



**HHS RESPONSE TO
SECTION 4 OF
EXECUTIVE ORDER
14294: *FIGHTING
OVERCRIMINALIZATION IN
FEDERAL REGULATIONS***

**U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES**

BASED ON COLLECTED HHS DATA



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Glossary of Relevant HHS Divisions

ACF	Administration for Children and Families
ASPR	Administration for Strategic Preparedness and Response
CDC	Centers for Disease Control and Prevention
FDA	Food and Drug Administration
IHS	Indian Health Service
NIH	National Institutes of Health
OCR	Office for Civil Rights
OS	Office of the Secretary



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Washington, D.C. 20201

DATE: May 8, 2026

TO: Russell Vought, Director
Office of Management and Budget

Through: Liesl Fowler, Executive Secretary
U.S. Department of Health and Human Services

FROM: Matthew Zorn, Deputy General Counsel
U.S. Department of Health and Human Services

SUBJECT: HHS Report on Criminal Regulatory Offenses: Implementation of Executive Order 14294, *Fighting Overcriminalization in Federal Regulation*

PURPOSE

This memorandum transmits the Department of Health and Human Services' report pursuant to Section 4 of Executive Order 14294. The report identifies criminal regulatory offenses, associated penalties, and applicable mens rea standards, and will be publicly posted and updated annually. The findings have been broken down by Divisions below:

*** ACF (Administration for Children and Families)**

Mens Rea Breakdown:
- Knowingly and willfully: 1

Penalty Type Breakdown:
- Fine: 1

*** ASPR (Administration for Strategic Preparedness and Response)**

Mens Rea Breakdown:
- Negligence: 1

Penalty Type Breakdown:
- Fine and/or Imprisonment: 1

*** CDC (Centers for Disease Control and Prevention)**

Mens Rea Breakdown:
- Not defined: 3

Penalty Type Breakdown:
- Imprisonment and/or fine: 3



Note: One of the three CDC entries (42 CFR 71.51(gg)) was included at HHS's request. CDC noted in the underlying inventory that it does not administer Title 19 and that enforcement decisions under 71.51(gg) would rest with DHS/CBP; CDC did not recommend including this provision in the submission to DOJ.

*** FDA (Food and Drug Administration)**

Mens Rea Breakdown:

- Strict liability: 7
- Specific intent to defraud or mislead or second conviction for violating the Federal Food, Drug, and Cosmetic Act: 7

Penalty Type Breakdown:

- Imprisonment and/or criminal fine: 14

*** IHS (Indian Health Service)**

Mens Rea Breakdown:

- 25 U.S.C. § 5306 (willfully as to misapplying): 1
- 18 U.S.C. § 1001 (knowingly and willfully): 1
- 18 U.S.C. 1001: knowledge; 31 U.S.C. 3729 to 3731: knowledge for applicable acts; and 18 U.S.C. 287: knowledge: 1

Penalty Type Breakdown:

- Fine, imprisonment: 2
- 18 U.S.C. 1001: fine, imprisonment; 31 U.S.C. 3729 to 3731: civil fine; and 18 U.S.C. 287: fine, imprisonment: 1

*** NIH/ FDA (National Institutes of Health / Food and Drug Administration)**

Number of Offenses: 2 (42 CFR § 11.6; 42 CFR § 11.66)

Mens Rea and Penalty Type Breakdown: These regulations are managed jointly by NIH and FDA; enforcement authority belongs to FDA, and the underlying offenses are enforceable under 21 U.S.C. §§ 331(jj), 333 and 42 U.S.C. § 282(j). NIH defers to FDA on the interpretation and application of these provisions.

*** OCR (Office for Civil Rights / Justice Department Health Care Fraud Unit)**

Mens Rea Breakdown:

- A person who knowingly (1) uses or causes to be used a unique health identifier; (2) obtains individually identifiable health information relating to an individual; or (3) discloses individually identifiable health information to another person.: 1

Penalty Type Breakdown:

- Criminal Fine/ Imprisonment: 1

*** Office of the Secretary (OS)**

Mens Rea Breakdown:

- Willfulness: 1

Penalty Type Breakdown:

- Fine and/or imprisonment: 1



Appendix A: HHS EO 14294 Compliance Report

I. Executive Summary

Pursuant to Section 4 of Executive Order 14294, the Department of Health and Human Services (HHS) conducted a comprehensive inventory and review of criminal regulatory offenses within its jurisdiction. This report is submitted to the Office of Management and Budget (OMB) in consultation with the Attorney General and is intended to meet all statutory and policy requirements of the Order.

HHS identified a total of 26 distinct criminal regulatory offenses across 8 Divisions and subcomponents. The Department's review confirms that while criminal enforcement authorities remain an essential tool to protect public health and program integrity, significant opportunities exist to improve clarity, transparency, and consistency in their application.

II. Statutory and Regulatory Framework

Section 4 of Executive Order 14294 requires agencies to:

- (1) identify all criminal regulatory offenses;
- (2) specify applicable penalties; and
- (3) define the applicable mens rea standard.

