

PRESIDENT'S OPIOID COMMISSION ISSUES FINAL RECOMMENDATIONS: IMPLICATIONS FOR HEALTH CARE STAKEHOLDERS

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In late October, President Trump declared the nation's opioid addiction crisis a public health emergency. Less than a week later, the President's Commission on Combating Drug Addiction and the Opioid Crisis (the "Commission") released its final report outlining 56 policy recommendations to inform future legislative and administrative action. Treatment providers, pharmaceutical manufacturers, and other stakeholders have an important opportunity to frame the next phase of the policy debate, ensure appropriate and reasonable responses by Congress and the Administration, and participate in response efforts.

In this first in a series of alerts on this topic, we review recent developments in the Administration's response to the crisis, highlight key provisions in the Commission's report and the emergency declaration, and underscore next steps and implications for health care stakeholders. Treatment providers and pharmaceutical manufacturers can play a critical role in shaping and prioritizing additional interventions and federal funding as policymakers contemplate new legislation and administrative actions. In later alerts, we will highlight opportunities and strategic imperatives for stakeholders across different segments of the industry.

THE ADMINISTRATION'S RESPONSE TO THE OPIOID ADDICTION CRISIS

Responding to the nation's growing opioid epidemic was one of the key issues of the 2016 presidential campaign. Soon after taking office, on March 29, 2017, President Trump signed an Executive Order establishing the Commission.[1] Chaired by New Jersey Republican Governor Chris Christie, the Commission held a series of meetings with an array of stakeholders to assess the scope and effectiveness of the federal response to the opioid crisis. On July 31, 2017, the Commission released an interim report with recommendations to strengthen the federal government's response. Chief among the recommendations in the interim report was for the President to declare a national emergency.[2]

Agencies across the Department of Health and Human Services ("HHS") have been executing against the five-point strategy to address the opioid crisis, which HHS announced in April 2017.[3]

The comprehensive strategy aims to:

- improve access to treatment and recovery services;
- promote use of overdose-reversing drugs;
- strengthen understanding of the crisis through better public health surveillance;

- provide support for cutting-edge research on pain and addiction; and
- advance better practices for pain management.

Following on the Commission's first interim recommendation, on October 26, 2017, President Trump directed the acting Secretary of HHS to declare a public health emergency using the authorities provided by the Public Health Service Act.[4] Acting HHS Secretary Eric Hargan formalized a 90-day declaration later that day.[5] Although the declaration does not make additional federal funds available, it provides federal departments and agencies with new flexibilities to shift existing funds to opioid-related initiatives. It also provides federal and state governments more authority to hire substance abuse specialists and expand access to treatment facilities, telemedicine services, and remote prescribing.

THE COMMISSION'S FINAL RECOMMENDATIONS AND IMPLICATIONS TO PROVIDERS

The Commission's final report, released November 1, 2017, made 56 recommendations to guide federal and state governments' ongoing efforts to combat the opioid addiction crisis.[6] Included in the report are recommendations to streamline federal funding opportunities, remove barriers to treatment, allow more emergency providers to deploy overdose-reversing drugs, and develop a comprehensive anti-drug media campaign. Notably, the final report does not estimate the amount of federal funding that may be required to carry out the Commission's recommendations, instead leaving that task to Congress.

The Commission's final report contains a number of recommendations of particular interest to the provider and pharmaceutical communities, including recommendations to:

- expand access to medication-assisted treatment ("MAT") programs by removing reimbursement barriers to substance abuse treatment within programs administered by the Centers for Medicare and Medicaid Services, the Indian Health Services, the Department of Defense, and the Veterans Administration, as well as establishing federal incentives to enhance MAT nationwide;
- enhance prescription drug monitoring programs ("PDMP") by providing Department of Justice grants to states to strengthen compliance with certain PDMP requirements and integrate PDMPs with patient electronic health records and overdose records;
- develop a national curriculum and standard of care for opioid prescribers and require prescribers seeking to renew Drug Enforcement Agency licenses to prescribe opioids to first demonstrate their participation in an opioid education program;
- grant waivers for all 50 states to eliminate the Medicaid institutions for mental diseases exclusion, or the "IMD exclusion," allowing Medicaid to reimburse providers for services delivered in residential treatment facilities larger than 16 beds;
- review reimbursement rates for substance use disorder treatment services to incentivize the use of non-addictive treatments for pain, addiction treatment, and MAT programs;

