
Health Law Enforcement: To 2025 and Beyond

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Overview of Enforcement of Federal Health Laws

- Department of Health & Human Services (HHS) – Robert F. Kennedy, Jr.
 - Office of the Inspector General (OIG)
 - Waste, fraud, and abuse
 - Medicaid, Medicare
 - Other programs
 - Office of Civil Rights (OCR)
 - Federal civil rights laws
 - Conscience and religious freedom laws
 - Health Insurance Portability and Accountability Act (HIPAA)
 - Patient Safety Act
 - Centers for Medicare & Medicaid Services (CMS)
 - Price Transparency
 - Medicare Part C and Part D

HHS Office of the Inspector General – Fraud, Waste, and Abuse

- Fraud – wrongful or criminal deception intended to result in financial or personal gain.
 - False representations of fact.
 - False statements.
 - Concealing information.
- Waste – thoughtless or careless expenditure, mismanagement, or abuse of resources to the detriment of the U.S. government.
 - Unnecessary costs.
 - Inefficient or ineffective practices, systems, controls.
- Abuse – excessive or improper use of a thing, or to use something in a manner contrary to the nature or legal rules for its use.
 - Financial
 - Non-financial

HHS Office of the Inspector General – Legal Authorities

- False and Fraudulent Claims – False Claims Act
- Anti-Kickback Statute
- Emergency Medical Treatment and Labor Act (EMTALA)
- Physician Self-Referrals – Stark Law
- Other Social Security Act Provisions
- Medicaid Fraud Control Units – Oversight of State Units
- [Civil Monetary Penalty Authorities | Office of Inspector General | Government Oversight | U.S. Department of Health and Human Services](#)

HHS Office of the Inspector General – Enforcement Trends - Present

- Federal Fiscal Year 2023 – Medicare & Medicaid combined – Improper payments totaled \$101.4 billion
 - 43% of all improper payments across the federal government
- Spring 2024 Semiannual Report to Congress – October 1, 2023 to March 31, 2024
 - Identified \$2.76 billion in expected recoveries
 - 195 recommendations, 60 audits, 18 evaluations
 - Initiated 712 civil and criminal actions
 - Excluded 1,795 people/entities from federal programs
- Fall 2024 Semiannual Report to Congress – April 1, 2024 to September 30, 2024
 - Identified \$4.36 billion in expected recoveries
 - 239 recommendations, 53 audits, 22 evaluations
 - Initiated 836 civil and criminal actions
 - Excluded 1,439 people/entities from federal programs

HHS Office of the Inspector General – Enforcement Trends - Past

- Spring 2013 Semiannual Report to Congress – October, 2012 to March, 2013
 - Identified \$7.08 billion in expected recoveries
 - Initiated 724 civil and criminal actions
 - Excluded 1,661 people/entities from federal programs
- Spring 2017 Semiannual Report to Congress – April 2017 to September 2017
 - Estimated total improper payments of \$96 billion
 - Identified \$2.04 billion in expected recoveries
 - Initiated 929 civil and criminal actions
 - Excluded 1,422 people/entities from federal programs
- Spring 2020 Semiannual Report to Congress – October 1, 2020 to March 31, 2021
 - Identified 1.96 billion in expected recoveries
 - Initiated 493 civil and criminal actions
 - Excluded 1,036 people/entities from federal programs

HHS Office for Civil Rights – Federal Civil Rights Laws

- Enforces certain federal civil rights laws against recipients of federal funds from HHS
- Title IV Civil Rights Act of 1964
- Section 504 of the Rehabilitation Act of 1973
- Title II of the Americans with Disabilities Act of 1990
- The Age Discrimination Act of 1975
- The Community Service Assurance Provisions of the Hill-Burton Act
- Section 1557 of the Affordable Care Act

HHS Office for Civil Rights – Conscience and Religious Freedom Laws

- Church Amendments – 42 U.S.C. 300A-7
 - Implements protections for both providers who have performed abortions or sterilizations and providers who have refused to perform abortions or sterilizations on moral grounds.
- Public Health Service Act, the Coates-Snowe Amendment – 42 U.S.C. 238N
 - Expands Church Amendments to include training and residency programs.
- Balanced Budget Act of 1997
 - Medicaid managed care organizations and Medicare Advantage plans can object to services on moral or religious grounds if certain requirements are met.
 - Certain religiously-oriented care facilities are exempt from certain licensure requirements.
- 2005 Consolidated Appropriations Act - Weldon Amendment
 - No federal funds can be given to a federal agency or program that discriminates against providers that refuse to provide abortions.
- Affordable Care Act
 - Implement protections for providers who do not perform assisted suicides, euthanasia, or mercy killing.

