



**Department
of Health**

NYS Regulatory Process Overview

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DOH's Legal Authority to Issue Regulations

- NYS Constitution empowers the NYS Legislature to enact laws on public health (NYS Constitution, Article 17, Section 3)
- NYS Legislature has enacted the Public Health Law (PHL) and various unconsolidated laws (“statutes”).
- The PHL creates the NYS Department of Health (DOH) and defines DOH’s authorities, and various PHL sections empower DOH to issue regulations.
- DOH’s power to regulate is a delegation of lawmaking power from the Legislature: **when DOH issues a regulation, it must ensure that the regulation is within its delegated authority.** Thus, each proposed regulation’s statutory authority must be analyzed.



DOH's Legal Authority to Issue Regulations

- Is it a “Commissioner’s regulation” or a “Council Regulation”?
 - It depends on the regulation’s statutory authority, not where the regulation is located.
 - DOH has grouped regulations together for simplicity
 - State Sanitary Code; 10 NYCRR Parts 405 (hospitals), 415 (nursing homes)
 - When choosing a place for a new regulation, sometimes it is not clear whether it is a Commissioner’s regulation or PHHPC regulation
 - Ex. PHL 2805-T General Hospital Clinical Staffing Committees

DOH's Legal Authority to Issue Regulations

- As a general matter, PHHPC adopts regulations relating to the State Sanitary Code, health care facilities, and health care agencies, subject to approval by the Commissioner of Health.
 - [PHL 225](#) provides PHHPC broad regulatory authority, by affirmative vote of a majority of its members, to establish, amend and repeal the State Sanitary Code.
 - [PHL 2803](#) provides PHHPC authority, by a majority vote of its members, to adopt and amend regulations pertaining to Article 28 of the PHL, which governs hospitals.

How a Regulation is Developed

1. Program staff draft a regulatory package, working along side their DLA assigned attorney and then submit the package for internal DOH approvals
2. Program obtains Office level approvals
3. DLA's Bureau of Program Counsel reviews and approves
4. General Counsel's Office reviews and approves
5. Commissioner's Office approval
6. Department of State Regulatory Review Unit (RRU)
7. Executive Chamber



How a Regulation is Developed

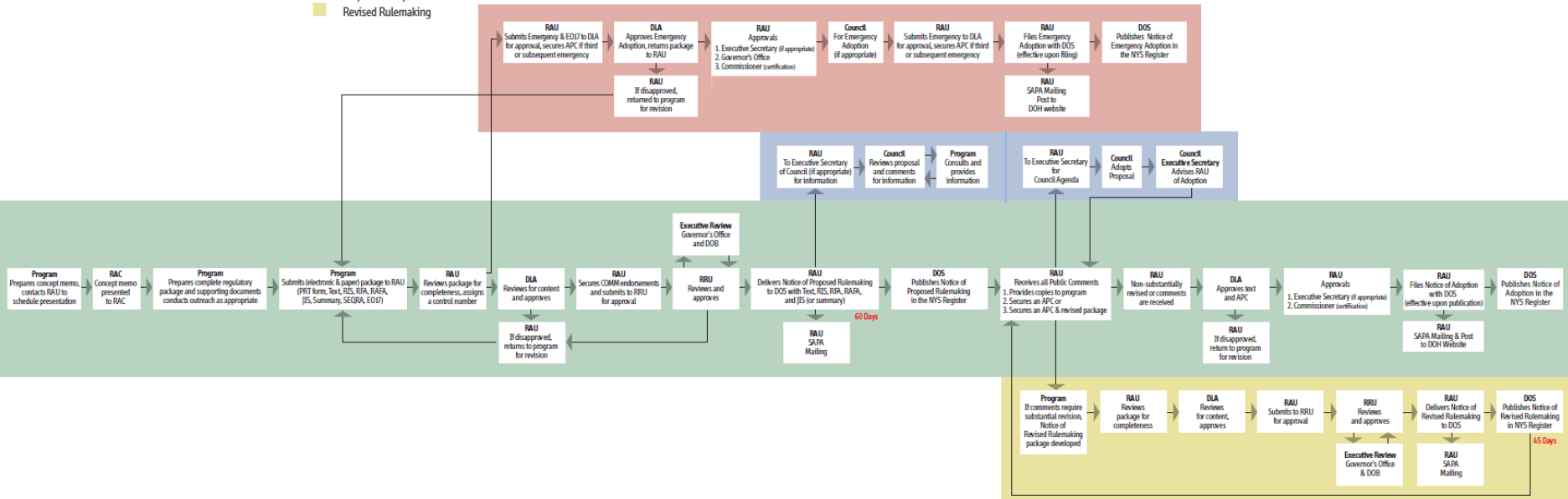
What happens next depends on whether:

