master Fellow of the American College of Osteopathic Internists (of which he is also Past President) and a Fellow of the Royal College of Physicians (London). He served five years as Director of Medical Education at Long Beach Medical Center, New York, and then six years as Chair of Medicine and Assistant Dean for Pre-Clinical Education at NYITCOM. He concurrently spent 14 years with the USAF Reserves, rising to the rank of Major and serving as a Flight Surgeon. He also served as Health Commissioner for Suffolk County, on New York's Long Island. He is the author or co-author of more than 75 peer-reviewed medical journal articles, and co-author of two books. Dr. Chaudhry was listed by Modern Healthcare magazine in 2016 as one of the 50 Most Influential Physician Executives and Leaders in America.



Danna Droz, JD, RPh
Prescription Monitoring Program Senior Manager, National Association of Boards
of Pharmacy

Ms. Droz is the Prescription Monitoring Program (PMP) InterConnect Senior Manager for the National Association of Boards of Pharmacy (NABP). She works with state

PMPs to enhance their ability to collaborate and utilize NABP tools to complement the state programs. Previously she served as the PMP director for Ohio and Kentucky, where she developed and operated the PMP in each state. Throughout her career, she has worked with pharmacists, physicians, dentists, veterinarians, nurses, hospitals, nursing homes, government officials and the pharmaceutical industry to promote compliance with the state and federal drug laws. Ms. Droz has experience in retail pharmacy, hospital pharmacy, and in long-term care pharmacy, in addition to her work in state governments, and is a frequent presenter on prescription monitoring programs and drug law topics, including pharmacy drug law, drug law for practitioners and drug diversion. She also consults with states that are considering modifications to a prescription monitoring program. Ms. Droz is a registered pharmacist licensed in Kentucky and Ohio and is admitted to the Bar in Kentucky and Ohio.



Victor J. Dzau, MD
President, National Academy of Medicine

In addition to his role as President of the National Academy of Medicine (NAM), Dr. Dzau serves as Vice Chair of the National Research Council. He is Chancellor Emeritus and James B. Duke Distinguished Professor of Medicine at Duke University

and the past President and CEO of the Duke University Health System. Previously, Dr. Dzau was the Hershey Professor of Theory and Practice of Medicine and Chairman of Medicine at Harvard Medical School's Brigham and Women's Hospital, as well as Bloomfield Professor and Chairman of the Department of Medicine at Stanford University. Dr. Dzau is an internationally acclaimed physician scientist and health leader whose work has improved health and medicine in the United States and globally. His seminal work in cardiovascular medicine and genetics laid the foundation for the development of the class of lifesaving drugs known as ACE inhibitors, used globally to treat hypertension and heart failure. At the NAM, he has advanced important initiatives, ranging from the Action Collaborative on Countering the U.S. Opioid Epidemic and the Action Collaborative on Clinician Well-Being and Resilience to recent efforts to improve health equity and address racism.



Neeraj Gandotra, MD
Chief Medical Officer, U.S. Substance Abuse and Mental Health
Services Administration

Prior to his role as the Chief Medical Officer at SAMHSA, Dr. Gandotra served as the Chief Medical Officer for the fourth largest nationwide addiction treatment network,

where he developed national strategies specifically aimed at reducing risk and improving outcomes. As Medical Director of Addiction Treatment Services at Johns Hopkins, he directed patient care through implementation of department initiatives and medical center resources. Dr. Gandotra has also worked as a Medical Director for federally qualified health centers and as the Medical Director at the Center for Addiction and Pregnancy. Dr. Gandotra is a member of the American Society of Addiction Medicine and the American Academy of Addiction Psychiatry, and he has worked with the Maryland State Attorney General on cases of physician misconduct, specifically those involving prescriptions of controlled substances. Dr. Gandotra has also served as a consultant for the NFL player's assistance program for substance use disorders and for the Nuclear Regulatory Commission.



Rahul Gupta, MD, MPH
Director of U.S. National Drug Control Policy

Dr. Gupta is the first medical doctor to ever lead the White House Office of National Drug Control Policy (ONDCP). Previously, he served as the Chief Medical and Health Officer, Interim Chief Science Officer and Senior Vice President at March of

Dimes. In his role, Dr. Gupta provided strategic oversight for March of Dimes' domestic and global medical and public health efforts. He recently served as clinical Professor in the Department of Medicine at Georgetown University School of Medicine, as well as Adjunct Professor in the Department of Health Policy, Management and Leadership in the School of Public Health at West Virginia University and visiting faculty at Harvard T.H. Chan School of Public Health. As a practicing primary care physician for 25 years, and a national and global thought leader and driver of innovative public policies on health issues, Dr. Gupta has served under two governors as the Health Commissioner of West Virginia. As the state's Chief Health Officer, he led state response-efforts to the opioid crisis and launched a number of pioneering public health initiatives.



