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**Federal Update: Trump Administration Releases the Make Our Children Healthy Again Strategy**

Today, the Make America Healthy Again (MAHA) Commission released the "Make Our Children Healthy Again (MOCHA) Strategy," which follows an earlier report that assessed key drivers of childhood chronic disease, including poor diet, chemical exposure, lack of physical activity and chronic stress, and overmedicalization. Executive Order 14212, signed by President Trump on February 13, tasks the commission with providing government-wide recommendations on policy and strategy to address the identified contributing causes and end the childhood chronic disease crisis.

The MOCHA Strategy outlines 128 actions intended to promote children's health by reshaping the federal government's research programs, realigning incentives through policy changes and deregulation, improving public outreach, and fostering public-private partnerships. The strategy is a high-level document that lacks clarity on which existing authorities the administration may use to implement policy changes, how proposed research priorities and policy initiatives will interact with existing programs, and what the commission intends with priorities like artificial intelligence and Medicaid quality metrics. AMCP will look for opportunities to engage with the Trump administration to gain further clarity on the MOCHA Strategy and elevate managed care pharmacists' role in improving population health. This summary highlights the MAHA Commission's recommendations related to health care programs.

***Reshaping the federal government's research programs:***
The first section of the report details how the commission would like to use the National Institutes of Health (NIH) to address many of Secretary Kennedy's long-held beliefs about the root causes of chronic diseases.

- *MAHA Chronic Disease Task Force:* The commission recommends that NIH establish a task force to align existing research programs with MAHA principles. The task force would initiate a Whole-Person-Health approach to chronic disease prevention research and intervention strategies that focus on wellness and resilience. The strategy teases new research initiatives that fit the Whole-Person-Health approach, including research into sleep and nutrition, the potential health benefits of "select high-quality supplements", and using fitness as a vital

sign. The strategy does not identify which institutes or existing NIH programs would fall under the task force's purview.

- *Real-World Data Platform:* The NIH is also tasked with developing a platform that would link datasets—including claims databases, electronic health records, and wearables data—into an integrated solution that would be available for researchers studying the causes of and treatments for chronic diseases. The commission maintains that NIH would uphold rigorous privacy and consent protections and rely on a unified set of data use and governance agreements. AMCP's Real-World Evidence (RWE) Initiative is working to enhance the integration of RWE into health care decision-making.
- *New approach methods:* The commission highlights the potential for new approach methods (NAMs) to provide earlier insights into chronic disease mechanisms through human-relevant models. While the strategy reports that the FDA, EPA, and NIH have agreed to use NAMs where appropriate, it is unclear whether this would impact the FDA's review of drugs and biologics.
- *Autism and vaccine injury:* The commission proposes to use the real-world data platform to study the root causes of autism. In a related proposal, the commission highlights a new vaccine injury research program at the NIH Clinical Center. AMCP is concerned that the commission is tacitly endorsing discredited claims that vaccines cause autism.
- *Prescribing patterns and impact on mental health:* The commission proposes that HHS organize a mental health diagnosis and prescription working group to evaluate prescribing patterns for drugs commonly prescribed for children's mental or behavioral health disorders. The FDA is also directed to update labels for older generic medications to better reflect the latest science.
- *Repurposed drugs:* The commission suggests that NIH and FDA collaborate to strengthen the use of repurposed drugs for the treatment of chronic diseases and facilitate FDA approval using collaborative clinical trial designs.
- *Childhood cancer and AI:* The commission directs NIH and the White House Office of Science and Technology Policy (OSTP) to develop an AI-driven approach to transform research and clinical trials related to pediatric cancer.
- *AI, mental health and addiction, and longitudinal research:* The commission outlined other priorities that can improve our understanding of chronic diseases and facilitate novel therapies or prevention strategies. These include using NIH's existing birth cohort data to conduct longitudinal studies of childhood chronic disease, directing more research funding to study mental health and addiction, and researching the integration of AI to improve the diagnosis and treatment of chronic diseases.

***Policy changes and deregulation:***

The second section highlights policy reforms that would incentivize individuals to make healthier choices and remove conflicts of interest at the FDA and other government agencies, both pillars of the MAHA agenda.

