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Blizzard of Executive Orders Signals Trump Administration's Healthcare Priorities

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As harsh winter weather swept the nation's capital, President Donald Trump commenced his second term by signing a blizzard of Executive Orders (EOs) that span many hot-button issues. Several of the EOs signal President Trump's agenda for the U.S. healthcare system. These EOs rescind former President Joe Biden's directives aimed at expanding healthcare coverage under the Affordable Care Act (ACA) and Medicaid and at lowering drug costs. They also instruct federal agencies to take certain steps with respect to sex and gender identity, which will change how the healthcare industry is regulated. One new EO draws an incomplete picture of a spectrum between purportedly unlawful practices. Federal agencies must now adopt new contractual provisions that could increase federal False Claims Act (FCA) enforcement risks for government contractors, healthcare, and downstream vendors. This practice group update summarizes President Trump's key EOs from a healthcare perspective and discusses their broader implications. Critically, this is an evolving area of what appears to be a focal point for the new Administration. We expect to revise this practice group update as appropriate.

What Happened? A Summary Chart

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This chart outlines salient EOs and their healthcare implications. A more in-depth discussion follows below.

President Trump's EO	Impact	Takeaway
EO 14148: Initial Rescission of Harmful Executive Orders and Actions	Revokes EO 14009. Revokes EO 14070. Revokes EO 14087.	Trump Administration pulls back on expanded ACA and Medicaid enrollment implemented by the Biden Administration. Revives EO 13765, which calls for a repeal of the ACA and directs the Department of Health and Human Services (HHS) and other federal agencies to waive, defer, or grant exemptions from certain ACA provisions. Revives EO 13813, which emphasizes competition among insurers and

		directs federal agencies to promote association health plans (AHPs), reducing short-term, limited-duration insurance (STLDI), and health reimbursement arrangements (HRAs). Calls into question the status of three CMMI models developed in response to EO 14087.
EO 14168: Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government (the "Sex EO")	Establishes policies for enforcing "sex-protective laws." Defines certain terms, such as "sex," "female," and "male," and directs all federal agencies to use these definitions when interpreting and applying federal law and Trump	Mandates changes to how federal agencies enforce and apply federal laws addressing sex-based discrimination, such as how the HHS Office for Civil Rights (OCR) enforces Section 1557 of the ACA. May prompt OCR to revise provisions prohibiting

	Administration policy. Directs HHS to issue "clear guidance" expanding on the EO's "sex-based definitions." Bars federal agencies from using federal funds to promote "gender ideology." Requires the Attorney General to issue guidance addressing sex-based distinctions in agency activities and rights under the Civil Rights Act of 1964. Revokes EO 14075. Revokes EO 13988.	discrimination on the basis of sex in its regulations. Calls into question the status of the federal government's appeals of court orders staying or enjoining OCR's final rule prohibiting discrimination on the basis of gender identity. May lead to legal and practical challenges due to the ambiguity of some of the definitions. For instance, under the definitions, a person's sex is assigned at "at conception," which is contrary to scientific evidence that sex differentiation occurs later in fetal development.
EO 14173:	Directs all	Federal

Ending Illegal Discrimination and Restoring Merit-Based Opportunity (the "DEI EO")	federal agencies to end DEI initiatives and directs the heads of federal agencies to add language in every contract or grant to effect the same result. Directs OMB to remove "DEI and DEIA principles . . . from Federal acquisition, contracting, grants, and financial assistance procedures" and end "all 'diversity,' 'equity,' 'equitable decision-making,' 'equitable deployment of financial and technical assistance,' 'advancing equity,' and like mandates, requirements, programs, or activities, as appropriate." Requires the Attorney General to develop a plan	contracts and grant awards must soon contain terms that will likely increase FCA enforcement risks for private parties that contract with the federal government. Government vendors and grantees that rely on or are subject to federal contracts, grants, or financial assistance related to DEI and DEIA principles could soon see significant changes to how such federal contracts, grants, and assistance are administered, including the termination of certain DEI- or DEIA-related programs or activities the Trump Administration deems impermissible

	to deter DEI programs or principles constituting illegal discrimination or preferences.	under the EO. Compliance with this EO's anti-DEI initiatives may prove to be the new vanguard for FCA claims, employment claims, and other civil litigation. The Attorney General is required to identify certain large institutions to target for potential civil compliance investigations. Thus, DEI programs operated by publicly traded and not-for-profit healthcare providers and insurers could soon be scrutinized by the federal government.
EO 14187: Protecting Children From Chemical and Surgical Mutilation (the "Gender	Establishes a policy that the federal government will not fund or otherwise support gender	This EO contemplates leveraging significant federal funding and enforcement

