

Making Sense of the Rapidly Changing Regulatory Environment

Health Law Webinar

March 12, 2025

Fredrikson

The logo for Fredrikson, featuring the name in a bold, black, sans-serif font. A red horizontal bar is positioned below the 'i' in 'Fredrikson', extending to the right and ending under the 'n'.

What Is An Executive Order?

- Derive from Article II executive authority.
- Around since Washington.
- Perhaps the most famous was issued by Lincoln.
- Manhattan Project, Japanese Internment, National Guard desegregating schools were executive orders.
- Longstanding tension about executive power.

Policy Agenda

- Policy throughline – what is favored and disfavored
- Executive policy tools
 - President: Executive Orders, Memoranda, Proclamations
 - Departments/Agencies: Regulations, Enforcement, Directives, Memoranda
 - Spending appropriations – contracts, grants, loans, workforce
- DOGE Mandate
 - Deregulate
 - Cut Costs

DOGE Deregulatory Roadmap – 7-Part Litmus Test

Agencies to make a list of regulations that are:

1. Unconstitutional/exceed executive authority;
2. Unlawful delegations of legislative power;
3. Not the "best reading" of statute;
4. Implicate matters of social, political, or economic significance that are not authorized by clear statutory authority;
5. Impose significant costs upon private parties that are not outweighed by public benefits;
6. Harmful to the national interest by impeding technological innovation, infrastructure development, disaster response, inflation reduction, R&D, economic development, energy production, land use, and foreign policy objectives; and
7. Impose undue burdens on small business and impede private enterprise and entrepreneurship.