- *Direct-to-consumer pharmaceutical advertising:* The commission's report highlights that the US is one of only two countries in the world that allow pharmaceutical manufacturers to market directly to consumers. The strategy urges FDA, HHS, FTC and DOJ to increase oversight and enforcement of existing rules governing DTC advertising. The report identifies campaigns run by DTC telehealth companies that leverage social media influencers as a priority. These arrangements have drawn criticism for disseminating misinformation and targeting vulnerable populations.
    - *Presidential Memorandum*: Also on September 9, President Trump signed a presidential memorandum addressed to HHS and FDA. The memorandum directs the agencies to initiate rulemaking to roll back the FDA's 1997 DTC advertising rule which relaxed standards regarding the information that manufacturers must share with consumers. According to an FDA fact sheet, the agency will remove the "adequate provision" loophole, which allows manufacturers to share only a major-risk statement in broadcasts and provide other required disclosures in other formats. The agency confirmed that it will increase the number of enforcement letters related to false or misleading advertisements and expand oversight to include digital advertising.
- *Conflicts of interest:* The commission's report repeats Sec. Kennedy's claims that the FDA and other government agencies exhibit regulatory capture. The strategy calls for transparency and efficiency in FDA's user fee programs; requires FDA advisory committee members to recuse themselves from matters where they have a personal financial interest; establishes public reporting requirements for research grants and consulting fees paid to advisory committee members; and requires NIH to create a public researcher payment database based on CMS's Open Payments system for physicians. The strategy also calls for a review of agencies' participation in projects or initiatives funded by agency foundations, such as the Reagan-Udall Foundation, to protect public health from corporate influence.
- *Vaccine framework:* The commission directs the White House Domestic Policy Council (DPC) and HHS to develop a vaccine framework that ensures America has the best childhood vaccine schedule, addresses vaccine injuries, leverages transparent science, corrects conflicts of interest, and ensures scientific and medical freedom. AMCP is concerned that the Trump administration's recent actions undermine public confidence in the CDC's vaccine recommendations and limit patient access via their community pharmacies.
- *Medicaid quality and care delivery:* The commission encourages CMS to collaborate with states on two initiatives meant to improve chronic care for children in Medicaid. AMCP is unclear how these reforms would interact with impending cuts to federal funding for Medicaid.
    - Medicaid quality metrics: The first initiative identified by the commission would establish quality metrics for Medicaid managed care organizations that promote measurable health improvements through nutrition coaching and fitness indicators.

The commission also urges HHS and CMS to refine quality measurement to promote health outcomes rather than healthcare utilization.

    - Medicaid prior authorization: The second initiative would enhance prior authorization requirements and prescribing safeguards to address the overuse of prescription medications by school-age children, particularly for conditions like ADHD. Another proposal would encourage CMS to collaborate with states to ensure that CHIP programs promote prevention and wellness activities.
- *Direct primary care:* The commission urges HHS to promote increased accessibility to direct primary care arrangements. H.R. 1 included a proposal that allows patients in high-deductible health plans to use HSA funds to pay for direct primary care fees.
- *Price transparency:* The commission directs HHS, Labor, and Treasury to fully implement hospital and insurer price transparency as authorized under the No Surprises Act. The administration could accomplish this through additional rulemaking; however, the CMS Center for Consumer Information and Insurance Oversight, which oversees implementation of the No Surprises Act, was targeted for staffing reductions earlier this year.
- *Reducing regulatory burdens in drug approvals:* The commission outlines how FDA will accelerate the approval of transformational treatments through the Commissioner's National Priority Voucher program, streamlining the process for patients to access investigational drugs through risk-based exemptions, updating policies that delay the availability of accurate personal health and digital health tools, and facilitating the use of regenerative medicine by modernizing policies as clinical data is established. AMCP supports accelerating patient access to innovative drugs, biologics, and digital therapeutics. We look forward to working with the Trump administration to pass the Access to Prescription Digital Therapeutics Act.
- *Medical device RWE:* The commission encourages the FDA to make real-world data available and use it to understand the impact of FDA-regulated medical products.

***Public outreach:***

The third section largely focuses on public outreach related to environmental health and the upcoming Dietary Guidelines. However, the commission noted public outreach campaigns that focus on the dangers of synthetic opioids; updating the label for OxyContin; public-facing clinical transparency reviews to assist patient and parent decision-making; increasing awareness of HRSA's pediatric mental health programs; and training school employees and librarians on how to recognize and respond to overdoses.

***Fostering public-private partnerships:***

The final section highlights areas where agencies may collaborate with the private sector to accelerate innovation in health-focused technologies. The report directs HHS to leverage available funding to drive community-led initiatives aimed at measurably reducing chronic disease in children. One example provided by the commission was using local health navigators to support family

lifestyle changes. HHS could use user fees associated with the ACA Navigator program to pay for such partnerships; earlier this year, HHS announced that it would reduce funding for the federal navigator program by 90%. Other areas identified for partnerships include promoting whole, healthy foods; phasing out food dyes and other additives; promoting fertility through education campaigns, and training health clinics; and funding precision agriculture and soil conservation activities.