

HEALTH POLICY ACADEMY 2023

Introduction to Regulatory Process

Session 3



ALLIANCE
FOR HEALTH POLICY



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John O'Brien, PharmD, MPH

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Now what?



Not as famous, but still very important!



FEDERAL REGISTER

The Daily Journal of the United States Government



30
YEARS

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*

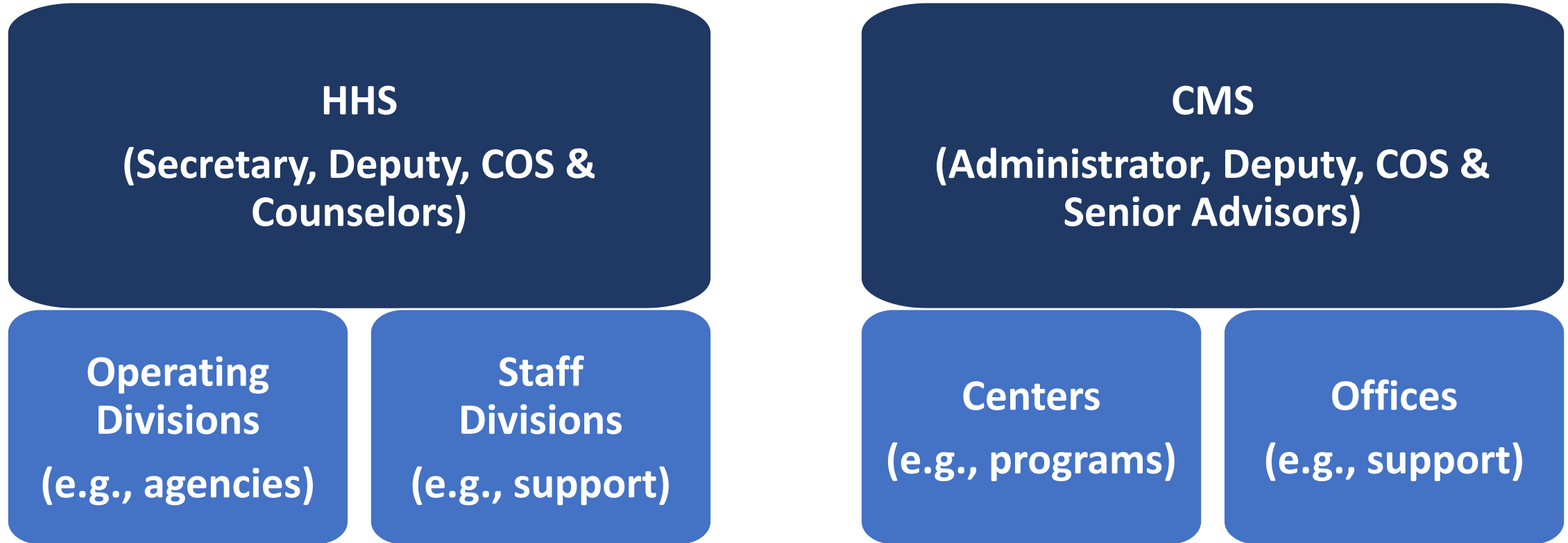
Guidance

- Published by the agency
- Do not have the force of law (subregulatory)
- Describe agency thinking about regulations
- *e.g., Medicare Claims Processing Manual, Qualified Health Plan FAQ*

