

RULEMAKING 101

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Rulemaking is governed by the Administrative
Procedure Act, Title 5, c. 375

Two major purposes of this presentation:

1. What to remember when granting rulemaking authority during the writing or consideration of legislation.
2. Committee process for reviewing a major substantive rule.

WHAT IS A RULE?

Definition of “Rule”

Title 5, section 8002, subsection 9:

9. Rule. "Rule" is defined as follows.

A. "Rule" means the whole or any part of every regulation, standard, code, statement of policy, or other agency guideline or statement of general applicability, including the amendment, suspension or repeal of any prior rule, that is or is intended to be judicially enforceable and implements, interprets or makes specific the law administered by the agency, or describes the procedures or practices of the agency.

** Rules and regulations are the same thing but we use the term “rule” in Maine.

Law is above rule

Statute always supersedes rule. If there is a disagreement between a law and a rule, the statute governs. Rules must comply with the law.

**This gets its own slide because it's a super-important concept!

Two categories of rules have existed
since January 1, 1996 (revision of APA)
Title 5, section 8071, subsection 2

Routine technical rules are procedural rules that establish standards of practice or procedure for the conduct of business with or before an agency and any other rules that are not major substantive rules as defined in paragraph B. Routine technical rules include, but are not limited to, forms prescribed by an agency; they do not include fees established by an agency except fees established or amended by agency rule that are below a cap or within a range established by statute.

Major substantive rules are rules that, in the judgment of the Legislature:

- (1) Require the exercise of significant agency discretion or interpretation in drafting; or
- (2) Because of their subject matter or anticipated impact, are reasonably expected to result in a significant increase in the cost of doing business, a significant reduction in property values, the loss or significant reduction of government benefits or services, the imposition of state mandates on units of local government as defined in the Constitution of Maine, Article IX, Section 21, or other serious burdens on the public or units of local government.

**Rules adopted prior to January 1, 1996 are routine technical.

**Legislative discretion applies.

Major Substantive Rules are subject to
review by the Legislature
Title 5, section 8071, subsection 3

3. Levels of rule-making process. In order to provide for maximum agency flexibility in the adoption of rules while retaining appropriate legislative oversight over certain rules that are expected to be controversial or to have a major impact on the regulated community, each agency rule authorized and adopted after January 1, 1996 is subject to one of 2 levels of rule-making requirements.

- A. Routine technical rules are subject to the rule-making requirements of subchapter II only.
- B. Major substantive rules are subject to the requirements of section 8072. After January 1, 1996, any grant of general or specific rule-making authority to adopt major substantive rules is considered to be permission only to provisionally adopt those rules subject to legislative review. Final adoption may occur only after legislative review of provisionally adopted rules as provided in section 8072.

The establishment or amendment of an agency fee by rulemaking is a major substantive rule, except for the establishment or amendment of a fee that falls under a cap or within a range set in statute, which is a routine technical rule.

Examples of routine technical rules

Title 22, §3790-A. Higher Opportunity for Pathways to Employment Program (excerpt only)

1. Program established. The department shall establish a student financial aid program based on need to be known as the Higher Opportunity for Pathways to Employment Program, referred to in this chapter as "the program," for a parent or caretaker relative of a minor child who is qualified to receive federal Temporary Assistance for Needy Families funds but does not receive Temporary Assistance for Needy Families cash assistance pursuant to chapter 1053-B and is matriculating in an education or training program, or is enrolled in a program providing remedial services necessary for the parent or caretaker relative to matriculate, that results in a high-value, industry-recognized certificate or similar credential, a postsecondary undergraduate 2-year degree or a postsecondary undergraduate 4-year degree in a health care, technology or engineering field. **The department shall specify the health care, technology and engineering fields for the postsecondary undergraduate 4-year degree in department rules.**

Enrollment in the program may not exceed 500 participants. To administer the program, the department may not divert funding from assistance and support services to families under the Temporary Assistance for Needy Families program pursuant to chapter 1053-B or from the operation of the Additional Support for People in Retraining and Employment - Temporary Assistance for Needy Families program pursuant to chapter 1054-A. If the commissioner reasonably anticipates that available funds will not support continued operation of the program, the commissioner shall limit or suspend enrollment or program services to the extent necessary to avoid negative effects to services provided under chapters 1053-B and 1054-A.

