COMPLIANCE SECTION
CONSUMER SAFETY BRANCH

Drugs and Medical Devices



FY26 ANNUAL TRENDS
FINAL ENFORCEMENT ACTIONS

Pursuant to 25 Texas Administrative Code 1.553(b)(1)(2)(3)

DMD Policies & Procedure Requirements

Drugs and Medical Devices (DMD) ensures drug manufacturers and distributors comply with minimum licensing standards to protect the health and safety of Texans.

DMD inspect prescription and over-the-counter (OTC) drug manufacturers and distributors to make sure they meet these standards. When voluntary compliance with the licensing standards cannot be achieved, DMD recommend regulatory actions.

DMD also provide technical assistance to licensees, answer questions from consumers and investigate complaints involving possible violations of the state requirements for drug manufacturers and distributors.

Prescription drug distributors are required to establish, maintain and adhere to all written policies and procedures required in 21 CFR, Part 205 - Section 205.50(g). Among these are policies and procedures for the receipt, security, storage, recall, inventory (including correcting all errors and inaccuracies), and distribution of prescription drugs (e.g., stock rotation; identifying, recording, and reporting losses or thefts; and disaster preparedness).

Drug Manufacturers and Distributors Defined

Drug Manufacturers:

A person who manufactures, prepares, propagates, compounds, processes, packages or repackages drugs, or a person who changes the container, wrapper or labeling of any drug package. A person licensed or approved by the United States Food and Drug Administration to engage in the manufacture of drugs consistent with the federal agency's definition of "manufacturer" under the agency's regulations and guidance implementing the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100 - 293). The term does not include a pharmacist engaged in compounding that is done within the practice of pharmacy and pursuant to a prescription drug order or initiative from a practitioner for a patient or prepackaging that is done in accordance with Occupations Code, §562.154.

Drug Distributors:

A person engaged in the wholesale distribution of prescription drugs, including, but not limited to, a distributor, wholesaler, own-label distributor, private-label distributor, jobber, broker, manufacturer warehouse, distributor warehouse, or other warehouse, manufacturer's exclusive distributor, authorized distributor of record, independent wholesale drug trader, specialty wholesale distributor, third-party logistics provider, retail pharmacy that conducts wholesale distribution, and a pharmacy warehouse that conducts wholesale distribution.