HHS Office for Civil Rights – HIPAA – Enforcement

- HIPAA Enforcement Rule – 45 C.F.R. Parts 160 and 164
 - Civil Monetary Penalties - 45 CFR §§ 160.400-426
- Impermissible Uses & Disclosures - 45 C.F.R. § 164.502
- Safeguards
 - Physical - 45 C.F.R. § 164.310
 - Administrative - 45 C.F.R. § 164.308
 - Risk Analysis Initiative – 45 C.F.R. § 164.308(a)(1)(ii)(A)
 - Technical - 45 C.F.R. § 164.312
- Patient Access - 45 C.F.R. § 164.524
 - Right to Access Initiative
- Minimum Disclosure Necessary - 45 C.F.R. § 164.502(b); 45 C.F.R. § 164.514(d)
- Notice of Breach to Those Affected - 45 CFR §§ 164.400-414

HHS Office for Civil Rights – HIPAA – Enforcement Over Time

	Complaints	Compliance Reviews	Technical Assistance	Total Cases	Of Those, Settlements or CMPs	% of Total Cases
2018	25089	438	7243	32770	10	0.0305%
2019	29853	338	9060	39251	10	0.0255%
2020	26530	566	5193	32289	19	0.0588%
2021	26420	573	4244	31237	14	0.0448%

HHS Office for Civil Rights – HIPAA – Enforcement Over Time

Year	Issue 1	Issue 2	Issue 3	Issue 4	Issue 5
2021	Impermissible Uses & Disclosures	Access	Safeguards	Administrative Safeguards	Breach - Notice to Individual
2020	Impermissible Uses & Disclosures	Safeguards	Access	Administrative Safeguards	Technical Safeguards
2019	Impermissible Uses & Disclosures	Safeguards	Access	Administrative Safeguards	Minimum Necessary
2018	Impermissible Uses & Disclosures	Safeguards	Administrative Safeguards	Access	Technical Safeguards

HHS Office for Civil Rights – Patient Safety Act

- The Patient Safety and Quality Improvement Act of 2005 – 42 U.S.C. 299, *et. seq.*
 - Voluntary reporting system
 - Enhance ability to assess patient safety and health care quality issues
- Authorizes HHS to impose Civil Monetary Penalties for violations of patient safety confidentiality
- Cannot disclose “patient safety work product”
- Patient Safety Rule – 42 C.F.R. Part 3, Subpart D
- Overlap with HIPAA, dual penalties not permissible.

Centers for Medicare & Medicaid Services – Price Transparency

- Public Health Service Act of 1944
 - Amended by the Patient Protection and Affordable Care Act of 2010
- Must establish, update, and make public a list of standard charges in services.
- CMS requirements in 45 C.F.R. Part 180.
 - Technical requirements
 - Data requirements
- Enforcement provisions – 45 C.F.R. 180.70.
 - Written Warnings
 - Corrective Action Plans
 - Civil Monetary Penalties

HHS Restructuring and Workforce Reductions

- Consolidation of Divisions – 28 to 15
 - Effects of consolidation
- Reduction in Force
 - 20,000 employees
 - CMS – 300 – 4% of workforce
 - FDA – 3,500 – 19% of workforce
 - CDC – 2,400 – 18% of workforce
 - NIH – 1,300 – 6% of workforce
 - From 82,000 to 62,000
- Reduced Regional Offices
 - From 10 to 5
 - New York, Boston, Chicago, Seattle, San Francisco