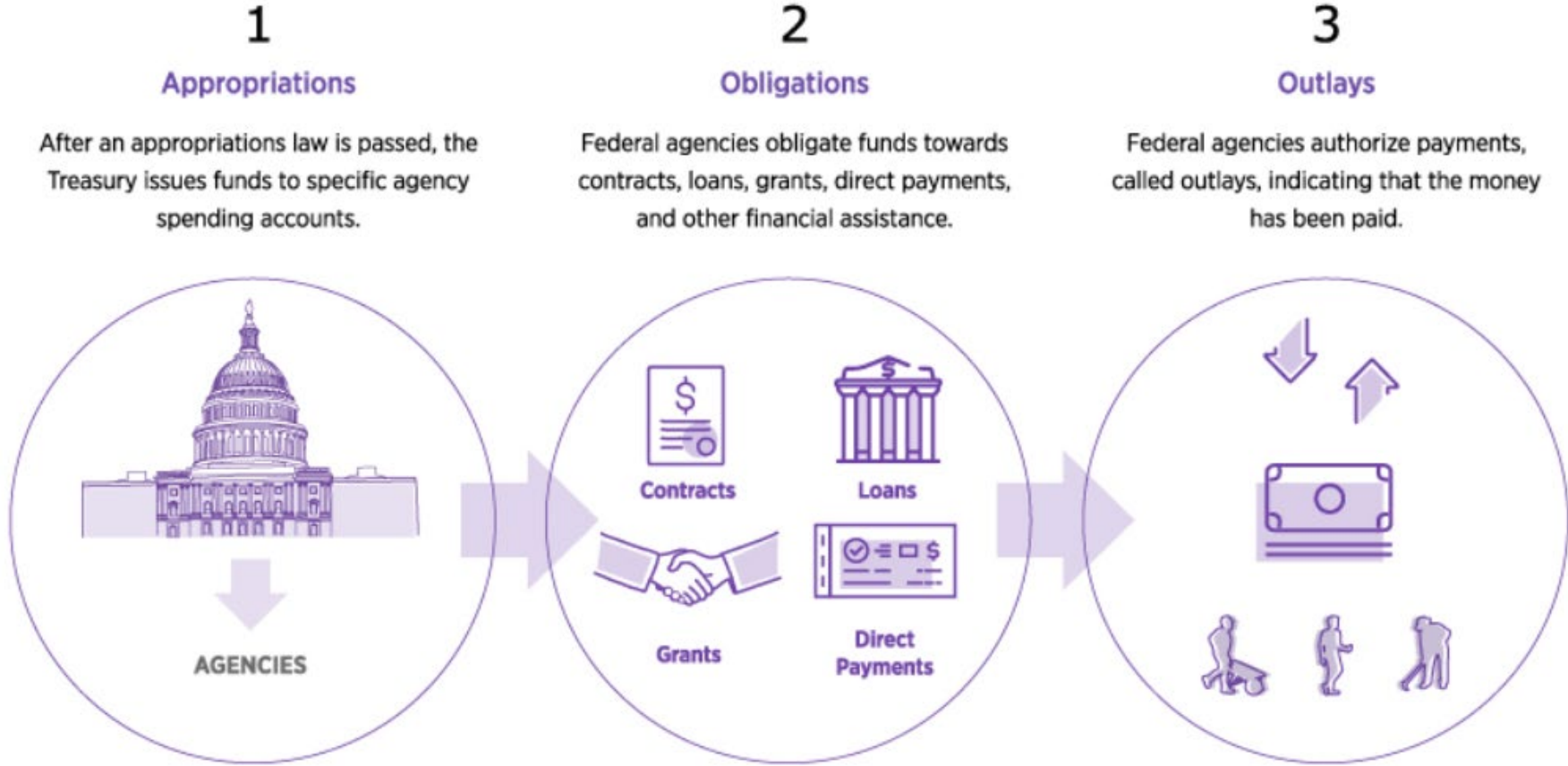
DOGE Deregulatory Roadmap

- Centralized Deregulatory Agenda.
- Mandatory – even for independent agencies.
- Triage enforcement.
- President/Attorney General final say on what the law means.
- 7-part litmus test for new regulations.
- Goal to eliminate agencies, too.

5-Part DOGE Cost Efficiency Initiative Roadmap

- Each Agency must:
 1. Justify contracts and grants.
 2. Review/terminate contracts and grants.
 3. Approve contracts and grants.
 4. Freeze contracting officer credit cards.
 5. Dispose of real estate.
- Led by: Agency/Department head and the agency's DOGE Team Lead.
- Workforce Reductions, too.

How Federal Dollars Move from Congress to the American People



Credit: St. Louis Fed

Cost Cutting Actions To-Date

- **Treasury Outlays – Held, Even When Due.**
 - Payment freeze – court cases.
 - Many contractors/grantees unpaid – legal right to payment; how to enforce.
- **Agency Obligations – Contracts Stopped/Terminated.**
 - Existing agreements – terminations – legal right to closeout costs.
 - Existing agreements – stop work orders – legal right to SWO costs.
 - Refusal to spend appropriations – Impoundment Act and Rescission Requests – court cases.
- **Appropriations – expire this Friday.**

Policy Agenda Reprise

- Future contract and grant terms will require adherence to new policy priorities.
 - Grants – OMB 2 CFR Part 200; agency supplements.
 - Contracts – Federal Acquisition Regulations (FAR); agency supplements.
 - Already seeing clause “deviations”.
 - Rogue contracting/grant officers.
- Voluntary agreements – accept money, agree to conditions.

....Why does this matter?

Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government

Sec. 2. *Policy and Definitions.* It is the policy of the United States to recognize two sexes, male and female. These sexes are not changeable and are grounded in fundamental and incontrovertible reality. Under my direction, the Executive Branch will enforce all sex-protective laws to promote this reality, and the following definitions shall govern all Executive interpretation of and application of Federal law and administration policy:

(a) “Sex” shall refer to an individual’s immutable biological classification as either male or female. “Sex” is not a synonym for and does not include the concept of “gender identity.”

(b) “Women” or “woman” and “girls” or “girl” shall mean adult and juvenile human females, respectively.

(c) “Men” or “man” and “boys” or “boy” shall mean adult and juvenile human males, respectively.

(d) “Female” means a person belonging, at conception, to the sex that produces the large reproductive cell.

(e) “Male” means a person belonging, at conception, to the sex that produces the small reproductive cell.

Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government

(f) “Gender ideology” replaces the biological category of sex with an ever-shifting concept of self-assessed gender identity, permitting the false claim that males can identify as and thus become women and vice versa, and requiring all institutions of society to regard this false claim as true. Gender ideology includes the idea that there is a vast spectrum of genders that are disconnected from one’s sex. Gender ideology is internally inconsistent, in that it diminishes sex as an identifiable or useful category but nevertheless maintains that it is possible for a person to be born in the wrong sexed body.

(g) Federal funds shall not be used to promote gender ideology. Each agency shall assess grant conditions and grantee preferences and ensure grant funds do not promote gender ideology.

Executive Order 14168 of January 20, 2025

Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government

Sec. 3. *Recognizing Women Are Biologically Distinct From Men.* (a) Within 30 days of the date of this order, the Secretary of Health and Human Services shall provide to the U.S. Government, external partners, and the public clear guidance expanding on the sex-based definitions set forth in this order.

(b) Each agency and all Federal employees shall enforce laws governing sex-based rights, protections, opportunities, and accommodations to protect men and women as biologically distinct sexes. Each agency should therefore give the terms “sex”, “male”, “female”, “men”, “women”, “boys” and “girls” the meanings set forth in section 2 of this order when interpreting or applying statutes, regulations, or guidance and in all other official agency business, documents, and communications.

(c) When administering or enforcing sex-based distinctions, every agency and all Federal employees acting in an official capacity on behalf of their agency shall use the term “sex” and not “gender” in all applicable Federal policies and documents.

Sec. 4. *Privacy in Intimate Spaces.*

(d) Agencies shall effectuate this policy by taking appropriate action to ensure that intimate spaces designated for women, girls, or females (or for men, boys, or males) are designated by sex and not identity.

Protecting Children From Chemical and Surgical Mutilation

Section 1. *Policy and Purpose.* Across the country today, medical professionals are maiming and sterilizing a growing number of impressionable children under the radical and false claim that adults can change a child's sex through a series of irreversible medical interventions. This dangerous trend will be a stain on our Nation's history, and it must end.

Countless children soon regret that they have been mutilated and begin to grasp the horrifying tragedy that they will never be able to conceive children of their own or nurture their children through breastfeeding. Moreover, these vulnerable youths' medical bills may rise throughout their lifetimes, as they are often trapped with lifelong medical complications, a losing war with their own bodies, and, tragically, sterilization.

Accordingly, it is the policy of the United States that it will not fund, sponsor, promote, assist, or support the so-called "transition" of a child from one sex to another, and it will rigorously enforce all laws that prohibit or limit these destructive and life-altering procedures.

Executive Order 14187 of January 28, 2025

Protecting Children From Chemical and Surgical Mutilation

of their associated and the altering procedures.

Sec. 2. Definitions. For the purposes of this order:

(a) The term “child” or “children” means an individual or individuals under 19 years of age.

(c) The phrase “chemical and surgical mutilation” means the use of puberty blockers, including GnRH agonists and other interventions, to delay the onset or progression of normally timed puberty in an individual who does not identify as his or her sex; the use of sex hormones, such as androgen blockers, estrogen, progesterone, or testosterone, to align an individual’s physical appearance with an identity that differs from his or her sex; and surgical procedures that attempt to transform an individual’s physical appearance to align with an identity that differs from his or her sex or that attempt to alter or remove an individual’s sexual organs to minimize or destroy their natural biological functions. This phrase sometimes is referred to as “gender affirming care.”

Executive Order 14187 of January 28, 2025

Protecting Children From Chemical and Surgical Mutilation

Sec. 3. *Ending Reliance on Junk Science.* (a) The blatant harm done to children by chemical and surgical mutilation cloaks itself in medical necessity, spurred by guidance from the World Professional Association for Transgender Health (WPATH), which lacks scientific integrity. In light of the scientific concerns with the WPATH guidance:

(i) agencies shall rescind or amend all policies that rely on WPATH guidance, including WPATH's "Standards of Care Version 8"; and

(ii) within 90 days of the date of this order, the Secretary of Health and Human Services (HHS) shall publish a review of the existing literature on best practices for promoting the health of children who assert gender dysphoria, rapid-onset gender dysphoria, or other identity-based confusion.