Drugs and Medical Devices License Types

2501 - Prescription Drugs

2502 - Nonprescription Drugs

2503 - Devices

2504 - Multiple Products

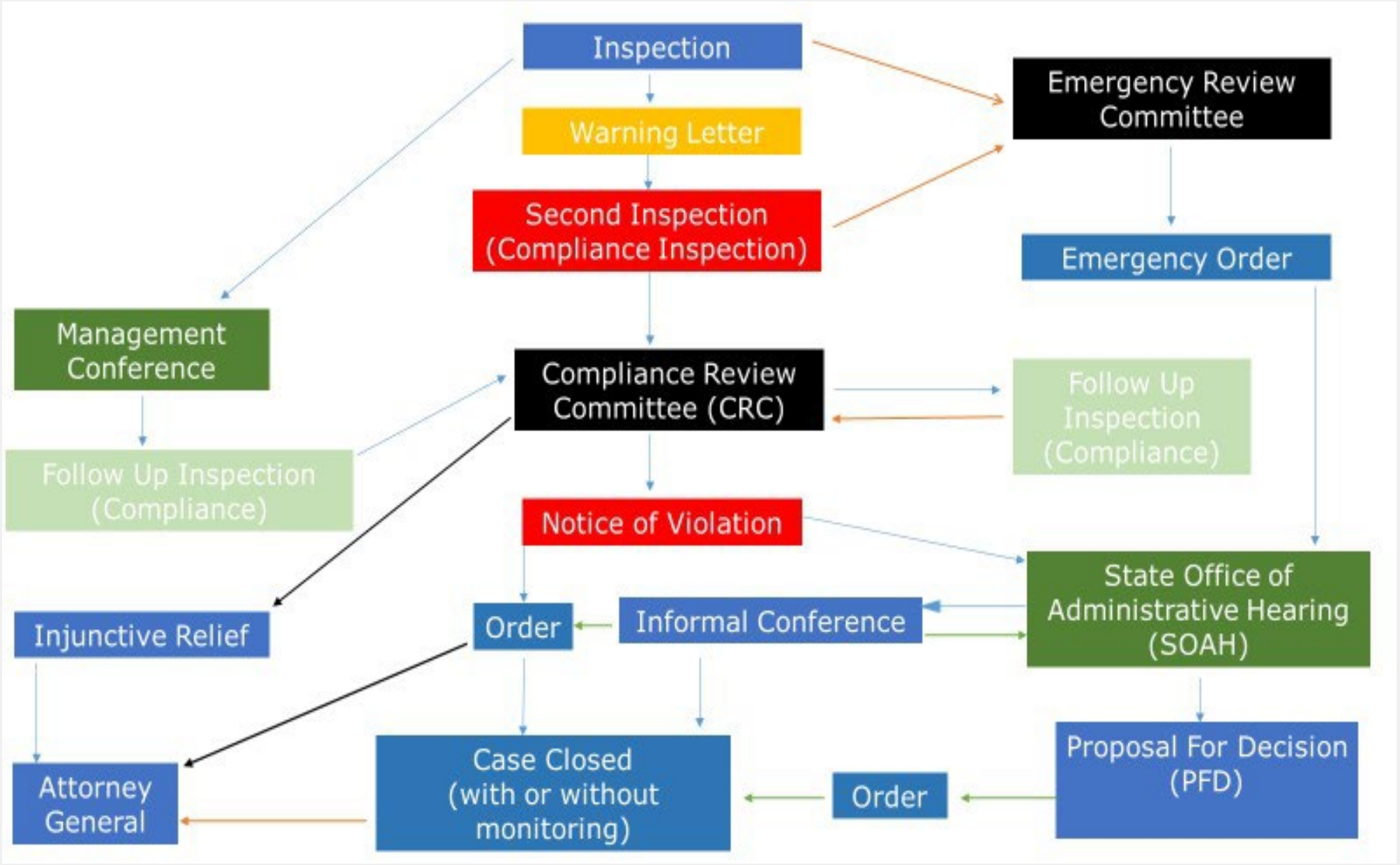
2506 - Tanning Facility

2510 - Pseudoephedrine

2511 - Bloodborne Pathogens

2520 - Owners

Drugs and Medical Devices Compliance Flowchart



TEXAS Health and Human Services

Texas Department of State Health Services

Cases referred to Compliance Year to Year Trends

FY22- 1

FY23- 7

FY24- 2

FY25- 4

FY26- 16

CRC Outcomes
Year to Year Trend

Notice of Violations (NOV) issued

FY22- 2

FY23- 10

FY24- 2

FY25- 4

FY26- 14

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Texas Department of State Health Services

Informal Conference (IC) Held Year to Year Trend

FY22- 0

FY23- 6

FY24- 1

FY25- 2

FY26- 7

State Office of Administrative Hearings (SOAH) Year to Year Trend

FY22- 0

FY23- 1

FY24- 1

FY25- 1

FY26- 1

Orders
Year to Year Trend

FY22- 0

FY23- 5

FY24- 2

FY25- 3

FY25- 9

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Texas Department of State Health Services

Attorney General (AG) Referrals Year to Year Trend

FY22- 0

FY23- 5

FY24- 1

FY25- 0

FY26- 4

Cases Closed With or Without Monitoring Year to Year Trend

Cases closed with monitoring

- Terms and conditions to be met are still pending
  - FY22- 1
  - FY23- 6
  - FY24- 2
  - FY25- 1
  - FY26- 7

Cases were closed without monitoring

- All terms and conditions are met
  - FY22- 0
  - FY23- 6
  - FY24- 5
  - FY25- 6
  - FY26- 20

Total Penalty Amount Proposed/Assessed

FY22 - $0

FY23- $16,000.00

FY24- $11,250.00

FY25- $5,500.00

FY26- $215,000.00

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Texas Department of State Health Services

