

# THE HEALTH REGULATORY PROCESS

Prof. Jessica Mantel

# HIPAA

*Each [covered entity (i.e., health plan, health care clearinghouse, and health care provider)] who maintains or transmits health information shall maintain reasonable and appropriate administrative, technical, and physical safeguards*

*(A) to ensure the integrity and confidentiality of the information;*

*(B) to protect against any reasonably anticipated—*

*(i) threats or hazards to the security or integrity of the information; and*

*(ii) unauthorized uses or disclosures of the information; and*

*(C) otherwise to ensure compliance with this part by the officers and employees of such person.*

Section 1172(d)(2) of the Social Security Act

*Standard: Disclosures for judicial and  
administrative proceedings*

*A covered entity may disclose protected health information . . . in response to a subpoena, discovery request, or other lawful process, that is not accompanied by an order of a court or administrative tribunal, if:*

- (A) The covered entity receives satisfactory assurance . . . from the party seeking the information that reasonable efforts have been made by such party to ensure that the individual who is the subject of the protected health information that has been requested has been given notice of the request; or*
- (B) The covered entity receives satisfactory assurance . . . from the party seeking the information that reasonable efforts have been made by such party to secure a qualified protective order . . . .*

*Standard: Uses and disclosures for research purposes*

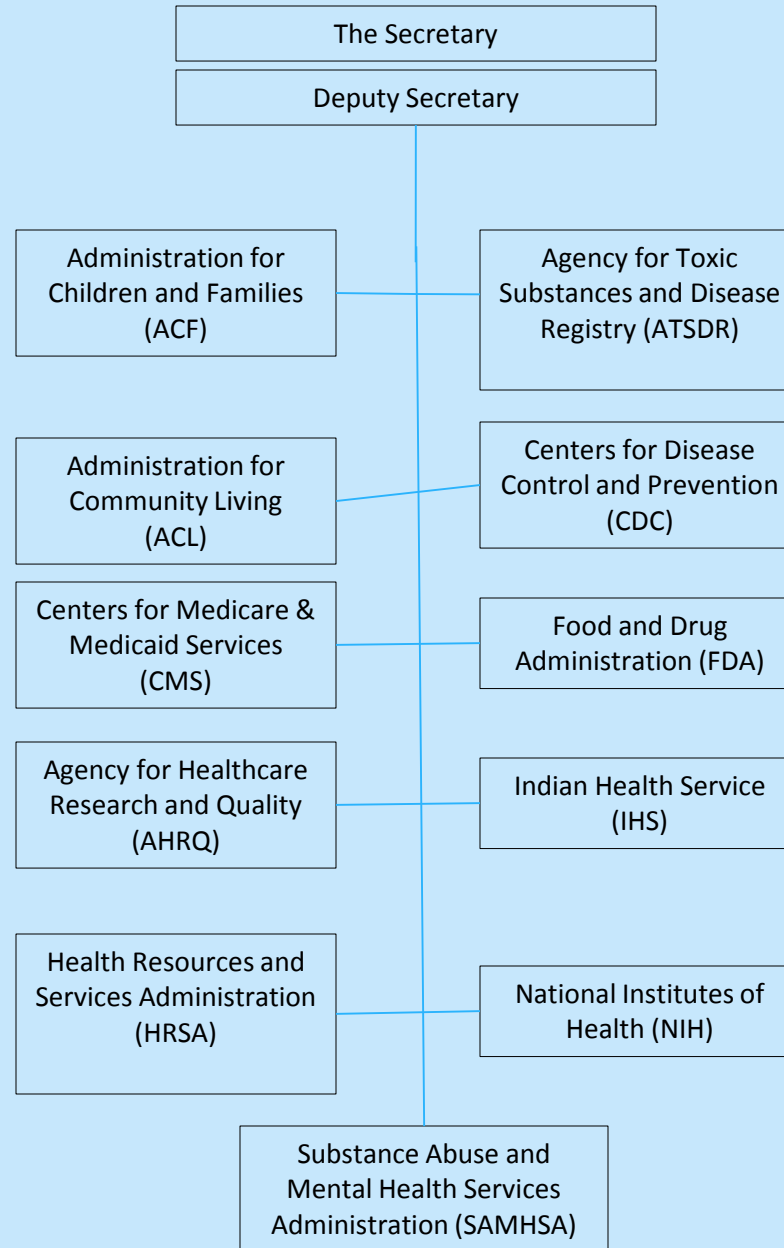
*A covered entity may use or disclose protected health information for research . . . provided that . . . the covered entity obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by Sec. 164.508 for use or disclosure of protected health information has been approved by either:*