- Commissioner vs. PHHPC/Council Regulations
- “Regular” vs. Emergency Regulations
- Revised Rulemaking
 - Substantial Revisions vs. Technical Changes
- Consensus Rulemaking

New York State Department of Health Rulemaking Process

RRU Regulatory Review Unit (Division of Budget)
 DLA Division of Legal Affairs
 COMM Commissioner
 RAU Regulatory Affairs Unit (DLA/DOH)
 DOS Department of State
 APC Assessment of Public Comment
 EO17 Executive Order 17
 RAC Regulatory Advisory Committee (DOH)

Emergency Adoption
 Council Adoption
 Proposed Adoption
 Revised Rulemaking



Committees and Councils

- Regulatory Advisory Committee (RAC)*
- Committee on Codes, Regulations and Legislation (Codes Committee)
- Public Health and Health Planning Council (PHHPC)

State Administrative Procedure Act (SAPA)

Contains both procedural and substantive requirements for rulemaking in order to provide regulated parties with simple, uniform administrative procedures.

The statute contains the elements for each of the SAPA documents which include:

- Rule Text
- Regulatory Impact Statement (RIS)
- Regulatory Flexibility Analysis for Small Businesses and Local Governments (RFASBLG)
- Rural Area Flexibility Analysis (RAFA)
- Job Impact Statement (JIS).

*The rule package should also include the Executive Order No. 17 Fiscal Checklist.



**Division of
the Budget**

SAPA Continued

Each agency shall strive to ensure that, to the maximum extent practical, its rules, regulations and related documents are written in a clear and coherent manner, using words with common and everyday meanings.

SAPA § 201

DOH Resources

Rules, Regulations, and Laws

<http://www.health.ny.gov/regulations/>

PHHPC Calendar and Information

https://www.health.ny.gov/facilities/public_health_and_health_planning_council/



The screenshot shows the New York State Department of Health website. At the top is the New York State logo. Below it is a navigation bar with links for Services, News, Government, and Local. A purple banner contains the Department of Health logo and links for Individuals/Families, Providers/Professionals, and Health Facilities. The main content area lists several categories: Rules, Regulations, & Laws; Executive Orders (with a link to Limits on Administrative Expenses and Executive Compensation); Project Sunlight Reporting (with a link to Project Sunlight Reporting); Research Compliance (with a link to Research Compliance); and Rules & Regulations (with links to Title 10 (Health), Title 18 (Social Services), Regulatory Agenda (NYS Department of Health), and Three, Five, Ten and Fifteen Year Regulation Review).

NEW YORK STATE

Services News Government Local

Department of Health Individuals/Families Providers/Professionals Health Facilities

You are Here: [Home Page](#) > Rules, Regulations, & Laws

Rules, Regulations, & Laws

Executive Orders

- [Limits on Administrative Expenses and Executive Compensation](#)

Project Sunlight Reporting

- [Project Sunlight Reporting](#)

Research Compliance

- [Research Compliance](#)

Rules & Regulations

- [Title 10 \(Health\)](#)
- [Title 18 \(Social Services\)](#)
- [Regulatory Agenda \(NYS Department of Health\)](#)
- [Three, Five, Ten and Fifteen Year Regulation Review](#)

DOS Resources

- Rulemaking Manual

https://dos.ny.gov/system/files/documents/2021/08/rulemakingmanual_08-21.pdf

- Rulemaking forms and format guidance documents

<https://dos.ny.gov/e-filing-rule-making-notice>



- State Register *submission and publication deadlines* (and to access archived Register publications) <https://www.dos.ny.gov/info/register.htm>
- **19 NYCRR § 261.4** Outline Style: Contains the specific numbering, lettering, order and layout of any rule to be published by DOS for the Official Compilation of Codes, Rules and Regulations.

Questions?