Total Penalty Amount Collected/ Remitted

FY22 - $415.00

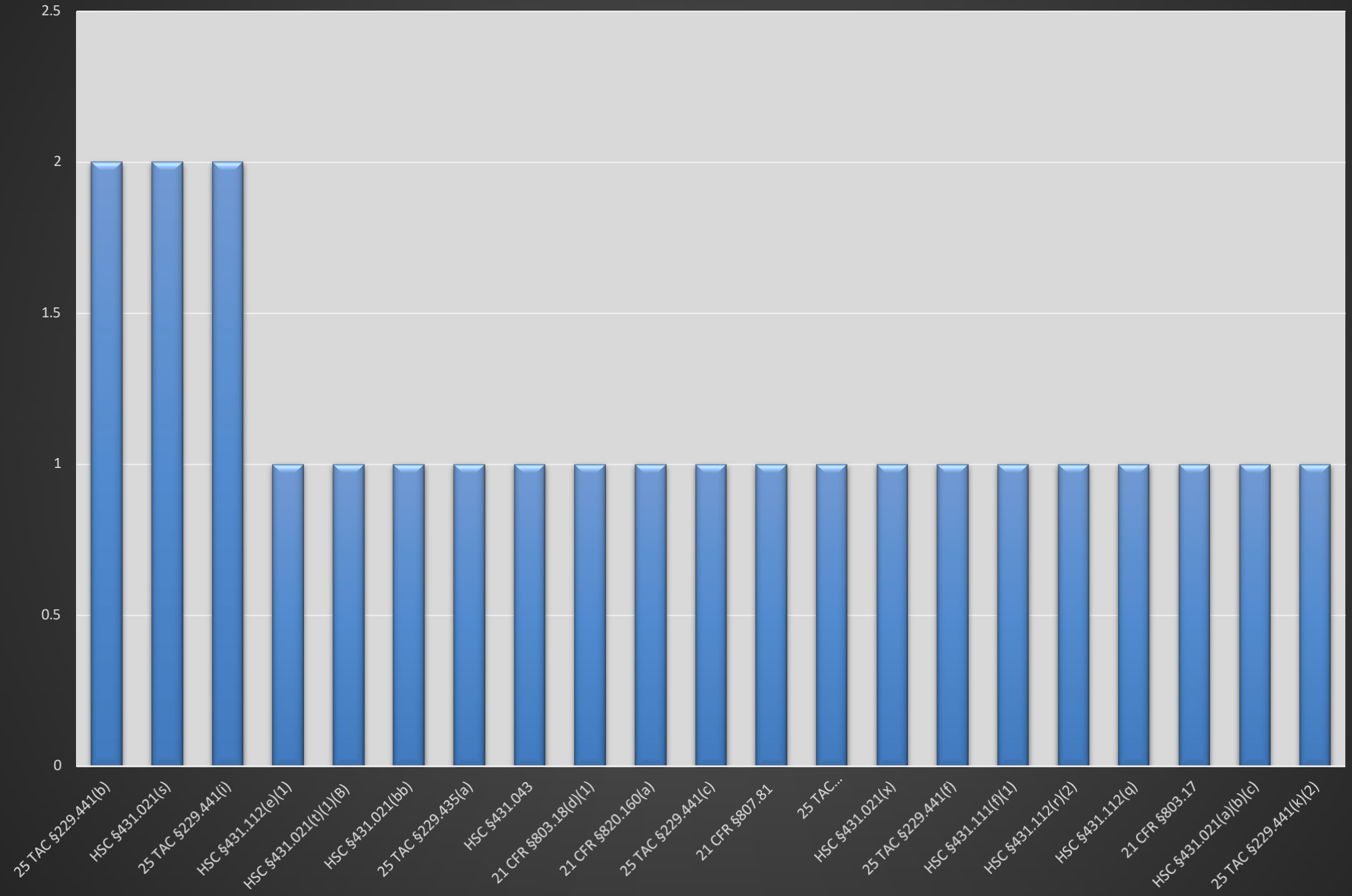
FY23- $0

FY24- $155.00

FY25- $1,033.00

FY26- $14,185.93