Affirming Care EO")	affirming care for pediatric patients suffering from gender dysphoria. Requires HHS to prevent practitioners participating in federal payor programs or hospitals that receive HHS grants from providing gender affirming care and introduces whistleblower protections for those that report violations of this EO. Requires HHS to withdraw its guidance document titled "HHS Notice and Guidance on Gender Affirming Care, Civil Rights and Patient Privacy" and issue new guidance protecting whistleblowers. Directs the Attorney General to prioritize	authorities to curtail pediatric patients' access to gender affirming care

	enforcement actions related to gender affirming care of pediatric patients.	

Why These EOs Matter

- *Let's Talk About Sex: The science of sexual development, the Administration's EOs, and the impact on federal enforcement actions*

President Trump's Sex EO establishes his Administration's policy that there are two "immutable" sexes: male and female. The Sex EO includes definitions for certain terms, including "sex," "male," and "female," that merge the concepts of sex and gender and assert a federal policy establishing, for the purposes of the Executive Branch, the notion that sex is binary (male or female). These definitions will govern how the Executive Branch interprets and applies federal law and will define in many respects the Trump Administration's efforts to address certain "culture war" topics that were a mainstay of President Trump's presidential campaign.

The Sex EO further directs HHS to issue guidance "expanding on the sex-based definitions" contained in the EO. These definitions may ultimately prove challenging to implement due to some ambiguities in the Sex EO and the contentious nature of the subject matter. For instance, the Sex EO dictates that "male" and "female" are defined by reference to the size of the reproductive cells a person produces and, by definition, are assigned "at conception." Yet, according the National Academy of Sciences, at conception all zygotes are phenotypically female. Although chromosomal sex in the zygote is established at the moment of conception, "all fetal genitalia are the same and are phenotypically female" until "the expression of a gene on the Y

chromosome induces changes that result in the development of the testes" after approximately six or seven weeks of gestation.[1] Consequently, the Sex EO's definitions could potentially confuse federal regulators, regulated entities, and the courts that will ultimately have to decide whether the Trump Administration has the right to define the question of a person's sex and whether the Administration has inadvertently done so in a way that means that all individuals, regardless of the parts that grow, are female.

Despite this ambiguity, by February 19, 2025, HHS must issue guidance related to the Sex EO, which will undoubtedly have significant implications for the healthcare industry. As one example, the Sex EO will likely impact how OCR enforces Section 1557 of the ACA. This section prohibits discrimination on the basis of race, color, national origin, age, disability, or *sex* in any health program or activity that receives federal financial assistance. OCR may also revise provisions in its regulations, such as 42 C.F.R. § 92.101, which prohibits discrimination on the basis of gender identity.

Moreover, under the Biden Administration (89 FR 37574), OCR aligned its reading of existing laws with the Supreme Court's decision in *Bostock*, a decision drafted by a first-term President Trump appointee, Justice Neil Gorsuch, which held that sex-based discrimination under Title VII includes discrimination on the basis of gender identity. The Sex EO expresses general disagreement with the Biden Administration's application of *Bostock* and calls on the Attorney General to help federal agencies align with the Trump Administration's reading of that decision. More immediately, the Gender Affirming Care EO casts doubt that the federal government will continue to pursue appeals of three federal court decisions, which stayed or enjoined OCR's final rule prohibiting discrimination on the basis of gender identity.[2]

Finally, the Sex EO bars the use of federal funds to promote "gender ideology," which the Sex EO defines as including "the idea that there is a vast spectrum of genders that are disconnected from one's sex," and directs federal agencies to take steps to discontinue any such funding. This could have serious consequences for programs funded by federal grants, such as the Family Counseling and Support for Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, Intersex+ Youth and Their Families grants administered by the Substance Abuse and Mental Health Services Administration (SAMHSA). The Sex EO also calls on the Attorney General to issue guidance addressing sex-based distinctions in agency activities, the "freedom to express the binary nature of sex," and the "right to single-sex spaces in workplaces and Federally funded entities covered by the Civil Rights Act of 1964."[3]

