

Introduction to the Regulatory Process

2025 HEALTH POLICY ACADEMY

April 10, 2025

Session 2

Moderator



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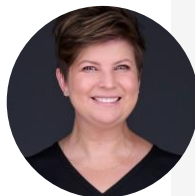
Speakers



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Stay in Touch

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Now What?



Not As Famous, but Still Very Important!



FEDERAL REGISTER

The Daily Journal of the United States Government



Implementation of Statutory Authority

Statutory
Authority
(new or
existing)



Regulations

- Published in the Code of Federal Regulations
- More granular details than the statute
- Carry the force of law
- ***e.g., Physician Fee Schedule, Notice of Benefits and Payment Parameters***

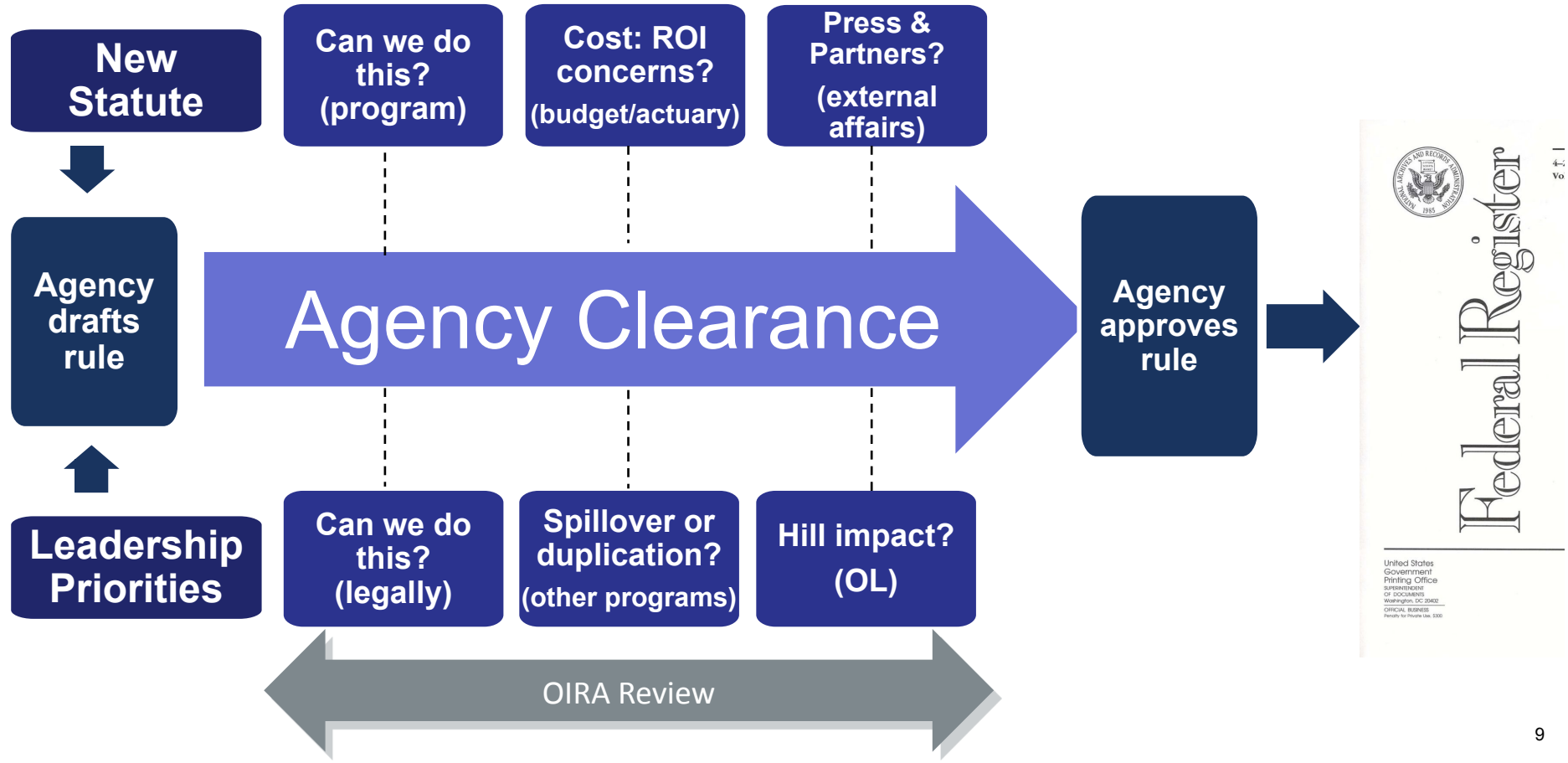
Guidance

- Published by the agency
- Do not have the force of law (subregulatory)
- Describe agency thinking about regulations
- ***e.g., Medicare Drug Price Negotiation Program***

Waivers & Demonstrations

- Temporary flexibility to test new approaches
- May or may not become permanent
- ***e.g., Medicare Diabetes Prevention Program (MDPP) Expanded Model***

Overview of Agency Clearance Process



Who Else Gets Involved?