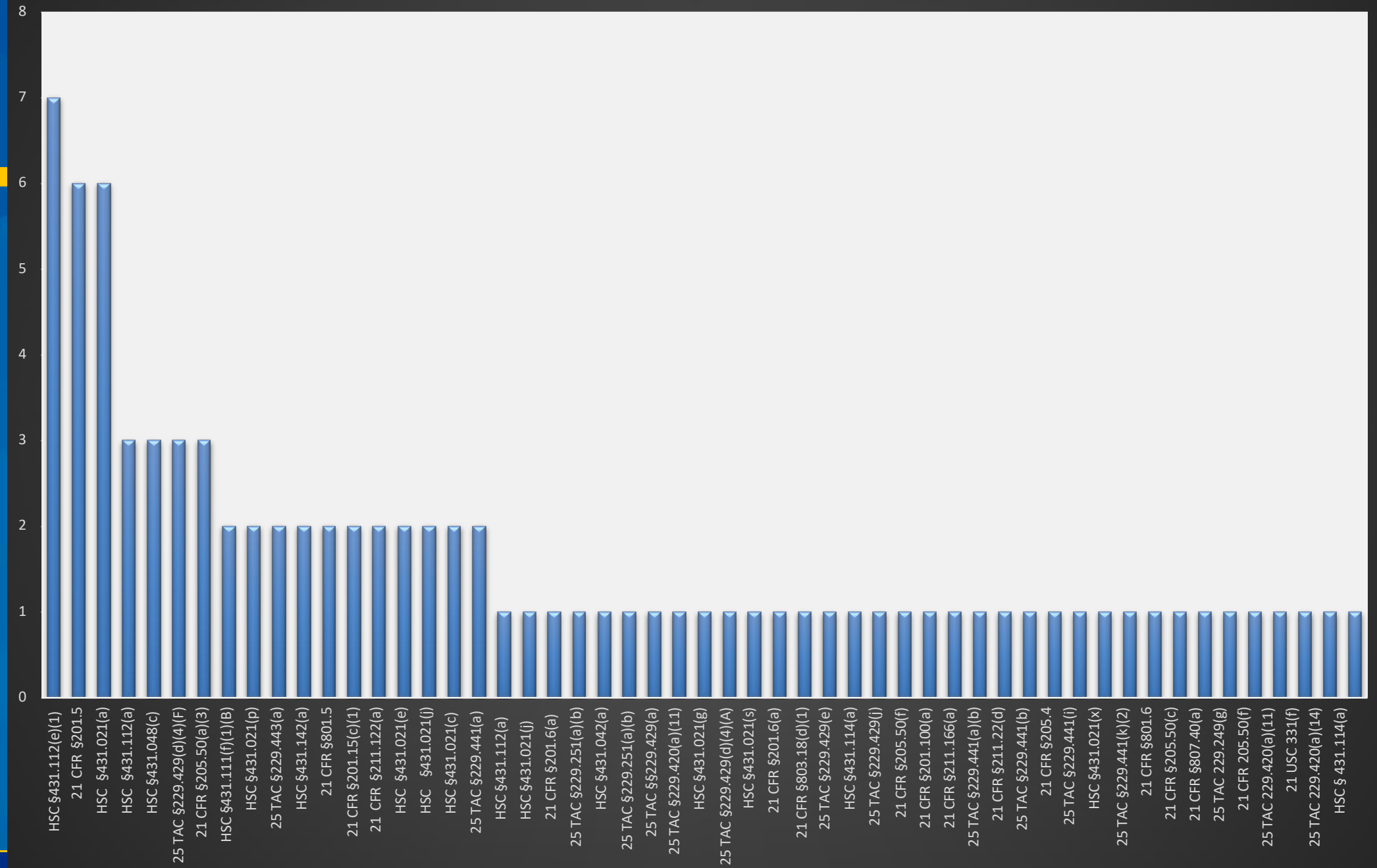
CITATIONS FOR FY22



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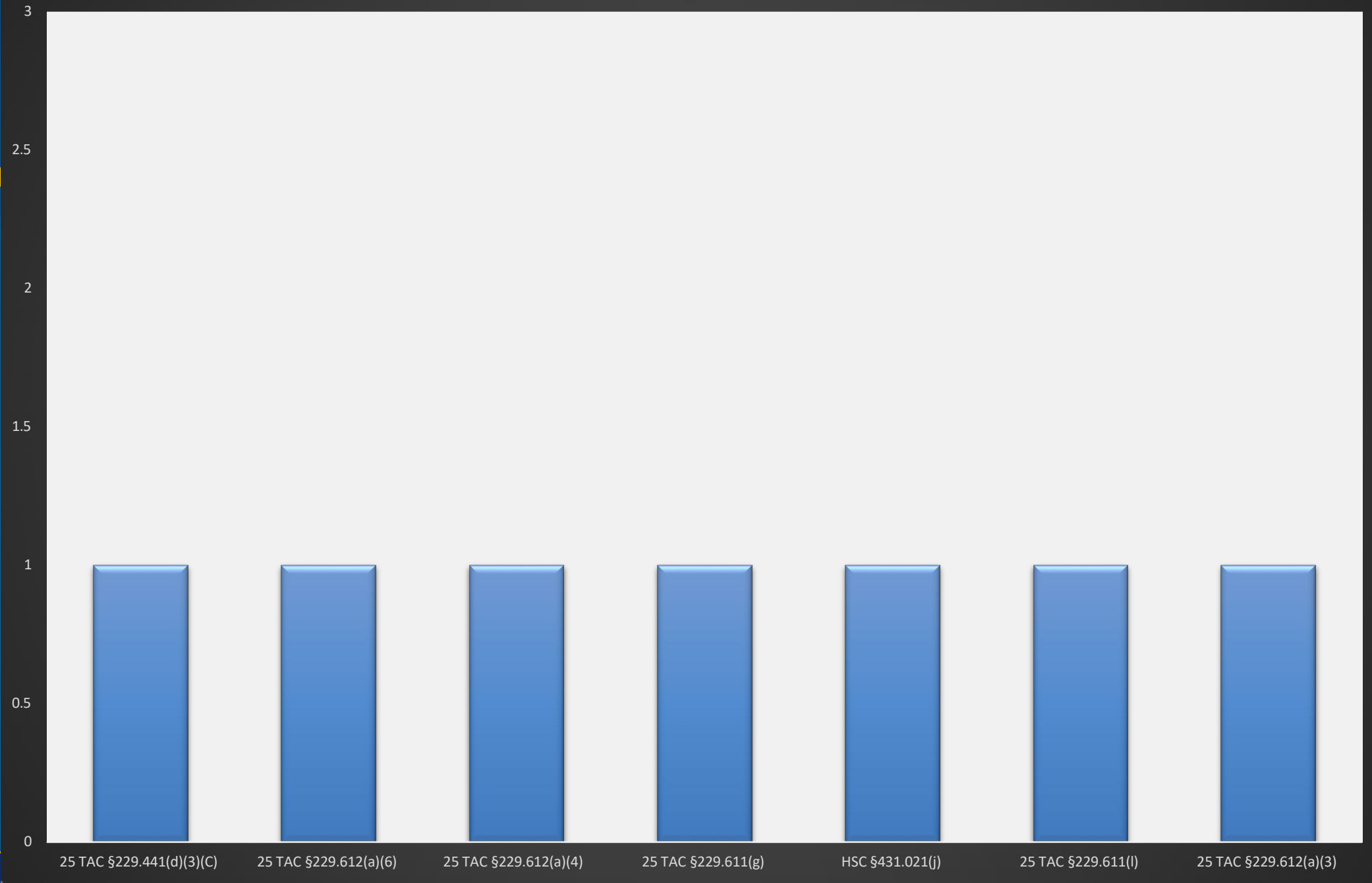