- *The DEI EO: Using civil enforcement statutes such as the FCA to deter private sector DEI initiatives*

President Trump's DEI EO addresses DEI and DEIA programs of both the federal government and private sectors and specifically names the medical community among the spaces that the Administration believes illegal DEI and DEIA policies pervade. The DEI EO specifically distinguishes between lawful efforts to enforce equal opportunity codified by the Civil Rights Act of 1964, which the DEI EO lauds as a legal "bedrock supported equality," and, on the other hand, the "dangerous, demeaning, and immoral" preferences of "illegal" DEI and DEIA initiatives. From the opening language, the DEO EO begs many questions. For example:

1. What policies promoting equality are supported, laudable, and justified by the Civil Rights Act of 1964?
2. How do those lawful policies differ from the "dangerous, demeaning, and immoral" policies

that comprise the sort of DEI and DEIA initiatives impacted by this EO?

3. In every instance that the DEI EO mentions DEI and DEIA policies, those policies are described as "illegal." Does the DEI EO mean that every DEI and/or DEIA policy is in fact illegal? And, does the Trump Administration intend to take the position that any entity, public or private, that receives federal funds (directly or indirectly) must now comply with the DEI EO?

The answers to these questions may be embedded in other provisions of the DEI EO. For instance, it directs the heads of federal agencies to add language in every contract or grant award (a) stating that the contractual counterparty or grant recipient agrees that "its compliance in all respects with all applicable Federal anti-discrimination laws is material to the government's payment decisions" for the purposes of the FCA and (b) requiring the "counterparty or recipient to certify that it does not operate any programs promoting DEI that violate any applicable Federal anti-discrimination laws."

These certifications matter. Under the FCA, [4] knowingly submitting false claims for payment (or certifications in support of such claims) can result in expensive litigation, steep damages, and (potentially) crippling fines. Entities that receive federal funds in any form run the increased risk that having a DEI program of any sort (even a program that protects only those rights protected by the Civil Right Act of 1964, which the DEI EO lauds) runs an incrementally higher risk of having to defend FCA cases that will undoubtedly test the parameters of the ambiguity embedded in this EO. Certifications anticipated by the DEI EO will increase FCA enforcement risks (e.g., whistleblower lawsuits), especially because the DEI EO also contemplates forcing government contractors and grant awardees to expressly agree that compliance with federal anti-discrimination law is material to the government's payment decisions. This will precipitate rising compliance costs within the healthcare industry.

Minimally, compliance programs should adapt in short order to ensure that certifications being made to the federal government, perhaps daily, are accurate.

In addition, the DEI EO directs the Office of Management and Budget (OMB) to remove "references to DEI and DEIA principles, under whatever name they may appear, from Federal acquisition, contracting, grants, and financial assistance procedures," purportedly in an effort "to streamline those procedures, improve speed and efficiency, lower costs, and comply with civil-rights laws . . . ." It also directs OMB to "[t]erminate all 'diversity,' 'equity,' 'equitable decision-making,' 'equitable deployment of financial and technical assistance,' 'advancing equity,' and like mandates, requirements, programs, or activities, as appropriate." These directives could have significant impacts upon private sector programs that rely on federal financial or technical assistance, whether under a government contract, grant, or other process. In what may be an early effect of the DEI EO, the National Institutes of Health (NIH) has reportedly emailed at least one university to terminate funding for a project, citing the DEI EO.

Finally, the DEI EO contemplates an Attorney General-led enforcement plan, due by May 20, 2025, to deter DEI programs broadly. The plan must identify potential civil compliance investigations of large institutions, including publicly traded corporations, nonprofits with assets of $500 million or more, and universities with endowments of more than $1 billion. This mandate suggests that large healthcare providers may be targets of direct, government-backed DEI-related enforcement actions from both whistleblowers and the government directly.