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6. Rules. **The department shall adopt rules to implement this section. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.**

Another routine technical example

Title 22, §1341. Hypodermic apparatus exchange programs

1. Certification of programs. The Maine Center for Disease Control and Prevention may certify hypodermic apparatus exchange programs that meet the requirements established by rule under subsection 2, paragraphs A to D.

A. The Maine Center for Disease Control and Prevention may not limit the number of hypodermic apparatuses provided by the programs to participants. B. The Maine Center for Disease Control and Prevention may not limit the number of hypodermic apparatuses that participants served by the programs may legally possess, transport or exchange.

2. Rules. The Maine Center for Disease Control and Prevention shall adopt rules pursuant to the Maine Administrative Procedure Act establishing requirements for hypodermic apparatus exchange programs and for program certification requirements. The rules must include but are not limited to:

- A. Procedures for the safe disposal of hypodermic apparatuses;
- B. Tracking the number of hypodermic apparatuses distributed and collected;
- C. Substance use disorder prevention and treatment education;
- D. Distribution of educational material regarding the dangers associated with the use of used hypodermic apparatuses;
- E. Application procedures for a certified hypodermic apparatus exchange program to apply for funds to operate the program including the purchase and disposal of hypodermic needles;
- F. Criteria for the award of funds to certified hypodermic apparatus exchange programs;
- G. Oversight of certified hypodermic apparatus exchange programs;
- H. Renewal every 5 years of department certification of hypodermic apparatus exchange programs;
- I. Complaint investigation procedures; and
- J. Criteria for decertification of hypodermic apparatus exchange programs.

Rules adopted or amended pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

A different sort of routine technical example

Title 22 (PMP) §7254. Exemption from opioid medication limits until January 2017; rulemaking

1. Exemption until January 2017. In addition to the exceptions established in Title 32, section 2210, subsection 2; section 2600-C, subsection 2; section 3300-F, subsection 2; section 3657, subsection 2; and section 18308, subsection 2, a licensed health care professional may prescribe opioid medication in an amount greater than the morphine milligram equivalents limited by Title 32, sections 2210, 2600-C, 3300-F, 3657 and 18308 as long as it is medically necessary and the need is documented in the patient's chart.

This subsection is repealed January 1, 2017 or on the effective date of the rules establishing exceptions to prescriber limits as provided in subsection 2, whichever is later. The Commissioner of Health and Human Services shall notify the Secretary of State, Secretary of the Senate, Clerk of the House of Representatives and Revisor of Statutes of this effective date when this effective date is determined.

2. Rulemaking. Notwithstanding section 7252, no later than January 1, 2017, the department shall adopt routine technical rules as defined in Title 5, chapter 375, subchapter 2-A to establish reasonable exceptions to prescriber limits in Title 32, sections 2210, 2600-C, 3300-F, 3657 and 18308, including for chronic pain and acute pain. **The rules must take into account clinically appropriate exceptions and include prescribers in the rule-making process including the drafting of draft rules and changes after the public hearing process to the extent permitted by Title 5, chapter 375. After July 1, 2017, any rules adopted by the department pursuant to this section are governed by section 7252.**

General grant of rulemaking authority to DHHS

Title 22, Ch. 1, Department of Health and Human Services; sub-ch. 2, Administration

§42. Rules and regulations

- 1. General.** The department shall issue rules and regulations considered necessary and proper for the protection of life, health and welfare, and the successful operation of the health and welfare laws. The rules and regulations shall be adopted pursuant to the requirements of the Maine Administrative Procedure Act.

**This section was enacted in 1977 so rules adopted pursuant to this section are routine technical. This is an oft-cited statutory authority on DHHS rules.