CITATIONS FOR FY23



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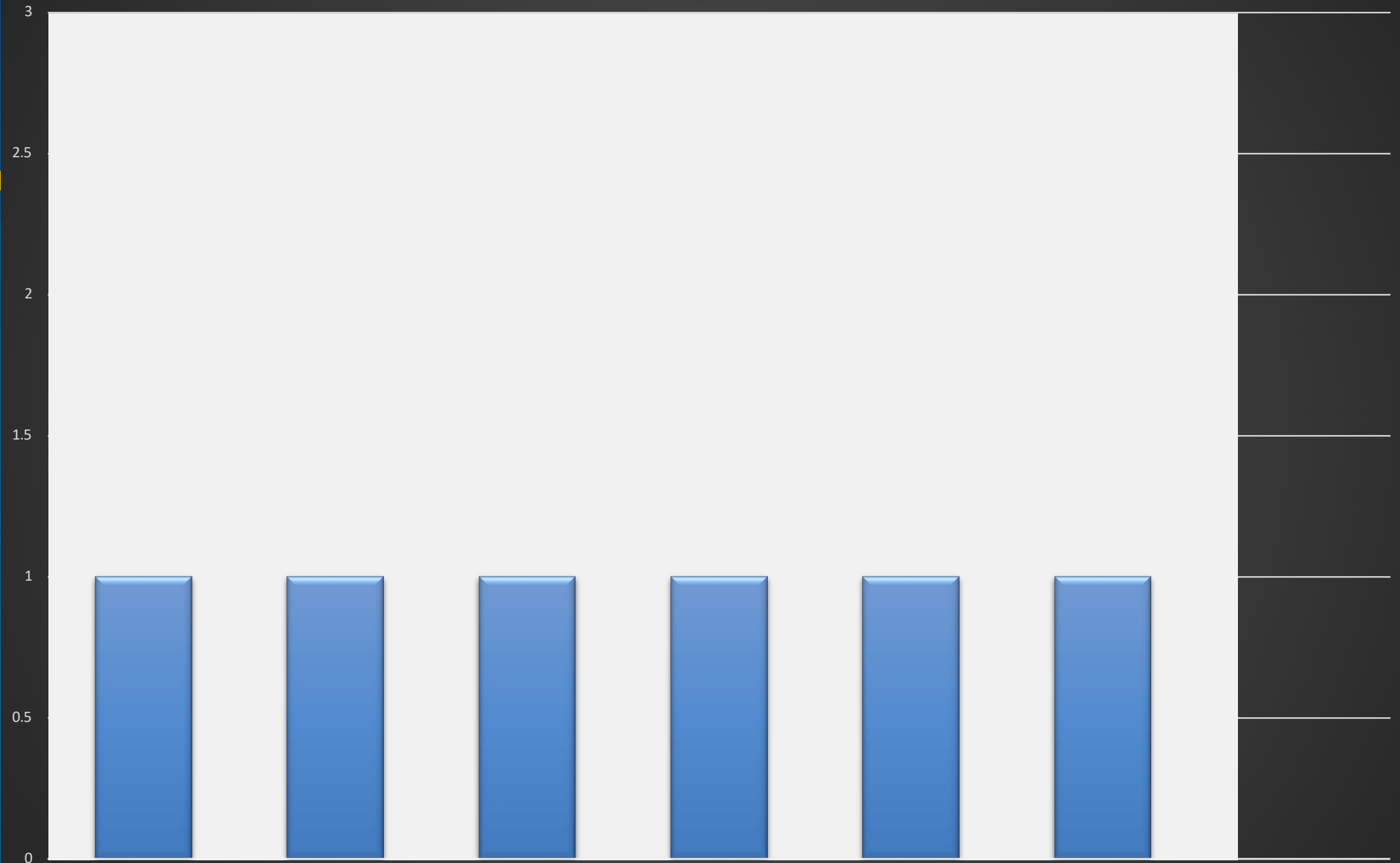
CITATIONS FOR FY24