(b) The Secretary of HHS, as appropriate and consistent with applicable law, shall use all available methods to increase the quality of data to guide practices for improving the health of minors with gender dysphoria, rapid-onset gender dysphoria, or other identity-based confusion, or who otherwise seek chemical or surgical mutilation.

Protecting Children From Chemical and Surgical Mutilation

Sec. 4. *Defunding Chemical and Surgical Mutilation.* The head of each executive department or agency (agency) that provides research or education grants to medical institutions, including medical schools and hospitals, shall, consistent with applicable law and in coordination with the Director of the Office of Management and Budget, immediately take appropriate steps to ensure that institutions receiving Federal research or education grants end the chemical and surgical mutilation of children.

Sec. 5. *Additional Directives to the Secretary of HHS.* (a) The Secretary of HHS shall, consistent with applicable law, take all appropriate actions to end the chemical and surgical mutilation of children, including regulatory and sub-regulatory actions, which may involve the following laws, programs, issues, or documents:

- (i) Medicare or Medicaid conditions of participation or conditions for coverage;
- (ii) clinical-abuse or inappropriate-use assessments relevant to State Medicaid programs;
- (iii) mandatory drug use reviews;
- (iv) section 1557 of the Patient Protection and Affordable Care Act;
- (v) quality, safety, and oversight memoranda;
- (vi) essential health benefits requirements; and
- (vii) the Eleventh Revision of the International Classification of Diseases and other federally funded manuals, including the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.

Protecting Children From Chemical and Surgical Mutilation

(c) prioritize investigations and take appropriate action to end deception of consumers, fraud, and violations of the Food, Drug, and Cosmetic Act by any entity that may be misleading the public about long-term side effects of chemical and surgical mutilation;

(d) in consultation with the Congress, work to draft, propose, and promote legislation to enact a private right of action for children and the parents of children whose healthy body parts have been damaged by medical professionals practicing chemical and surgical mutilation, which should include a lengthy statute of limitations; and

Several Orders Address Abortion Funding

- Because we rarely get questions about these, we won't address them.
- They involve both domestic and foreign funding.

Expanding Access to In Vitro Fertilization

Section 1. *Purpose and Policy.* Today, many hopeful couples dream of starting a family, but as many as one in seven are unable to conceive a child. Despite their hopes and efforts, infertility struggles can make conception difficult, turning what should be a joyful experience into an emotional and financial struggle. My Administration recognizes the importance of family formation, and as a Nation, our public policy must make it easier for loving and longing mothers and fathers to have children.

In vitro fertilization (IVF) offers hope to men and women experiencing fertility challenges. Americans need reliable access to IVF and more affordable treatment options, as the cost per cycle can range from \$12,000 to \$25,000. Providing support, awareness, and access to affordable fertility treatments can help these families navigate their path to parenthood with hope and confidence.

Therefore, to support American families, it is the policy of my Administration to ensure reliable access to IVF treatment, including by easing unnecessary statutory or regulatory burdens to make IVF treatment drastically more affordable.

Sec. 2. *Lowering Costs and Reducing Barriers to IVF.* Within 90 days of the date of this order, the Assistant to the President for Domestic Policy shall submit to the President a list of policy recommendations on protecting IVF access and aggressively reducing out-of-pocket and health plan costs for IVF treatment.

HIPAA Privacy Rule to Support Reproductive Health Care Privacy

- Published: April 26, 2024.
- Effective Date: June 25, 2024.
- Compliance Date: December 23, 2024, except for the Notice of Privacy Practices (NPP) requirements.
- NPP Compliance Date: February 16, 2026.
- Applies to all covered entities and business associates.

HIPAA: Reproductive Health Care Privacy

- Ongoing Litigation – *Texas v. HHS*
 - Texas Attorney General sought to block the 2024 Reproductive Privacy Rule, if not all of the HIPAA Privacy Rule.
 - Opposition briefs to cross-motions for summary judgment were originally due by March 7, 2025.
 - On January 31, 2025, the court granted HHS’s request to “hold all current deadlines in abeyance to allow incoming leadership personnel at [HHS] additional time to evaluate their position in this case and determine how best to proceed.” The parties are to provide a status report by **May 1, 2025**.
- Narrow injunction in *Purl v. HHS* does not extend to other parties beyond the named plaintiffs.