**We always write the standard rulemaking language that you have seen many times already in this presentation:

Rules adopted or amended pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A

Examples of major substantive rules

Title 32, c. 143, Dental Professions, §18391. Amalgam brochures; posters

1. Brochure; poster. The Director of the Bureau of Health within the Department of Health and Human Services shall develop a brochure that explains the potential advantages and disadvantages to oral health, overall human health and the environment of using mercury or mercury amalgam in dental procedures. The brochure must describe what alternatives are available to mercury amalgam in various dental procedures and what potential advantages and disadvantages are posed by the use of those alternatives. The brochure may also include other information that contributes to the patient's ability to make an informed decision when choosing between the use of mercury amalgam or an alternative material in a dental procedure, including, but not limited to, information on the durability, cost, aesthetic quality or other characteristics of the mercury amalgam and alternative materials. The director shall also develop a poster that informs patients of the availability of the brochure.

The Director of the Bureau of Health shall, in consultation with the Department of Environmental Protection, adopt the brochure and the poster described in this subsection through major substantive rules pursuant to Title 5, chapter 375, subchapter 2-A.

2. Display. A dentist who uses mercury or a mercury amalgam in any dental procedure shall display the poster adopted by the Department of Health and Human Services, Bureau of Health under this section in the public waiting area of the practice setting and shall provide each patient a copy of the brochure adopted by the bureau under this section. The Department of Health and Human Services shall also post on its publicly accessible website a copy of the brochure that is suitable for downloading and printing by dentists, patients and other interested parties.

More major substantive examples

Title 22, §3174-Z. Private, nonmedical and board and care institutions

Rules concerning the principles for reimbursement for private, nonmedical and board and care institutions must be **major substantive rules** as defined in Title 5, chapter 375, subchapter II-A.

Title 22, c. 1603, CONTROLLED SUBSTANCES PRESCRIPTION MONITORING

§7252. Rulemaking

The department may adopt rules necessary to implement the provisions of this chapter. Rules adopted pursuant to this section are **major substantive rules** as defined in Title 5, chapter 375, subchapter 2-A.

****Note earlier slide for routine technical rulemaking provision (adopted for a temporary purpose to avoid a full major substantive rulemaking):**

§7254, sub- §2

Rulemaking. Notwithstanding section 7252, no later than January 1, 2017, the department shall adopt routine technical rules as defined in Title 5, chapter 375, subchapter 2-A to establish reasonable exceptions to prescriber limits in Title 32, sections 2210, 2600-C, 3300-F, 3657 and 18308, including for chronic pain and acute pain. The rules must take into account clinically appropriate exceptions and include prescribers in the rule-making process including the drafting of draft rules and changes after the public hearing process to the extent permitted by Title 5, chapter 375.

After July 1, 2017, any rules adopted by the department pursuant to this section are governed by section 7252.

Mixed routine technical and major substantive

Title 22, c. 1673 Child Care Facilities, §8302-A. Rules for child care facilities and family child care providers

1. **Rules for child care facilities.** Rules for child care facilities must include, but are not limited to, rules pertaining to the following:

- A. Child to staff ratios;
- B. The health and safety of the children and staff, including training on communicable diseases;
- C. Water for drinking and cooking;
- D. Wastewater;
- E. Rabies vaccinations for pets;
- F. The quality of the program provided;
- G. Rp
- H. The administration of medication;
- I. Licensing procedures; and

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J. Requiring a criminal background check that meets the requirements of 42 United States Code, Section 9858f(b) for each child care staff member. For the purposes of this paragraph, "child care staff member" means an individual:

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- (1) Who is employed by a child care facility for compensation, including a contract employee or self-employed individual; or
- (2) Whose activities involve the care or supervision of children for a child care facility or unsupervised access to children who are cared for or supervised by a child care facility.

"Child care staff member" does not include an individual who is related to all children for whom child care services are provided or a contractor performing maintenance and repairs at the child care facility who does not have unsupervised access to children who are cared for or supervised by the child care facility.

Rules adopted pursuant to this subsection are routine technical rules pursuant to Title 5, chapter 375, subchapter 2-A, except that rules adopted pursuant to paragraph J to comply with 42 United States Code, Section 9858f(b) are major substantive rules pursuant to Title 5, chapter 375, subchapter 2-A.

Another example for child care...