TEXAS Health and Human Services

Texas Department of State Health Services

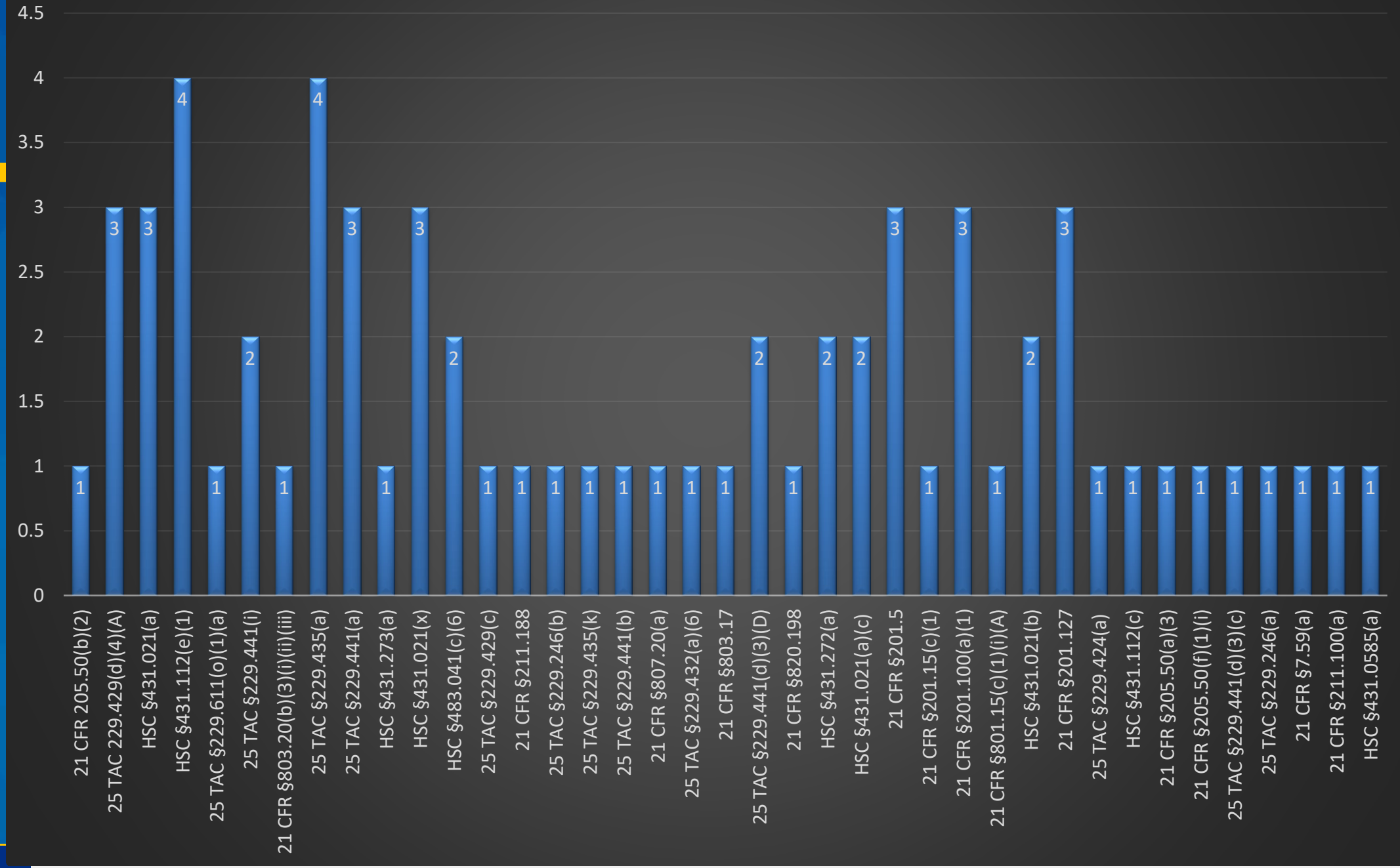
