



CALIFORNIA DEPARTMENT OF  
**CONSUMER**  
AFFAIRS



# Rulemaking Process Overview

**Kristy Schiedge**

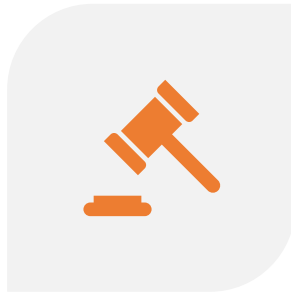
*Attorney IV*

DCA Legal Affairs Division

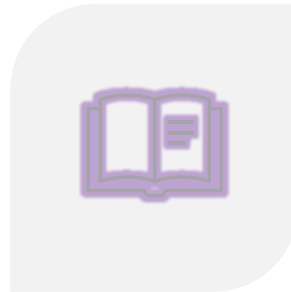
March 28, 2024, Board Meeting

California Board of Naturopathic Medicine

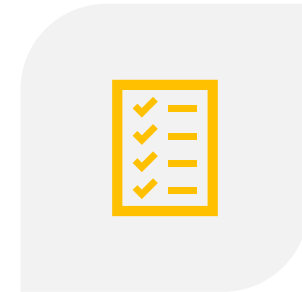




A regulation has  
the force of law



Board Regulations  
are in  
Division 40 of  
Title 16 of the  
California Code of  
Regulations



State agencies  
must adopt  
regulations  
following the  
process specified  
in the APA

# What is a regulation?

A regulation is defined in the Administrative Procedure Act (APA) as:

*“Every rule, regulation, order, or standard of general application, or the amendment, supplement, or revision of any rule, regulation, order, or standard adopted by any state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure.”*

*Government Code section 11342.600*

# Why are regulations necessary?

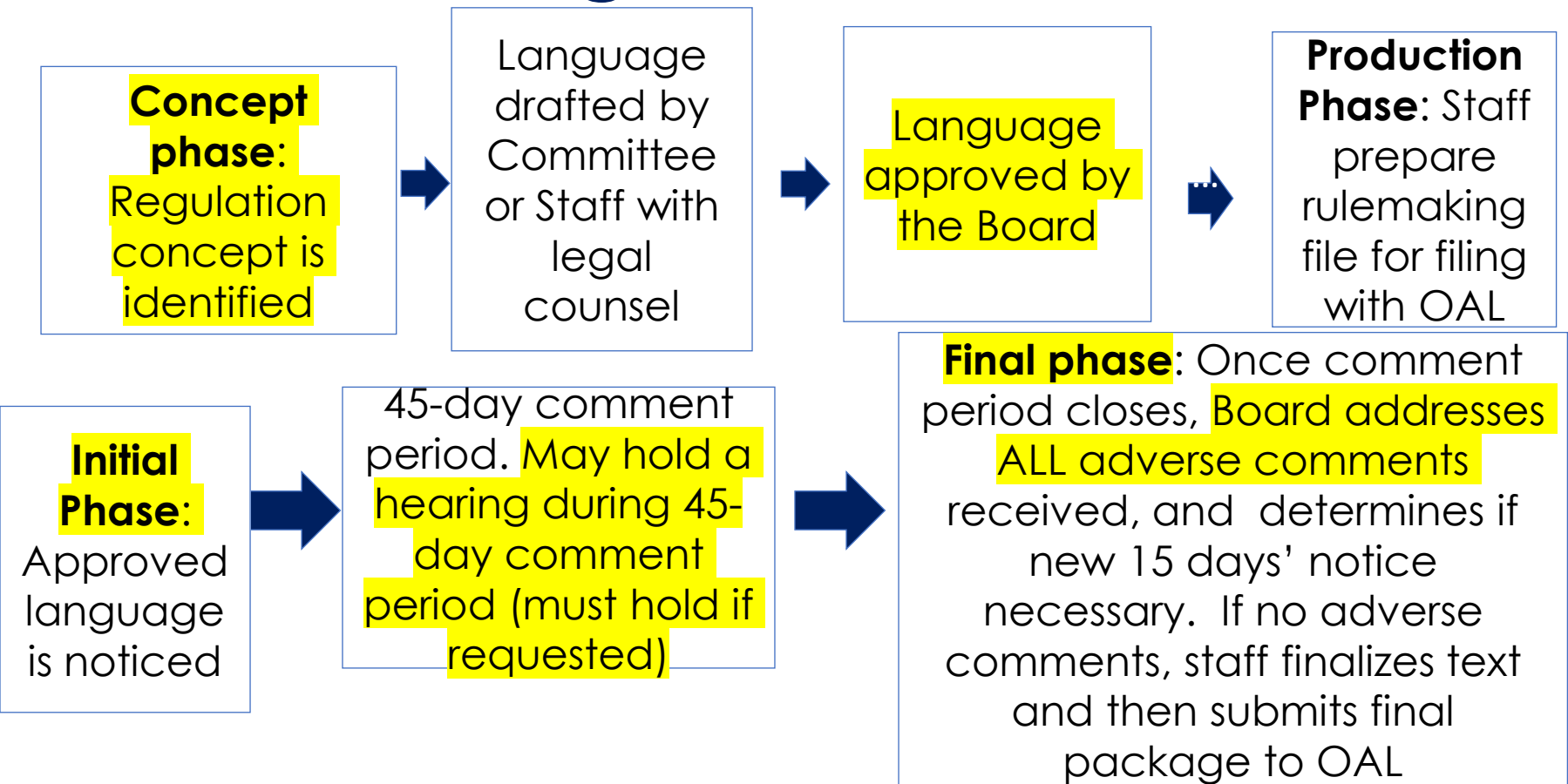
- Regulations are necessary whenever a law enacted by the legislature is not “self-executing” AND
- A regulation is needed to implement, interpret or make the law more specific

## When should regulations be considered?

“The application fee shall be no more than \$500 and **may** be increased to not more than \$600.”