Waivers & Demonstrations

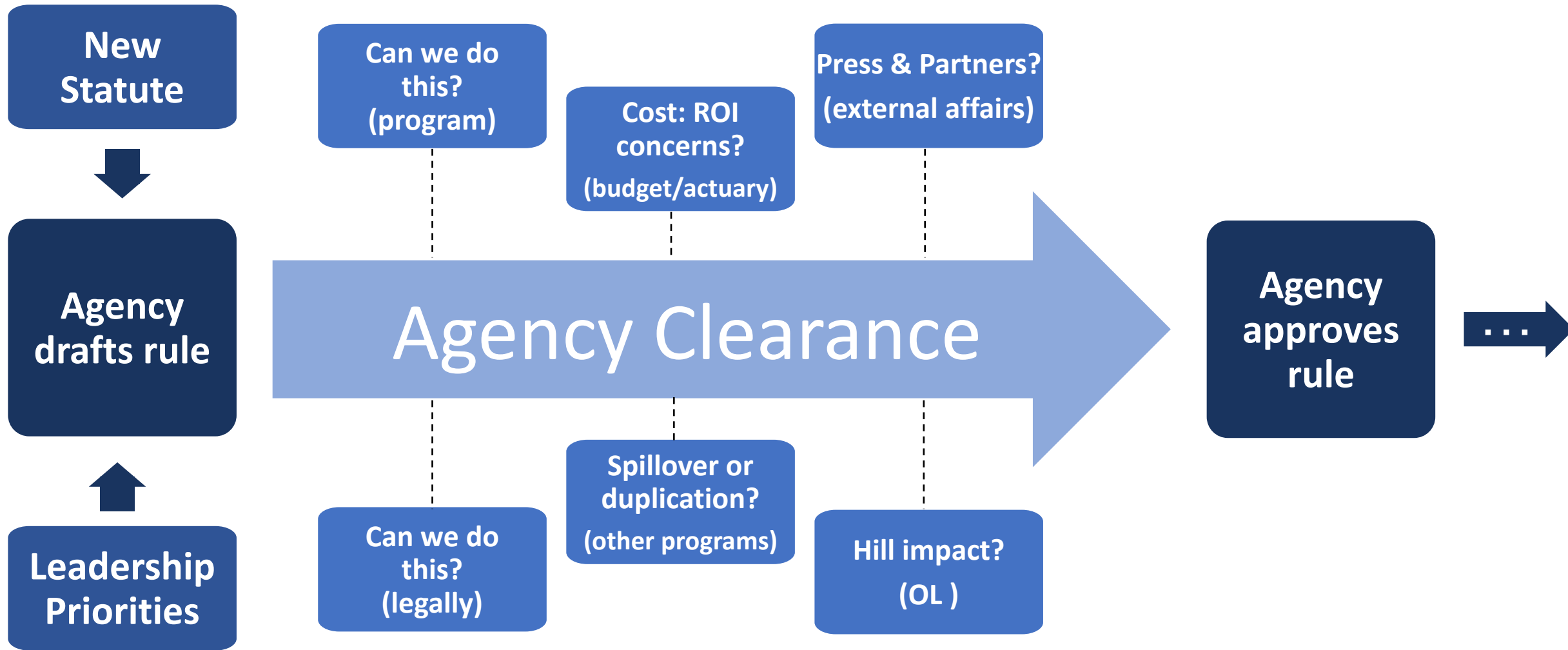
- Temporary flexibility to test new approaches
- May or may not become permanent
- *e.g., ACO REACH, "Community Engagement"*

Understanding Department and Agency Structure



1. The Department of Health & Human Services and HHS agencies typically each have their own legal counsel and experts in financing, external affairs, and legislative affairs
2. Most agency staff are career civil servants, not political appointees

Overview of Agency Clearance Process





Sara Singleton, MPH

Principal

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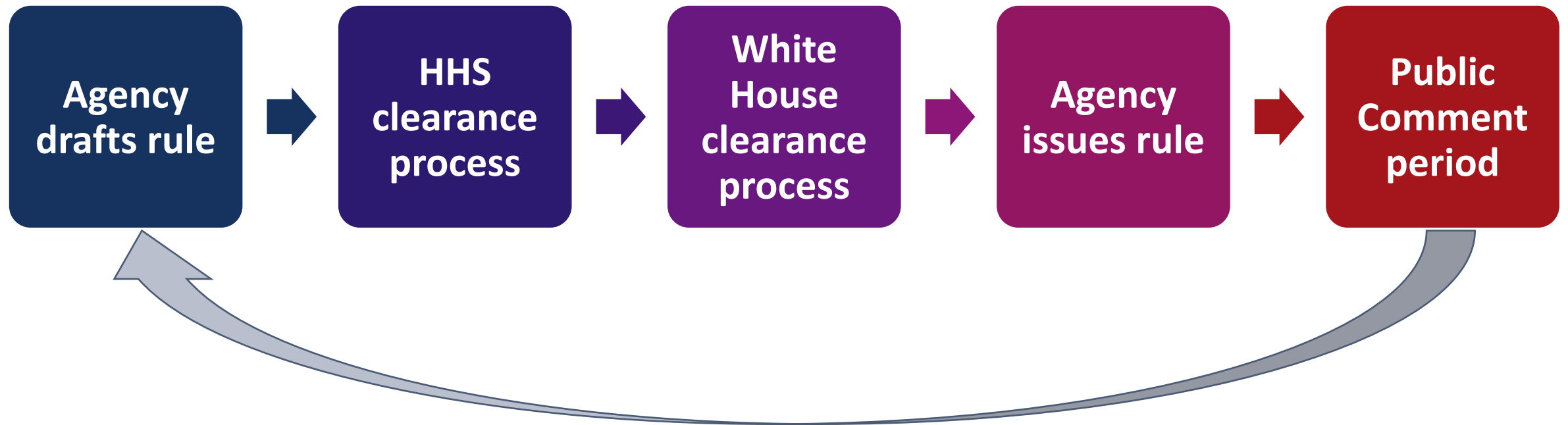
Alliance for Health Policy