CITATIONS FOR FY25



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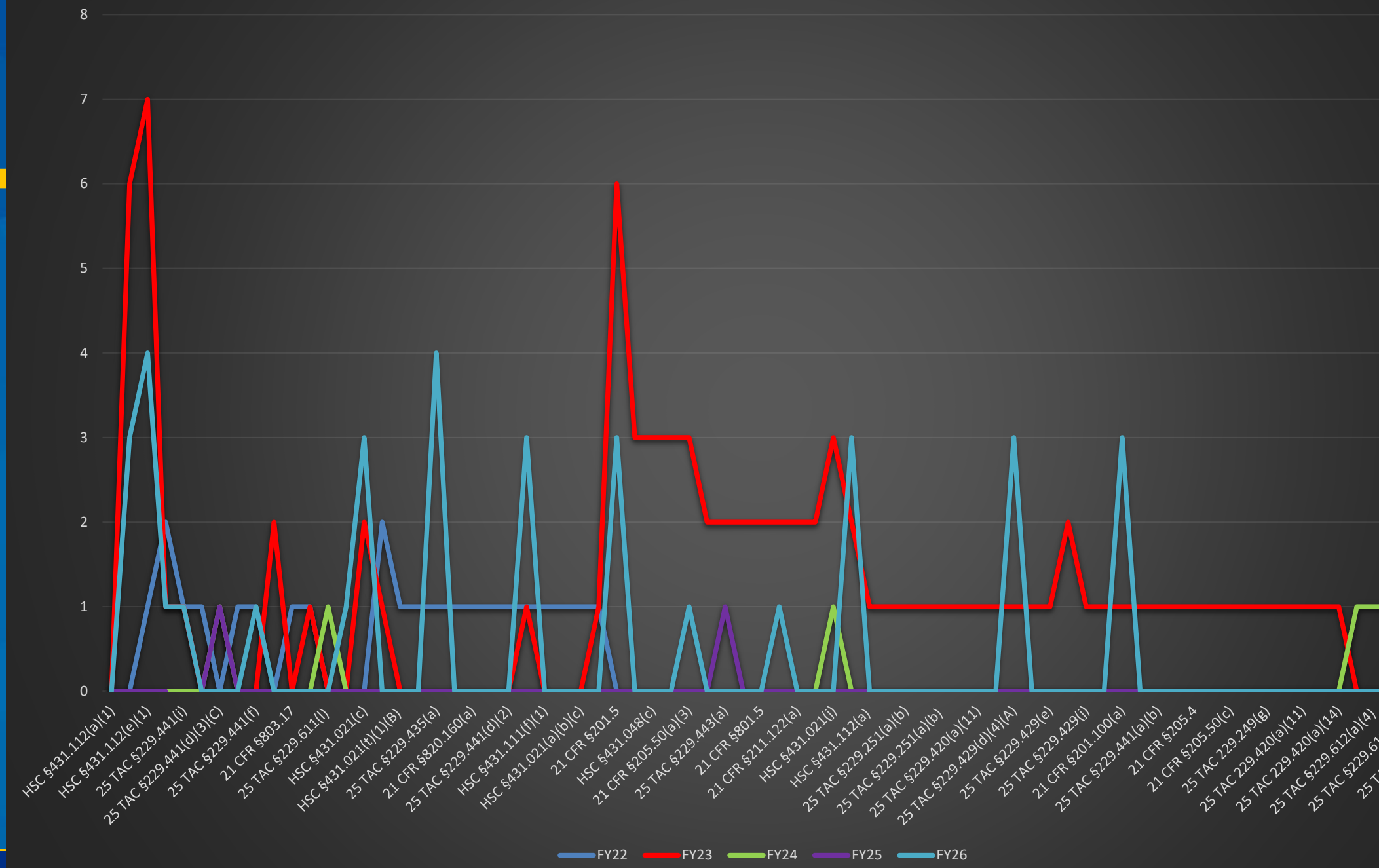
CITATIONS FOR FY26