*(A) An Institutional Review Board (IRB); or*

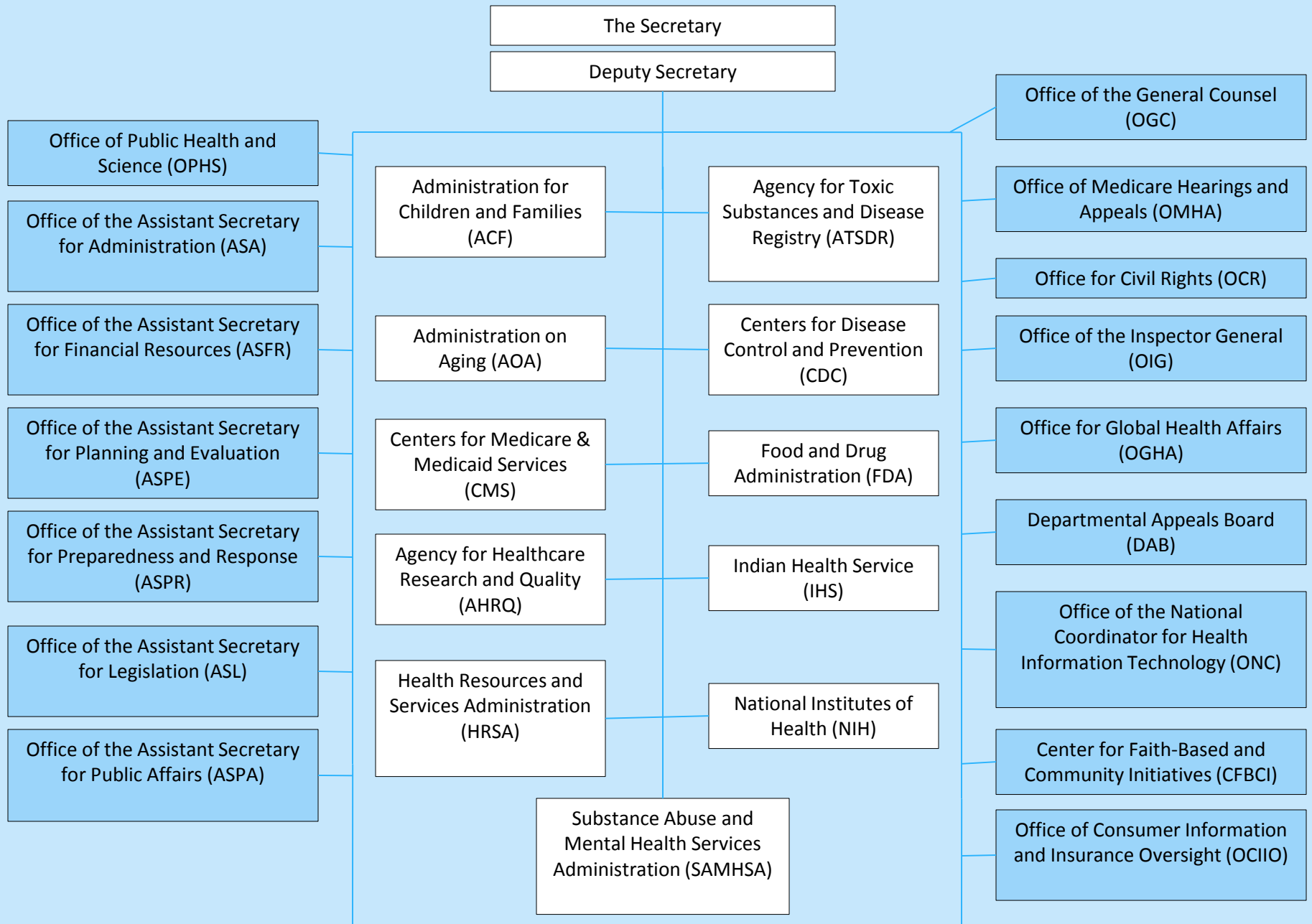
*(B) A privacy board . . . .*

42 C.F.R. § 164.512(i)

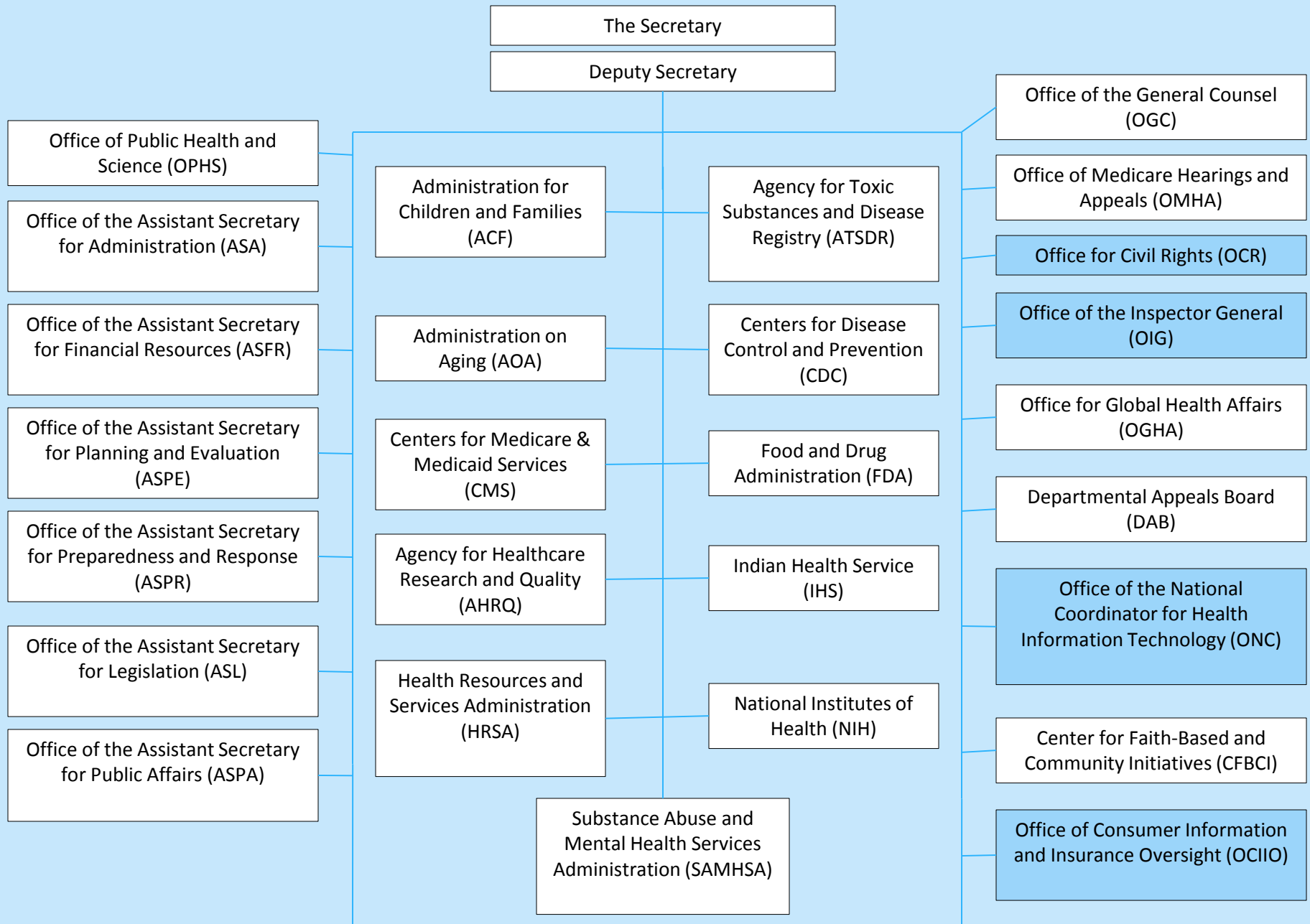
# HHS Agencies



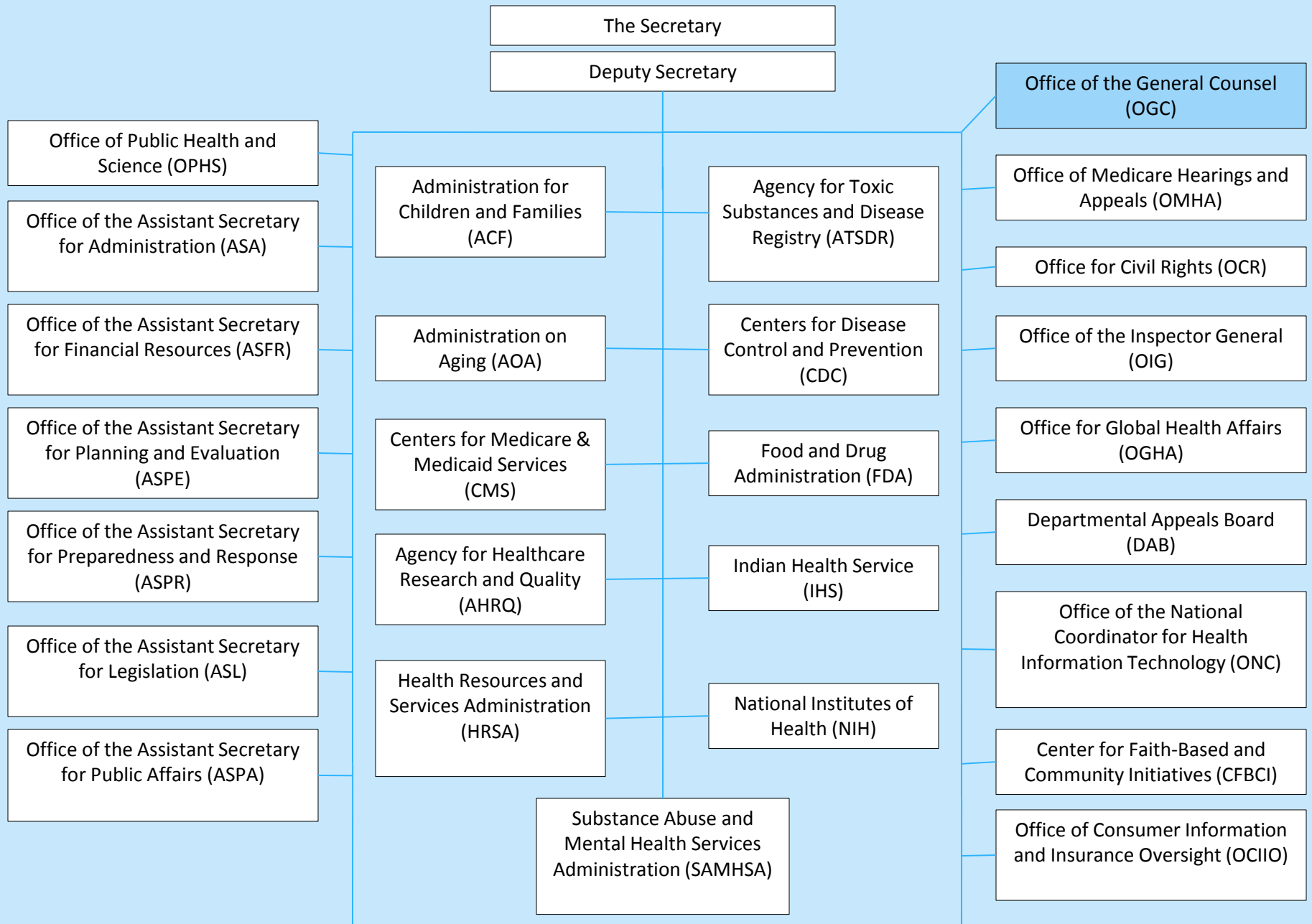
# HHS Organizational Chart



# HHS Organizational Chart



# HHS Organizational Chart





# **OTHER FEDERAL ‘HEALTH’ AGENCIES**

- Veterans Administration (VA) and Department of Defense (DOD)
- Environmental Protection Agency (EPA)
- Occupational Safety and Health Administration (OSHA)
- Department of Labor (DOL)
- Department of Homeland Security

# **STATE AND LOCAL HEALTH AGENCIES**

- State and Local Health Departments
- Board of Medicine
- Department of Welfare
- Department of Insurance

# Sources of Government Regulation

- (1) Statutes (Congress/Statute legislature)
- (2) Regulations (Government agency)
- (3) Agency guidance (Government agency)

# Regulations

Defined: A rule issued by an agency have the force and effect of law

Process: Notice and Comment Rulemaking

1. Notice of Proposed Rulemaking
2. Public comments
3. Final Rule

Where Located?: Code of Federal Register (CFR)

# Guidance

Defined: Publications that communicate agency's interpretation of relevant statutes and regulations.

- Clarifies ambiguity in a statute/regulation
- Signals how agency intends to implement/enforce a statute/regulation
- Agency's opinion on how a statute/regulation applies to specific scenario

Legal Effect: Does not have the force and effect of law, but may be practically binding

Where Located?: All over

- Agency web site
- Notices published in Federal Register
- Preamble (i.e., discussion section) of Final Rule
- Manuals guiding regulated entities
- Manuals guiding agency personnel

\*Lawyers should always review relevant agency guidance before advising client!