2. Rules for family child care providers. Rules for family child care providers must include, and are limited to, rules pertaining to the following:

- A. Cardiopulmonary resuscitation;
- B. Water for drinking and cooking;
- C. Wastewater;
- D. Rabies vaccinations for pets;
- E. Recording the times, reasons and numbers of children involved when more than 12 children are cared for;
- F. Ongoing training for providers on health and safety issues, including training on communicable diseases. This training must be offered at times that are convenient to the providers;

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- G. Child to staff ratios;
- H. Health and safety of the children and staff;
- I. Procedures for waivers of rules and for suspension and revocation of certification; and
- J. Rp.
- K. Requiring a criminal background check that meets the requirements of 42 United States Code, Section 9858f(b) for a family child care provider and each child care staff member. For the purposes of this paragraph, "child care staff member" means an individual:

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- (1) Who is employed by a family child care provider for compensation, including a contract employee or self-employed individual;
- (2) Whose activities involve the care or supervision of children for a family child care provider or unsupervised access to children who are cared for or supervised by a family child care provider; or
- (3) Who is 18 years of age or older and who resides in the home of a family child care provider.

"Child care staff member" does not include an individual who is related to all children for whom child care services are provided or a contractor performing maintenance and repairs at the home of a family child care provider who does not have unsupervised access to children who are cared for or supervised by the family child care provider.

Rules adopted pursuant to paragraphs A to F are **routine technical rules** pursuant to Title 5, chapter 375, subchapter 2-A and rules adopted pursuant to paragraphs G to K are **major substantive rules** pursuant to Title 5, chapter 375, subchapter 2-A.

Process of proposing and adopting a rule

1. **Agency proposes a draft rule.** “Agency” is defined in statute in 5 MRSA §8002, sub-§9:

"Agency" means any body of State Government authorized by law to adopt rules, to issue licenses or to take final action in adjudicatory proceedings, including, but not limited to, every authority, board, bureau, commission, department or officer of the State Government so authorized; but the term does not include the Legislature, Governor, courts, University of Maine System, Maine Maritime Academy, community colleges, the Commissioner of Education for schools of the unorganized territory, school administrative units, community action agencies as defined in Title 22, section 5321, special purpose districts or municipalities, counties or other political subdivisions of the State.

2. **Fact sheet preparation.** Preparation of the rule governed by §8057-A, sub-§§1, 2 and 4 and §8063-B. Agency must provide the following on a fact sheet:

- Statutory authority;
- Principal reasons for the rule;
- A comprehensive but concise description of the rule that accurately reflects the purpose and operation of the rule;
- Estimate of the fiscal impact of the rule;
- Analysis of the rule;
- A brief summary of the relevant information considered during the development of the rule;
- Primary sources of information relied on when developing the rule including professional judgment.

3. Public hearings. Public hearings are held if the agency believes it is useful, if required by statute, if it is a major substantive rule, or if it is requested by 5 people. If a public hearing is held, written statements can be provided up to 10 days of the hearing. If no public hearing is held, there is still a required comment period and notice required.

4. Notice (SoS site). Notice of proposed rules is required. This is coordinated through the Office of the Secretary of State. Notice must be provided 17-24 days before a public hearing and 30 days before a comment deadline and the notice must include:

- Statutory authority;
- Agency liaison information;
- Time and place of public hearing;
- Information of where, and in what form, to submit comments ;
- Substance of the rule;
- The small business impact.

5. Notice is provided to the Legislature (i.e. the legislative committee) at the same time. (In addition, the legislative committee receives notifications of emergency adoptions within 10 days, regulatory agenda, adopted rules and annual list of rulemaking activities (by Feb. 1).

6. Attorney General. After the public hearing and comment period and any minor changes to the rule have occurred, the rule goes to the Office of the Attorney General for approval of “form and legality” (5 MRSA §8056, sub-§1, ¶A and sub-§6).

7. Adoption of routine technical rules. At the time of adoption, the agency adopts a written statement explaining the factual and policy basis for the rule. The statement includes information of comments received, organizations or individuals that testified at the public hearing and summaries of testimony. The statement also addresses comments, explains any changes to the rule in response to comments and failure to adopt suggested changes. The adopted rule must be consistent with the proposed rule except to the extent of addressing comments. If the rule is “substantially different” from the proposed rule, the agency must request comments from the public on the changes.