Christopher M. Jones, PharmD, DrPH, MPH

CAPT, U.S. Public Health Service, Acting Director, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention

CAPT Christopher Jones currently serves as the Acting Director of the National Center for Injury Prevention and Control. In this role, he oversees all aspects of the Injury

Center and provides scientific leadership to drive the Center's strategic direction and advance the Center's strategic priorities of preventing drug overdose, suicide and adverse childhood experiences. Dr. Jones has worked in multiple leadership roles in public health and behavioral health, including at the Substance Abuse and Mental Health Services Administration, U.S. Food and Drug Administration and the U.S. Department of Health and Human Services. He maintains an active research portfolio and has authored more than 100 peer-reviewed publications on the topics of substance use, drug overdose, adverse childhood experiences, mental health, and other violence and injury topics.



Jake Nichols, PharmD, MBA

Co-Founder, President and Chief Executive Officer, Renovo Health

Jake Nichols is a pharmacist in long-term recovery with extensive experience in community pharmacy, academia, primary care, managed care and the pharmaceutical industry. He specializes in the treatment of substances use disorders, with a focus on

medication for addiction treatment. He speaks regularly at conferences across the country, highlighting his experiences as a patient along with the importance and value of treatment. Through his fifteen-year struggle with substance use, Dr. Nichols found his calling in the field and has dedicated his career to helping patients and their families suffering from this debilitating chronic disease. By providing clinical support for clinicians treating patients with substance use disorder and serving as a vocal advocate for treatment, he has established himself as a key resource within the field. Dr. Nichols has shared the story of his own struggles with addiction at more than 200 pharmacy, nursing and medical schools across the country. He also regularly facilitates patient and parent support groups. Jake is currently a Co-founder, President and CEO at Renovo Health, a comprehensive SUD outpatient treatment program that provides evidence-based care, mentorship and behavioral health services.



Josh M. Sharfstein, MD

Vice Dean for Public Health Practice and Community Engagement, John Hopkins Bloomberg School of Public Health

Dr. Sharfstein is Professor of the Practice in Health Policy and Management at the Johns Hopkins Bloomberg School of Public Health, where he also serves as Vice

Dean for Public Health Practice and Community Engagement and as Director of the Bloomberg American Health Initiative. A pediatrician by training, he is a former Health Commissioner of Baltimore, Principal Deputy Commissioner of the U.S. FDA, and Health Secretary of Maryland. As Health Commissioner of Baltimore, he led an effort to expand access to addiction treatment with bupreno-prhine that contributed to a two-thirds decline in fatal heroin overdoses over the course of a decade. As a leader in the effort to address the opioid crisis, Dr. Sharfstein has advised states and localities, published articles in professional journals and the lay press, taught a class for doctoral students, and co-authored the book, "The Opioid Epidemic: What Everyone Needs to Know," published in 2019 by the Oxford University Press.



Steve Singer, PhD

Vice President of Education and Outreach, Accreditation Council for Continuing Medical Education

Dr. Singer oversees development of programs and resources to support the ACC-ME system of accredited CME providers, ACCME-recognized state accreditors, and

accreditation volunteers, including the annual ACCME Meeting and ACCME's online learning portal, ACCME Academy. Dr. Singer also oversees the educational support for Joint Accreditation for Interprofessional Continuing Education, a collaborative initiative founded by ACCME, American Nurses Credentialing Center (ANCC), and Accreditation Council for Pharmacy Education (ACPE). Dr. Singer's liaison responsibilities for the ACCME include the National Academy of Medicine's Action Collaboratives on Clinician Well-Being and Resilience and Countering the U.S. Opioid Epidemic, the Agency for Healthcare Research and Quality (AHRQ) evidence-based Care Transformation Support (ACTS) initiative, and other partnerships to elevate the role of continuing education as a strategic asset for healthcare change. Dr. Singer received his doctorate in neuropharmacology from the Stritch School of Medicine.