- *The Gender Affirming Care EO: Defunding and investigating pediatric gender dysphoria care*

President Trump's Gender Affirming Care EO purports to defund and may criminalize support for "gender affirming care" for pediatric patients suffering from gender dysphoria. According to the American Psychiatric Association, gender dysphoria is a mental health condition defined as a "marked incongruence between one's experienced/expressed gender and assigned gender, of at least six months' duration, as manifested by at least two or more" of certain characteristics further set forth in the fifth edition of the Diagnostic and Statistical Manual of Mental Health Disorders (DSM-5) and "is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning."[5] The Gender Affirming Care EO defines "gender affirming care" (or what the EO also calls "chemical and surgical mutilation") in reference to the use of puberty blockers, sex hormones, and surgical procedures.

The Gender Affirming Care EO impacts the healthcare community on many levels. Scientifically, this EO instructs HHS to ignore certain scientific guidance while directing it to publish a review of existing literature on best practices for promoting health in children with gender dysphoria, among other related conditions. This EO does not provide guidance for how HHS is to handle disagreements among the scientific community, if they exist, and instead implies that HHS should issue studies that agree with the White House's beliefs regarding gender affirming care.

From a care perspective, the Gender Affirming Care EO directs HHS to gather data to guide future practices for treating such minors, although there is no timeline for the development of this data nor is there any guidance for how minors suffering from gender dysphoria now are to be treated in the interim except to (a) outlaw certain existing practices, (b) defund certain types of care, (c) threaten to pull federal funding from any medical centers that provide gender affirming care, and (d) criminalize certain types of gender affirming care

even if such care is the result of a carefully crafted medical plan by licensed professionals.

In its mandate to end gender affirming care, HHS must now take regulatory and subregulatory action to review:

- Medicare or Medicaid Conditions of Participation or Conditions for Coverage;
- clinical-abuse or inappropriate-use assessments relevant to state Medicaid programs;
- mandatory drug use reviews;
- Section 1557 of the ACA;
- quality, safety, and oversight memoranda;
- essential health benefits requirements; and
- ICD-11 and other federally funded manuals, such as the DSM-5.

HHS must also promptly withdraw its March 2, 2022, guidance document titled "HHS Notice and Guidance on Gender Affirming Care, Civil Rights and Patient Privacy" and issue new guidance protecting whistleblowers who take action to ensure compliance with the Gender Affirming Care EO.

Ultimately, this EO has immense healthcare implications. The Attorney General must prioritize enforcement of this EO, which specifically directs the DOJ towards drug manufacturers and practitioners for enforcement efforts. The EO suggests that disagreeing statements by dissenting members of the medical community may be prosecuted as a "deception of consumers." It also contemplates federal agencies using a wide range of funding and enforcement authorities, from the Medicare and Medicaid Conditions of Participation to Food, Drug, and Cosmetic Act enforcement actions, to deter private sector institutions and medical professionals from providing gender affirming care to pediatric patients.

- *Impact on the Healthcare Marketplace: Revocation of EOs 14009 and 14070*

Under EO 14009, President Biden had called for a Special Enrollment Period in response the COVID-19 pandemic to allow Americans to seek health insurance coverage via the Federally Facilitated Marketplace created by the ACA. EO 14009 directed the heads of the relevant federal agencies to review and rollback any policies or practices that could reduce or undermine coverage under Medicaid or the ACA. President Biden's EO 14070 built upon EO 14009 and directed federal agencies to identify additional policies and practices to increase consumer enrollment in healthcare coverage by, among other things, expanding eligibility for and lowering the costs of enrollment in the ACA Marketplaces, Medicaid, and Medicare.

President Trump's revocation of EO 14009 suggests that the Trump Administration will seek to curtail pandemic-era ACA and Medicaid enrollment policies implemented by the Biden Administration. It also revives EO 13765, which effectively re-establishes President Trump's policy of seeking a repeal of the ACA and, pending such repeal, directs HHS and other federal agencies with authority under the ACA once again to exercise their discretion to waive, defer, grant exemptions from, or delay the implementation of certain ACA provisions. This EO seeks to provide greater flexibility to states and to encourage a free market for healthcare services and insurance. Efforts to reduce enrollment eligibility under the ACA and Medicaid will likely reduce Americans' access to affordable health insurance. This will likely increase uninsured rates and, as a ripple effect, cause higher prices for insurance and health services nationwide.