Executive Order 14221 of February 25, 2025

**Making America Healthy Again by Empowering Patients
With Clear, Accurate, and Actionable Healthcare Pricing In-
formation**

Pursuant to Executive Order 13877 of June 24, 2019 (Improving Price and Quality Transparency in American Healthcare to Put Patients First), my Administration issued paradigm-shifting regulations to put patients first by requiring hospitals and health plans to deliver meaningful price information to the American people. These regulations require hospitals to maintain a consumer-friendly display of pricing information for up to 300 shoppable services and a machine-readable file with negotiated rates for every single service the hospital provides; health plans to post their negotiated rates with providers as well as their out-of-network payments to providers and the actual prices they or their pharmacy benefit manager pay for prescription drugs; and health plans to maintain a consumer-facing internet tool through which individuals can access price information.

Executive Order 14221 of February 25, 2025

**Making America Healthy Again by Empowering Patients
With Clear, Accurate, and Actionable Healthcare Pricing In-
formation**

Unfortunately, progress on price transparency at the Federal level has stalled since the end of my first term. Hospitals and health plans were not adequately held to account when their price transparency data was incomplete or not even posted at all. The Biden Administration failed to take sufficient steps to fully enforce my Administration's requirement that would end the opaque nature of drug prices by ensuring health plans publicly post the true prices they pay for prescription drugs.

Executive Order 14221 of February 25, 2025

Making America Healthy Again by Empowering Patients With Clear, Accurate, and Actionable Healthcare Pricing Information

Sec. 3. Fulfilling the Promise of Radical Transparency. The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services shall take all necessary and appropriate action to rapidly implement and enforce the healthcare price transparency regulations issued pursuant to Executive Order 13877, including, within 90 days of the date of this order, action to:

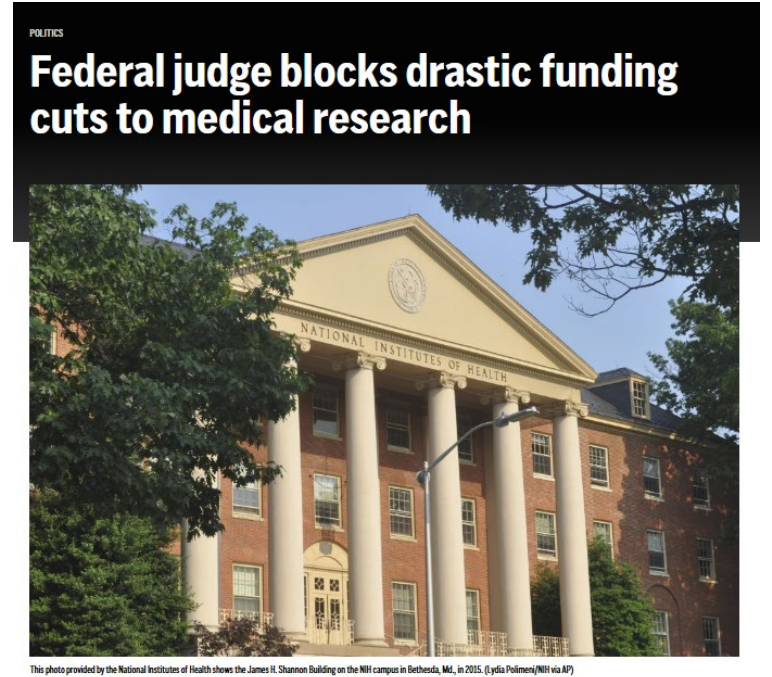
(a) require the disclosure of the actual prices of items and services, not estimates;

(b) issue updated guidance or proposed regulatory action ensuring pricing information is standardized and easily comparable across hospitals and health plans; and

(c) issue guidance or proposed regulatory action updating enforcement policies designed to ensure compliance with the transparent reporting of complete, accurate, and meaningful data.