8. Effective date and time restrictions. The rule may not take effect until at least 5 days after filing with the Secretary of State. The agency must adopt the rule within 120 days of final date of submission of comments to the agency and approved by the Attorney General within 150 days of final submission of comments.

9. Rulemaking required by the public. A person can petition an agency to undertake rulemaking. If 150 people petition, the agency must undertake rulemaking (5 MRSA §8055).

10. Legislative review of major substantive rules. The rule is “provisionally adopted” after going through the same process for a major substantive rule. The agency must submit the provisionally adopted rule to the Executive Director of the Legislative Council by the second Friday in January of the regular session. The agency submits the following:

- Full text of the rule with the new language underlined and old language being deleted struck through (similar to a bill);
- Summary of content and a copy of the existing rule being amended or repealed;
- Circumstances that require the rule;
- Economic impact;
- Any other information required by statute.

A resolve is drafted if the rule request is received on time. If the rule is filed late, the legislative council treats it like an after deadline bill. If the legislature chooses NOT to review the rule, the rule cannot go into effect.

Legislative review of a major substantive rule

The legislative committee review process is governed by **5 MRSA §8072, sub-§4:**

4. Committee review. The committee shall review each provisionally adopted rule and, in its discretion, may hold public hearings on that rule. A public hearing under this subsection must be advertised in the same manner as required by legislative rules then in effect for advertisement of public hearings on proposed legislation. The committee's review must include, but is not limited to, a determination of:

- A. Whether the agency has exceeded the scope of its statutory authority in approving the provisionally adopted rule;
- B. Whether the provisionally adopted rule is in conformity with the legislative intent of the statute the rule is intended to implement, extend, apply, interpret or make specific;
- C. Whether the provisionally adopted rule conflicts with any other provision of law or with any other rule adopted by the same or a different agency;
- D. Whether the provisionally adopted rule is necessary to fully accomplish the objectives of the statute under which the rule was proposed;
- E. Whether the provisionally adopted rule is reasonable, especially as it affects the convenience of the general public or of persons particularly affected by it;
- F. Whether the provisionally adopted rule could be made less complex or more readily understandable for the general public;
- G. Whether the provisionally adopted rule was proposed in compliance with the requirements of this chapter and with requirements imposed by any other provision of law; and
- H. For a rule that is reasonably expected to result in a significant reduction in property values, whether sufficient variance provisions exist in law or in the rule to avoid an unconstitutional taking, and whether, as a matter of policy, the expected reduction is necessary or appropriate for the protection of the public health, safety and welfare advanced by the rule.

**The Committee then makes a recommendation to the Legislature on the rule. The committee authorizes final adoption, final adoption of part of the rule, final adoption with specifically requested amendments, or disapproved. If the Legislature takes no action, the rule may go into effect.

**Final adoption of the rule must be within 60 days of the effective date of the legislation approving the rule (or part of the rule) or adjournment if the rule is not acted on by the Legislature. Rules become effective within 30 days after filing with the Secretary of State or the date in the agency rule.

Committee voting on a major substantive rule

Voting Procedure for a Major Substantive Rule filed within the rule acceptance period: After reviewing the rule, the committee has the following options for voting on the resolve:

- **OTP** to authorize adoption of the rule with no changes.
 - **ONTP** – A *failure to act* on a rule filed within the acceptance period authorizes adoption; killing the resolve is considered a failure to act on the rule; if the committee wishes to authorize the rule, an OTP vote is generally recommended.
- **OTP-A**
 - To authorize adoption of the rule if changes are made to the rule; or
 - *Not* to authorize adoption of the rule.

Voting Procedure for a Major Substantive Rule that is submitted late: After reviewing the rule, the committee has the following options for voting on the resolve:

- **OTP** to authorize adoption of the rule with no changes.
- **OTP-A**
 - To authorize adoption of the rule if changes are made to the rule; or
 - Not to authorize adoption of the rule (but note that ONTP has *the same effect* for late-filed rules).
- **ONTP** – for late-filed rules, the legislature must *affirmatively authorize* adoption of the rule or it may not be adopted; killing the resolve provides no authorization; if the committee wishes not to authorize the rule it can either vote ONTP on the resolve or OTP-A to expressly not authorize adoption of the rule.