The revocation of EO 14009 also revives EO 13813 and thereby re-establishes President Trump's policy of "promoting competition in healthcare markets and limiting excessive consolidation throughout the healthcare system" and pushes

federal agencies to implement federal rules and guidelines that may expand access to association health plans (AHPs), reducing short-term, limited-duration insurance (STLDI) and health reimbursement arrangements (HRAs). Accordingly, healthcare plans are likely to see a renewed emphasis on federal rulemaking intended to provide greater flexibility to AHPs, STLDIs, and HRAs.

- *Impact on the Healthcare Payment and Delivery Models: Revocation of EO 14087*

EO 14087 directed the Center for Medicare and Medicaid Innovation (CMMI) within HHS to consider testing new healthcare payment and delivery models aimed at lowering cost-sharing for commonly used drugs. This EO also called for a report on any models selected for testing. In response, HHS developed three models:

- The Medicare High-Value Drug List Model, which would allow Medicare Part D sponsors to offer a list of approximately 150 generic drugs with a maximum co-payment of $2 for a month's supply.
- The Cell & Gene Therapy (CGT) Access Model, which would allow CMS, on behalf of state Medicaid agencies, to structure and coordinate multistate outcomes-based agreements with participating manufacturers of CGTs, with the goal of helping Medicaid beneficiaries with rare and severe diseases to access promising, but often high-cost, specialty drugs.
- The Accelerating Clinical Evidence Model, which would adjust Medicare Part B payments for certain drugs to incentivize manufacturers to expedite and complete confirmatory clinical trials.

With the revocation of EO 14087, the statuses of these three models are in limbo. Although CMMI previously released a request for information in connection with the Medicare High-Value Drug List Model and opened applications for the CGT Access Model, none of these models have been activated.

CMMI's statutory authority to develop and test payment and service delivery models is unaffected by the revocation of EO 14087. However, if these models are indeed disfavored by the President, as his revocation suggests, these models could fall by the wayside once he appoints new CMMI leadership.

Next Steps

President Trump's recent EOs have generated much uncertainty. Federal agencies are now tasked with providing regulatory details to the mandates of these Executive Orders. Regulatory changes should be expected as new federal agency heads are appointed and the Executive Branch works to implement the President's agenda. While it is too early to tell for certain how these EOs will be implemented, a clear shift in policy stances will impact healthcare businesses of virtually every variety. Akerman has a multidisciplinary team of healthcare, healthcare litigation, employment, and immigration practitioners that are ready to help answer any questions that you might have about how these EOs impact you or your business.

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[1] *Exploring the Biological Contributions to Human Health: Does Sex Matter?* 45, 50, Institute of Medicine (U.S.), Committee on Understanding the Biology of Sex and Gender Differences (Theresa M. Wizemann and Mary-Lou Pardue, eds., 2001).

[2] *Tennessee v. Becerra*, 739 F. Supp. 3d 467 (S.D. Miss. July 3, 2024); *Texas. v. Becerra*, 739 F. Supp. 3d 522 (E.D. Tex. July 3, 2024); *Florida v. HHS*, 739 F. Supp. 3d 1091 (M.D. Fla. July 3, 2024).

[3] Notably, this EO revoked President Biden's EO 14075, which had directed HHS to protect "LGBTQI+ individuals' access to medically necessary care from harmful State and local laws and practices" and to strengthen "non-discrimination protections on the basis of sex, including sexual orientation, gender

identity, and sex characteristics, in its programs and services, consistent with EO 13988."

[4] 31 U.S.C. § 3729.

[5] It is notable that at least one recent study estimates that as many as 66% of all adolescents suffering from gender dysphoria are at significant risk for self-harm up to and including suicide. Hannah K. Mitchell, BMBS, et al., *Prevalence of Gender Dysphoria and Suicidality and Self-Harm In A National Pediatric Database*, 6 (12) Lancet Child Adolesc. Health 876 (2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC9746123/. Setting aside the question of whether this specific statistic is accurate, the Gender Affirming Care EO does not direct any federal agency on any sort of timeline, expedited or otherwise, to identify ways to help individuals suffering from this long-recognized mental health disorder in a manner that would comply with this EO.