HHS Agency Effort re: Indirect Cost Rates

- Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates, NOT-OD-25-068.
- Indirect Costs = “facilities” + “administration”.
- 15% standard rate – new and *existing retroactive to Feb 7, 2025.*
- Lawsuit by 22 states – preliminary injunction.
- \$35 billion annual research grants.



....Why does this matter?

Affordable Care Act (ACA) Section 1557 Rule

- ACA section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age or disability in a health care program or activity if any part receives federal financial assistance.
- Department of Health and Human Services (HHS) issued implementing rules at 42 CFR Part 92: May 2016 Obama Administration rule; June 2020 Trump administration rule; May 2024 Biden Administration Rule.

Current Section 1557 Rule Summary

- Applies to nearly all of healthcare, including: any health program or activity that receives direct or indirect HHS funding; HHS administered programs and activities; health insurance exchanges.
- States that Medicare Part B payments are federal financial assistance for purposes of section 1557 and other civil rights laws.
- Requires providers, insurers and other covered entities to provide free information on availability of language assistance services.
- Prohibits healthcare providers and other covered entities from discriminating in the use of patient care decision support tools; nondiscrimination rule applies to use of artificial intelligence, algorithms, and predictive analytics.

Current Section 1557 Rule Summary

- Applies Section 1557's prohibition against discrimination based on sex to pregnancy, sexual orientation, gender identity and sex characteristics.
- Requires that covered health care activities via telehealth must be accessible to persons with disabilities or with limited English proficiency.
- Clarifies the application of Section 1557 nondiscrimination requirements to health insurance plans.

Compliance Deadlines

Section 1557 Requirement	Compliance Deadline
All requirements not specified in this table	July 5, 2024
Designate a 1557 Coordinator (if more than 15 employees)	November 2, 2024
Notice of Nondiscrimination	November 2, 2024
Nondiscrimination based on Protected Characteristic, including Sex: Health Insurance Coverage	The first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2025, for coverage not previously subject to Section 1557
Nondiscrimination based on Disability: Health Insurance Coverage Benefit Designs	The first day of plan year on or after January 1, 2025
Nondiscrimination in Use of Patient Care Decision Support Tools	May 1, 2025
Nondiscrimination Policies and Procedures Adoption and Training	July 5, 2025
Notice of Availability of language assistance and auxiliary aids and services	July 5, 2025

Expect Further Changes

- Several courts have enjoined enforcement of “gender affirming” provisions of the rule (appeals are pending).
- January 28, 2025 Trump Administration Executive Order rescinded policy decisions that extended Section 1557 protections to gender identity.
- January 21, 2025 EO “Ending Illegal Discrimination....”; March 7, 2025 HHS Office of Civil rights announces investigations into four medical schools and hospitals.

Telehealth

- Absent Congressional action, most Medicare coverage of telehealth ends 3/31.
- Most Medicare telehealth will end without action.

Permanent Telehealth

- Behavioral/mental health care in their home.
- There are no geographic restrictions for originating site for Medicare behavioral/mental telehealth services on a permanent basis.
- Behavioral/mental telehealth can be audio-only.
- Marriage and family therapists and mental health counselors can serve as Medicare distant site providers.

DHS Getting Rid Of Notice And Comment?

- The March 3, 2025 FR includes “Policy on Adhering to the Text of the Administrative Procedure Act.”

Effective immediately, the Richardson Waiver is rescinded and is no longer the policy of the Department. In accordance with the APA, “matters relating to agency management or personnel or to public property, loans, grants, benefits, or contracts,” are exempt from the notice and comment procedures of 5 U.S.C. 553, except as otherwise required by law. Agencies and offices of the Department have discretion to apply notice and comment procedures to these matters but are not required to do so, except as otherwise required by law. Additionally, the good cause exception should be used in appropriate circumstances in accordance with the requirements of the APA. The

Office of the Secretary
PUBLIC PARTICIPATION IN RULE
MAKING

Statement of Policy

Notice is hereby given of a statement of policy on public participation in rule making issued by the Secretary. As a matter of policy, the Department will use notice of proposed rule making procedures in certain cases where not required by law. The Secretary's statement reads as follows:

Generally, before rules and regulations are issued by Government agencies, the Administrative Procedure Act (APA) provides that notice of the proposed rule making must be published in the FEDERAL REGISTER and interested persons must be given an opportunity to participate in the rule making through submission of data, views, or arguments.