New Assistant Secretary for Enforcement

- New division
- Oversees:
 - Departmental Appeals Board (DAB)
 - Office of Medicare Hearings and Appeals (OMHA)
 - Office of Civil Rights (OCR)
- Justification:
 - Streamline similar programs and skillsets
 - Encourage efficiency and management
- Concerns:
 - Weakening of OCR
 - Intertwining enforcement with provider appeals
 - Political influences

2025-Onwards HHS Enforcement Priorities

- Overpayments
 - Fee-for-service – \$32 billion in 2024
 - Providers – \$31 billion in 2024
- Recovery
 - Currently only a fraction
- Reporter: “Can you guarantee that Medicare, Medicaid, Social Security will not be touched?” President Trump: “I have said it so many times . . . We’re not going to touch it. Now, we are going to look for fraud.” - Cabinet Meeting, February 26, 2025
- “The President said over and over and over, ‘We’re not going to touch Social Security, Medicare or Medicaid.’ We’ve made the same commitment. Now, that said, what we are going to do is go into those programs and carve out the fraud, waste and abuse, and find efficiencies.” - US House of Representatives Speaker Mike Johnson, February 26, 2025

Other Enforcement Priorities: HHS OCR

- Antisemitism
 - Investigation of four medical schools following reports of antisemitic incidents at 2024 commencement ceremonies
- Merit-based opportunity and discrimination
 - Initiated investigation of race-based admissions in California medical school.
 - Initiated investigation into four medical schools and hospitals due to the consideration of race, color, national origin, or sex.
- Participation in sports based upon sex
 - Determined that the Maine Department of Education's governance of school sports discriminated based upon sex.
- Puberty blockers and hormone treatments in youth
 - Rescission of prior guidance "Gender Affirming Care, Civil Rights, and Patient Privacy"
 - Initiated investigation of pediatric hospital for allegedly terminating employee who refused, on the basis of her religious and personal beliefs, to administer puberty blockers and cross-sex hormones to children.
 - Launched an online portal where whistleblowers can submit a tip or complaint regarding the chemical or surgical mutilation of children.

Other Enforcement Priorities: CMS

- Effective January 2021.
- 2022 – 2 hospitals – Civil Monetary Penalties totaled \$1,097,500
- 2023 – 11 hospitals – Civil Monetary Penalties totaled \$1,947,010
- 2024 – 3 hospitals – Civil Monetary Penalties totaled \$966,084
- 2025 – 8 hospitals so far – Civil Monetary Penalties totaling \$759,878
- President Trump – February 2025 Executive Order – Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information
 - Incentivizes urgency for hospitals to abide by the hospital price transparency regulations
 - Signals upcoming investigations into the accuracy of the prices publicly listed.
 - Clearly states that enforcement will increase substantially.

Former HHS OIG Inspector General Christi Grimm

- Christi Grimm, Inspector General for HHS, fired on January 24, 2025
 - Juliet Hodgkins, current Acting Inspector General
 - Thomas March Bell, nominee for Inspector General
 - Not yet confirmed
- Part of group of 17 inspector generals fired across different agencies.
- Terminated effective immediately.
- Inspector General Act of 1978 requires 30-day notice to Inspector Generals and justification provided to Congress.
 - Did not occur.
- Inspector Generals, including Grimm, filed suit for injunction and reinstatement, currently pending.

Summary

- Enforcement efforts over time have not substantially differed from year to year.
- Changing regulatory environment with departures from previous positions.
 - Federal civil rights
 - Conscience and religious discrimination
- Stated goal of Trump administration is to increase enforcement efforts.
 - Fraud, waste, and abuse
 - Price transparency
- Effect of HHS consolidation
 - Less employees
 - Desire for more enforcement
 - Remaining legal challenges
 - Possible additional deference to HHS determinations under Assistant Secretary for Enforcement

Recommendations

- Get ahead of the game
 - If a hospital, double check your price transparency listings and verify accuracy of pricing information.
 - Retain traceable documentation to support claims.
 - Revisit anti-discrimination policies and religious and conscience accommodation policies.
- Expect more pushback
 - DAB appeals, PRRB appeals, and other regulatory redetermination proceedings may defer more heavily to agency's determination.
 - HHS may push more heavily for civil monetary penalties than in the past
- The dust has not yet settled
 - More changes incoming
 - Stay informed
 - Seek assistance