Additionally, agencies must publicly post these findings and update them annually, while considering whether offenses are included in the report when making enforcement decisions.

III. Methodology

HHS conducted a Department-wide data call across all Divisions. Each component identified regulations enforceable through criminal penalties and provided:

- Citation and description;
- Authorizing statutory authority;
- Applicable mens rea standard; and
- Penalty type and range.

The results were consolidated into a standardized inventory.

IV. Findings

A. Scope of Criminal Regulatory Authorities

HHS identified 26 criminal regulatory provisions spanning public health enforcement, biomedical research compliance, food and drug safety, controlled substances, and program integrity.

These authorities are distributed across multiple subagencies, including CDC, FDA, ASPR, and others, reflecting the breadth of HHS's mission.



B. Mens Rea Analysis

The Department’s review identified substantial variation in the mens rea standards applicable to criminal regulatory offenses across HHS. These standards range from strict liability to more traditional criminal intent requirements such as knowledge, willfulness, or specific intent to defraud or mislead.

A significant portion of identified offenses, particularly within FDA’s regulatory framework, rely on either strict liability or heightened statutory standards tied to specific intent to defraud or mislead. This reflects longstanding enforcement models under the Federal Food, Drug, and Cosmetic Act, where public health considerations have historically supported lower or specialized intent thresholds in certain contexts.

At the same time, several offenses identified in the Department’s inventory incorporate knowledge- or willfulness-based standards derived directly from underlying statutory authorities, including provisions such as 18 U.S.C. § 1001 (false statements), 31 U.S.C. §§ 3729–3731 (False Claims Act), and other program-specific statutes. These provisions generally align with traditional principles of criminal liability by requiring proof that a defendant acted knowingly or willfully.

The review also identified a subset of regulatory provisions—particularly within CDC-administered authorities—where the applicable mens rea is not explicitly defined in regulatory text. In these cases, the operative mental state must be inferred from underlying statutes or general criminal law principles, which may create ambiguity for regulated entities and enforcement personnel.

In more limited instances, the Department identified negligence-based standards or hybrid formulations tied to specific statutory schemes, as well as provisions where the applicable mens rea is described through cross-references or supplemental explanatory material rather than clearly articulated in the regulation itself.

Overall, the variation in mens rea standards reflects the diversity of HHS’s statutory authorities and mission areas. However, this variability may also contribute to inconsistency in interpretation and application, as well as uncertainty for regulated parties seeking to understand the legal consequences of noncompliance. Consistent with Executive Order 14294, these findings underscore the importance of clearly defining applicable mental states in regulatory text and prioritizing criminal enforcement in cases involving knowing, willful, or otherwise culpable misconduct.

Key Observations:

- A substantial portion of offenses rely on strict liability or similarly low-threshold standards.
- Several provisions lack clearly defined mens rea requirements in regulatory text.
- Some provisions rely on statutory language incorporating knowledge or willfulness standards.



This variation may create uncertainty for regulated entities and complicate consistent enforcement.

C. Penalty Structures

Criminal penalties vary widely, including:

- Fines ranging from thousands to hundreds of thousands of dollars;
- Imprisonment terms generally up to one year for misdemeanor offenses, with higher penalties in certain statutory contexts; and
- Combined penalties including both fines and imprisonment.

In several instances, penalty ranges were not clearly specified in regulatory text and required reference to underlying statutes.

D. Transparency and Accessibility

The review found that:

- Criminal regulatory authorities are not consistently consolidated in a single, publicly accessible format;
- Regulated entities may face challenges identifying applicable criminal provisions and associated standards; and
- Cross-referencing between regulations and statutes is often required to determine enforcement implications.

E. Enforcement Implications

Consistent with Executive Order 14294, HHS affirms that:

- Criminal enforcement should prioritize intentional, knowing, or willful misconduct;
- Civil and administrative remedies remain appropriate for many regulatory violations; and
- Inclusion in this report should inform enforcement discretion.

V. Policy Determinations

HHS has determined that the following reforms may be justified in the following areas:

1. *Clarification of Mens Rea Standards.* HHS will work with DOJ to ensure that future regulations explicitly define applicable mental states.
2. *Reduction of Strict Liability Reliance.* Where appropriate, HHS will evaluate alternatives to strict liability criminal enforcement.
3. *Enhanced Public Transparency.* HHS will publish and maintain a centralized, publicly accessible inventory of criminal regulatory offenses.



4. *Consistent Enforcement Framework.* The Department will develop internal guidance to ensure consistent application of criminal referral standards.

VI. Implementation Plan

HHS will:

- Establish an annual review and update cycle;
- Coordinate with OMB and DOJ on policy alignment;
- Develop standardized templates for future regulatory actions; and
- Engage stakeholders to improve clarity and compliance.

VII. Conclusion

This report fulfills the requirements of Executive Order 14294 Section 4 and reflects HHS's commitment to transparency, fairness, and effective governance. By improving clarity in criminal regulatory enforcement, HHS will better protect public health while ensuring that enforcement actions are targeted, proportionate, and consistent with due process.