The APA exempts from this requirement matters relating to public property, loans, grants, benefits, or contracts. Legislation has been introduced to repeal this exemption. The Administrative Conference of the United States has recommended, however, that Government agencies require public participation in accordance with the APA provisions when formulating rules in the five exempt categories listed above, without waiting for the statute to be amended.

Our implementation of the Conference's recommendation should result in greater participation by the public in the formulation of this Department's rules and regulations. The public benefit from such participation should outweigh any administrative inconvenience or delay which may result from use of the APA procedures in the five exempt categories.

Effective immediately, all agencies and offices of the Department which issue rules and regulations relating to public property, loans, grants, benefits, or contracts are directed to utilize the public participation procedures of the APA, 5 U.S.C. 553. Although the APA permits exceptions from these procedures when an agency for good cause finds that such procedures would be impracticable, unnecessary or contrary to the public interest, such exceptions should be used sparingly, as for example in emergencies and in instances where public participation would be useless or wasteful because proposed amendments to regulations cover minor technical matters.

Dated: January 28, 1971.

RODNEY H. BRADY,
Assistant Secretary
for Administration.

[FR Doc.71-1604 Filed 2-4-71;8:48 am]

Discussion Questions

- Is there going to be less enforcement now? Can I take more risks now?
- How do federal and state investigations relate? What if state and federal compliance requirements are different?
- I strongly disagree with some of these orders, what do I do?
- How do we discuss compliance under these orders without bringing politics into our workplace?
- How do we make decisions when everything keeps changing?

Risk Assessment – Funding Risks

- Define all ways that federal funding supports your organization. Try to track those sources to the source – agency, program, appropriation – do they flow through other entities first (prime contractor, state agency, etc.).
- Are those programs likely to be targeted by DOGE cost cutting?
- How dependent is your organization on federal funds?
- Lawsuits against your organization.
- Disruptions caused by disputes not involving your organization.

Risk Assessment – Regulatory Risks

- Define regulations that impact your organization – for better or worse.
- How do they fare under the 7-part litmus test?
- Is enforcement a priority for the agency? Can others enforce it?
- Are there similar or conflicting regulations at the state or local level?
- Costs of compliance v. risks of noncompliance.
- Stakeholder perspectives.
- Company values.

Decide How You Will Decide/Trust Your Process

- Triage defined risks based on your unique situation and risk tolerance.
- Consider the following:
 - Establish standard operating procedures (SOPs) to guide your response to regulatory changes over time. Using a defined process helps ensure your organization cuts out the noise and only uses signals to work through decisions.
 - Create a decision tree to help your organization navigate dynamic risks and make sound decisions that align with your organization's values and risk tolerance.
 - Equip professionals throughout your organization with the tools they need to make decisions that are appropriate to their level of authority and discretion.
- Cut out the noise and trust your process.

ICE: What Can They Do?

- Immigrations and Customs Enforcement has the same basic powers as any police agency.
- Until recently, Federal policy instructed ICE to refrain from enforcement in “sensitive areas” like schools, churches and medical facilities.
- The Trump Administration has terminated that policy.
- ICE can now do what other police can do, which is go to public location.

ICE: What Can They Do?

- Police/ICE can't go where the public can't sans search warrant.
- An arrest warrant is not a search warrant.
- HIPAA has a law enforcement exception that is surprisingly broad.
- But HIPAA is a floor. State law Often provides heightened protection. Never rely on national articles about what law enforcement may obtain.

Presenters



Marguerite Ahmann
Attorney
612.492.7495
mahmann@fredlaw.com



David Glaser
Attorney
612.492.7143
dglaser@fredlaw.com



Nena Lenz
Attorney
612.492.7427
nlenz@fredlaw.com



Ralph Topinka
Attorney
612.492.7400
rtopinka@fredlaw.com

Fredrikson



Where Law and Business Meet[®]