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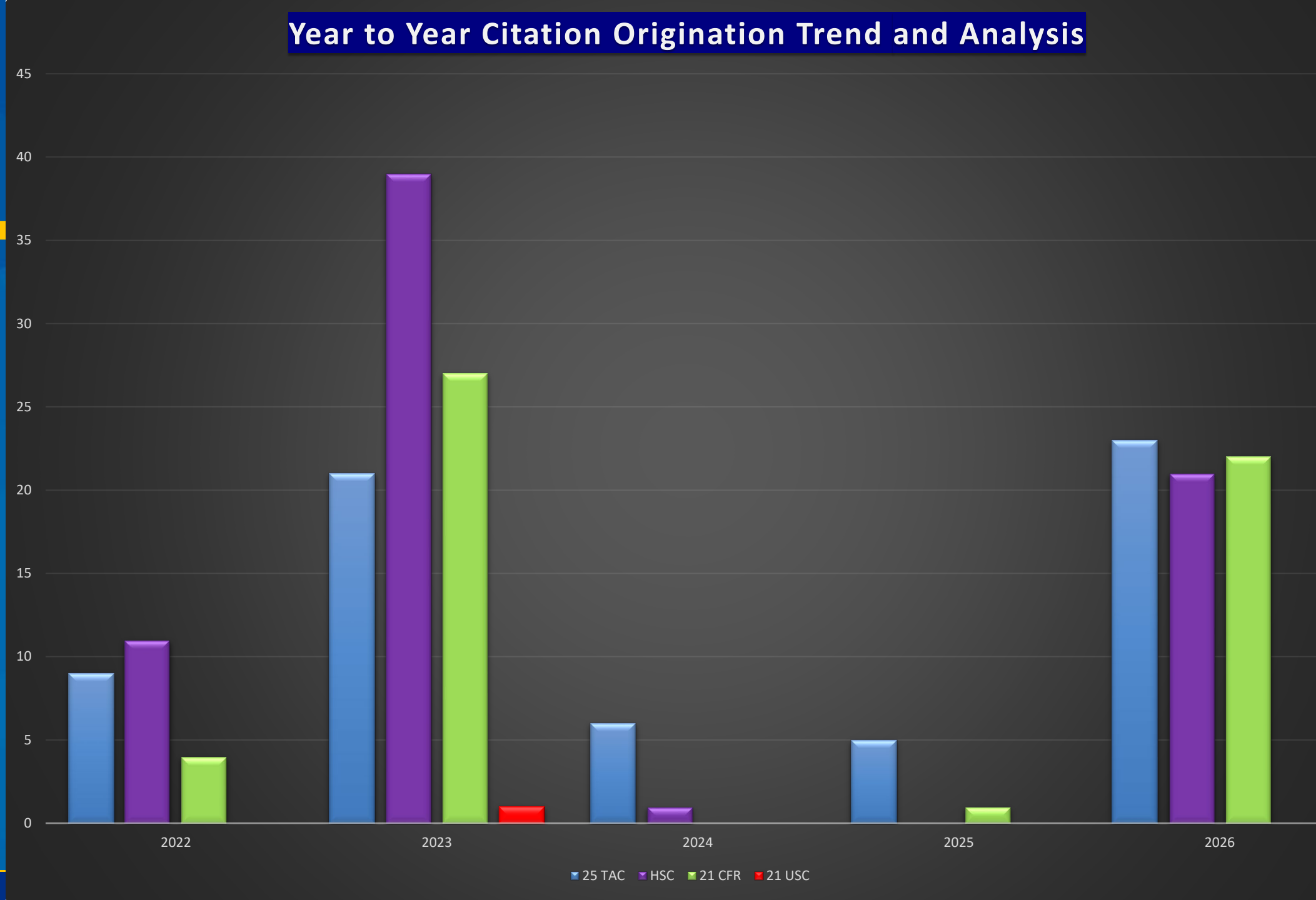
CITATIONS FOR FY22,FY23,FY24,FY25 & FY26



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Year to Year Citation Origination Trend and Analysis



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Thank You