- review federal guidelines regarding first responders' ability to administer overdose-reversing medications and allow emergency medical technicians to also administer such medications and in higher doses;
- develop uniform block grants to states for opioid-related activities that decrease the administrative burden states encounter when applying for multiple grants from multiple agencies; and
- increase federal research funding for the National Institutes of Health, in particular the National Institute on Drug Abuse, the National Institute of Mental Health, and the National Institute on Alcohol Abuse and Alcoholism.

NEXT STEPS

Following President Trump's emergency declaration and completion of the Commission's final report, much of the policymaking focus is expected to shift to Congress. The ongoing challenges in combating the opioid addiction crisis have been the subject of numerous hearings on Capitol Hill throughout 2017. There is bipartisan agreement that fully addressing this issue will require further action through both new authorizing legislation and additional funding. Congress and the Administration are expected to use the Commission's recommendations as a road map for considering new policy and addressing federal funding.

Despite the growing scope and complexity of the crisis, numerous competing year-end priorities and a shrinking legislative calendar suggest more congressional action is likely to occur in 2018. Stakeholders across the health care continuum can play an important role in educating policymakers on the need for and implications of particular policy changes and federal funding decisions. Now is the time for stakeholders to fine-tune their advocacy priorities, strengthen their messaging, and develop a robust strategy for engaging key leaders on Capitol Hill and across the Administration.

HOW WE CAN HELP

K&L Gates' Health Care Policy and Health Regulatory practice can assist providers, pharmaceutical manufacturers, and other stakeholders in this area. K&L Gates' Public Policy and Law practice is closely tracking developments as states and the federal government respond to the opioid crisis. We assist stakeholders in the full range of state and federal advocacy on this issue, including development and refinement of legislative proposals and messaging; facilitating stakeholder engagement with Congress, the Administration, advocacy groups, and think tanks; and identifying opportunities for clients to serve as trusted advisors and thought leaders. Our team pairs its substantive experience in health care law and policy with the political insights of more than 50 bipartisan lawyers and government affairs professionals to develop comprehensive advocacy strategies for our clients.

[1] Presidential Executive Order Establishing the President's Commission on Combating Drug Addiction and the Opioid Crisis (March 29, 2017), *available at*: <https://www.whitehouse.gov/the-press-office/2017/03/30/presidential-executive-order-establishing-presidents-commission>.

[2] President's Commission on Combating Drug Addiction and the Opioid Crisis, President's Commission on Combating Drug Addiction and the Opioid Crisis Interim Report (2017), *available at* www.whitehouse.gov/sites/whitehouse.gov/files/ondcp/commission-interim-report.pdf.

[3] Opioids: The Prescription Drug & Heroin Overdose Epidemic, U.S. Department of Health and Human Services, <http://www.hhs.gov/opioids> (last visited November 6, 2017).

[4] Presidential Memorandum for the Heads of Executive Departments and Agencies on Combatting the National Drug Demand and Opioid Crisis (Oct. 26, 2017), *available at* <https://www.whitehouse.gov/the-press-office/2017/10/26/presidential-memorandum-heads-executive-departments-and-agencies>.

[5] Opioid Public Health Emergency Declaration, U.S. Department of Health and Human Services (Oct. 26, 2017), <https://www.hhs.gov/sites/default/files/opioid%20PHE%20Declaration-no-sig.pdf>.

[6] President's Commission on Combating Drug Addiction and the Opioid Crisis, President's Commission on Combating Drug Addiction and the Opioid Crisis Final Report (2017), *available at* www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_11-2-2017.pdf.

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