INTRO TO THE REGULATORY PROCESS

SARA SINGLETON

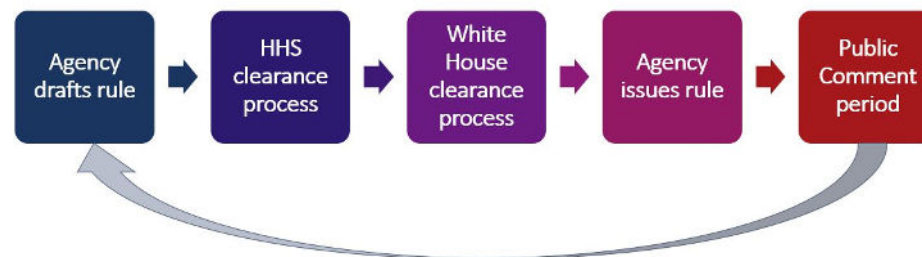


Overview of Regulatory Clearance Process



HHS Clearance Process

- HHS Exec Sec sends rule to:
 - Offices within OS
 - All relevant HHS agencies
- Exec Sec receives back all comments.
- Works with Counselor and other necessary parties to resolve disputes



HHS Agencies



ADMINISTRATION FOR
CHILDREN & FAMILIES



The Office of the National Coordinator for
Health Information Technology



HHS Clearance Process

Key Players in the Office of the Secretary:



Additional OS offices such as Office for Civil Rights, Office of Global Affairs, Office of the National Coordinator of Health Information Technology may also be involved in reviewing or issuing rules

White House Clearance Process

- Office of Secretary (Exec Sec) sends rule to Office of Management and Budget which sends it out for review to:
 - Office of Information and Regulatory Affairs
 - Domestic Policy Council
 - White House Counsel
 - Office of Science and Technology Policy
 - Council of Economic Advisors
 - National Economic Council
 - Other relevant departments
- Counselor/White House adjudicate disagreements that arise in review



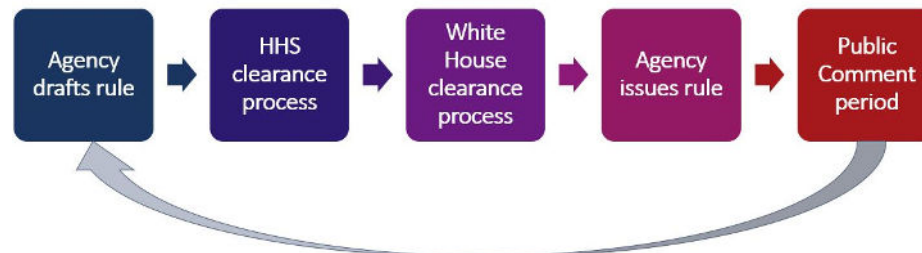
Agency Issues Rule

- Rule is published in the federal register for inspection
- Usually a Notice of Proposed Rulemaking; in certain circumstances an Interim Final Rule
- “Significant” rules must include estimate of costs and benefits and alternate solutions
- Preamble is an important portion of the rule to read to understand intent and additional detail



Public Comment Period

- Comment period usually between 30-60 days; sometimes as long as 180
- Sometimes agency may hold public hearings/meeting during comment period
- Agency must consider, and respond to (but not adopt) all comments that are submitted
- Decisions are not based on the number of comments on any side of an issue
- Agency then decides to open an additional comment period, terminate rulemaking, change based on “logical outgrowth”, or issue final similar to proposed





Jeremy Sharp
Managing Director
Waxman Strategies

HHS Interagency Process

Jeremy Sharp – Waxman Strategies

April 14, 2023

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



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

Moderated Q & A