Tonia Socha-Mower, MBA, EdD

Executive Director, American Association of Dental Boards

A pioneer in the public health arena, Dr. Socha-Mower is the Chief Executive Officer of the American Association of Dental Boards (AADB). She first gained national attention when she started the first dental clinic in the United States that was em-

bedded in a medical and mental health clinic in a student health center on a college campus. She ultimately was promoted to be the Director of Counseling, Medical and Dental Services at Morehead State University in eastern Kentucky while teaching in the School of Biomedical Sciences. Governor Steven Beshear also appointed her to the Kentucky Board of Dentistry, where she served to protect the public. Driven by a passion to help others, Tonia is best known for inspiring collaboration and change while developing creative solutions to obstacles. She earned two Master level degrees in Biology and Business before her doctorate.



Melissa Weimer, DO, MCR, FASAM

Associate Professor of Medicine and Public Health at Yale School of Medicine and Yale School of Public Health

Dr. Weimer is a clinician-educator board certified in both Internal Medicine and Addiction Medicine. In addition to her work as an Associate Professor at Yale, she

is the Director of the Yale Addiction Medicine Consult Service and Associate Program Director for the Yale Addiction Medicine Fellowship program. Dr. Weimer has a clinical and research focus on improving the care of patients with addiction and its associated comorbidities and has specialty expertise in the treatment of complex pain. She is passionate about expanding the workforce of healthcare professionals who treat individuals with substance use disorders. Dr. Weimer is a national leader in hospital-based addiction treatment models, pain and addiction education. She has written curricula for health care professionals through the American Academy of Addiction Psychiatry Providers' Clinical Support System, the American Medical Association and American Society of Addiction Medicine Buprenorphine Mini-Course, and the podcast "Curbsiders." She is a board member of the American Society of Addiction Medicine and chairs their committees on Treatment of Substance Use Disorders and the Clinical Practice Guidelines Methodology.

# **Opioid Regulatory Collaborative Members**

#### **American Association of Dental Boards**

The American Association of Dental Boards is a national association that encourages the highest standards of dental education by promoting higher and uniform standards of qualification for dental practitioners. Membership is comprised of boards of dentistry, advanced education boards, present and past members of those boards, board administrators, board attorneys, educators, practitioners, and other oral health stakeholders. As the national face of state dental boards, we influence the licenses of over half a million oral health practitioners through the regulation of dentists, dental therapists, hygienists, and assistants by our governing members. Our mission is simple: To serve as a resource by providing a national forum for exchange, development, and dissemination of information to assist dental regulatory boards with their obligation to protect the public. For more information, visit https://www.dentalboards.org.

#### **Federation of State Medical Boards**

The Federation of State Medical Boards (FSMB) is a national non-profit organization representing all medical boards within the United States and its territories that license and discipline allopathic and osteopathic physicians and, in some jurisdictions, other health care professionals. The FSMB serves as the voice for state medical boards, supporting them through education, assessment, research and advocacy while providing services and initiatives that promote patient safety, quality health care and regulatory best practices. To learn more about FSMB, visit www.fsmb.org. You can also follow FSMB on Twitter (@theFSMB).

#### **National Association of Boards of Pharmacy**

The National Association of Boards of Pharmacy (NABP), found in 1904, is the impartial professional organization that supports the state boards of pharmacy in protecting public health. NABP helps support patient and prescription drug safety, through examinations that assess pharmacist competency, pharmacist licensure transfer and verification services, and various pharmacy accreditation programs. Our membership and staff combine diverse skills and backgrounds, which helps us create innovative programs that meet the public health protection needs of today – with an eye on the future.

#### **National Council of State Boards of Nursing**

Empowering and supporting nursing regulators across the world in their mandate to protect the public, NCSBN is an independent, not-for-profit organization. As a global leader in regulatory excellence, NCSBN champions regulatory solutions to borderless health care delivery, agile regulatory systems and nurses practicing to the full scope of their education, experience and expertise. A world leader in test development and administration, NCSBN's NCLEX® Exams are internationally recognized as the preeminent nursing examinations. NCSBN's membership is comprised of the nursing regulatory bodies (NRBs) in the 50 states, the District of Columbia and four U.S. territories. There are three exam user members and 27 associate members that are either NRBs or empowered regulatory authorities from other countries or territories. For more information, please visit https://www.ncsbn.org.