Stay in Touch

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Regulatory Process at HHS

Jeremy Sharp – Waxman Strategies

April 10, 2025

HHS Agencies

- Most action is at the agency level
- Each agency has its own “personality”
- Very different ways of implementing policy
- Based on very different legal authorities



HRSA
Health Resources & Services Administration



SAMHSA
Substance Abuse and Mental Health
Services Administration



ATSDR



ASPR

ADMINISTRATION FOR
CHILDREN & FAMILIES

How do HHS agencies work with the rest of the government?

HHS

- Initiates some new policies
- Oversees agency implementation
- Engages WH/OMB
- Reviews & signs off
- Convenes and drives collaboration

White House/OMB

- Drives implementation of Presidential priorities
- Facilitates gov't wide clearance process
- Reviews and signs off
- Convenes and drives collaboration

Other Gov't or Other HHS Agencies

- Reviews some policies
- Collaborate when expertise & authority needed or implicated

How and when to engage?

Informal v. formal decision-making processes

Agency driven policy v. HHS or White House driven policies

Limits on communications during formal regulatory processes

Use of stakeholders

Relationships, relationships, relationships



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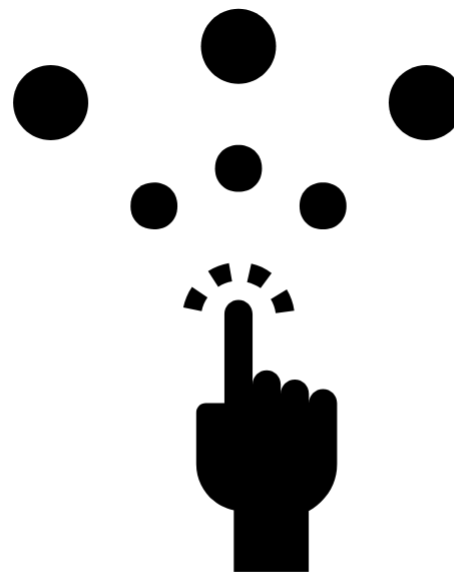
2025 Health Policy Academy

Panel #2: Introduction to the Regulatory Process

Kristi Martin, Director, Camber Collective

Agency and Hill Interactions

- The US Department of Health and Human Services (HHS) has many entry points for engagement with Hill staffers
 - Office of the Assistant Secretary of Legislation (ASL)
 - Agency Offices of Legislation (OL)
- These executive offices can provide facilitate communication between HHS and Capitol Hill and can serve as key points of contact
- Interactions between ASL, OLs, and Hill offices can take many forms, including correspondence, technical assistance, updates on implementation, etc.
- Important to build relationships



Created by Kamin Ginkaew
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What's the Difference Between ASL and OL?

There are different reasons you may go to the Department's ASL and an agency's OL

- Primary link between Office of Secretary and Congress
 - Staffed by political appointments
 - Supports Department's legislative agenda
 - Grant and contract notification system to Congress
 - Notifying and coordinating with Congress regarding the Secretary's travel and event schedule
 - Coordinate budget distribution and briefings
 - Prepares witnesses and testimony for Congressional hearings
 - Coordinate audits for the Department, including GAO
- Primary link between individual Agency/Operating Division and Congress
 - Staffed by career civil servants
 - Technical assistance on bills
 - Tracks, evaluates and develops provisions of annual legislative proposals for agency
 - Coordinates activities with ASL and serves as the ASL's principal contact point on legislative and Congressional relations
 - Coordinates agency's participation in Congressional hearings except Appropriations Committee hearings specifically on the appropriation budget
 - Coordinate audits for the agency, including GAO and OIG

Office of the Assistant Secretary for Legislations

Agency Office of Legislation

Deeper Dive into Types of Engagements

Correspondence



- Public letter
- Written response
- Goes through clearance process
- Coordinated by ASL and/or OL depending on who the letter is addressed to

Technical Assistance



- Confidential
- Provides feedback on operations and interaction affects from agency SMEs
- Generally provided as written feedback
- Coordinated by OL

Staff Briefings



- Confidential
- Updates on program implementation from agency SMEs
- Provides opportunity for questions
- Coordinated by OL

Moderated Q&A

Thank you!