Is the Board’s fee \$500 or \$600 to process an application?

# General Overview of Rulemaking Process





# Regulatory Phases for a Regular Rulemaking

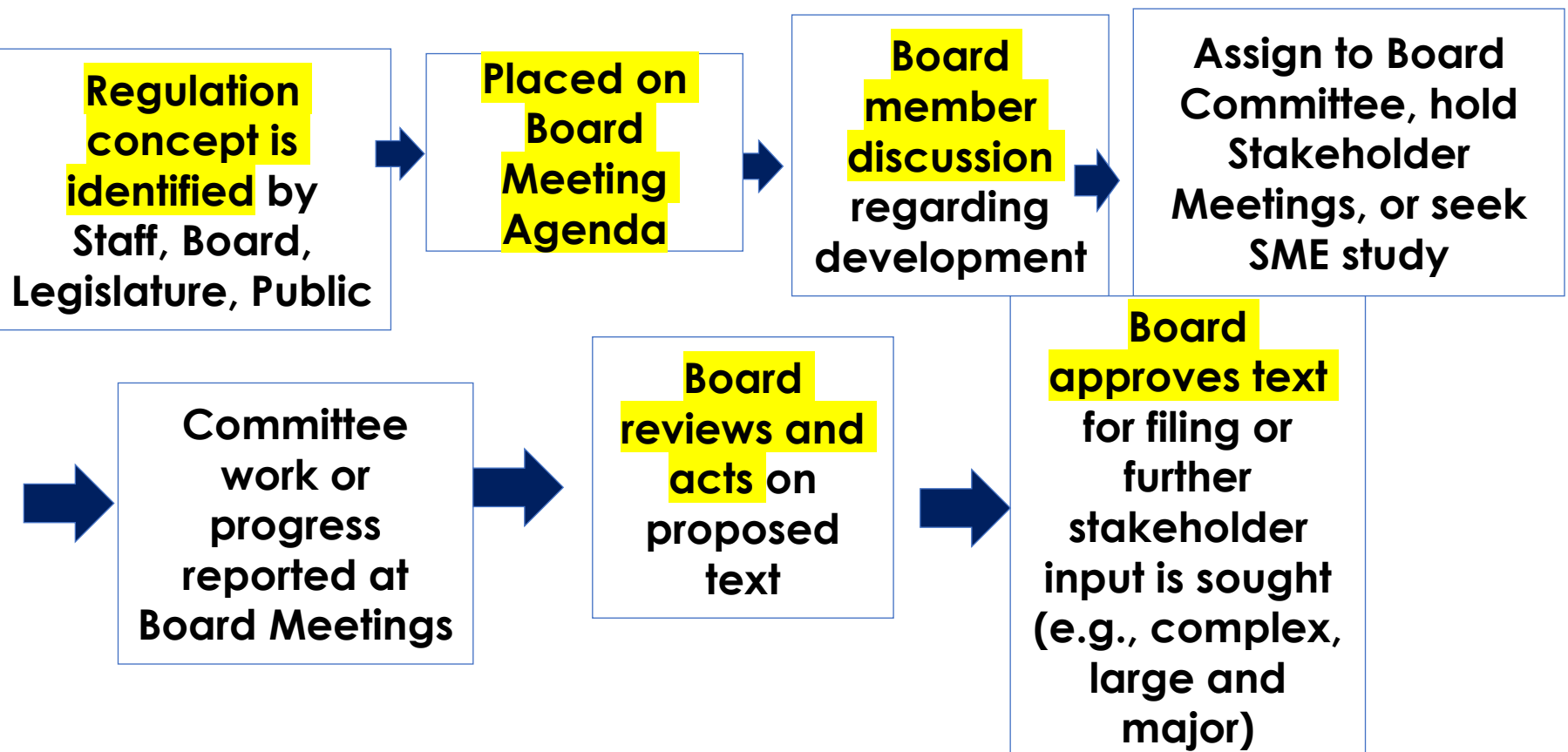
1. Concept
2. Production
3. Initial
4. Final



# Concept Phase

1. Define the problem.
2. Describe the objectives you hope to achieve.
3. Brainstorm possible solutions.
4. Consult with those who would be affected.  
(**Required:** complex and/or large proposals  
(Gov't. Code § 11346.45(a) and for major  
regulations (1 CCR 2001(d))).
5. List and evaluate the costs and benefits.
6. Choose an option/solution and be prepared to explain why it is the preferred solution.

# Board Member Role in Concept Development



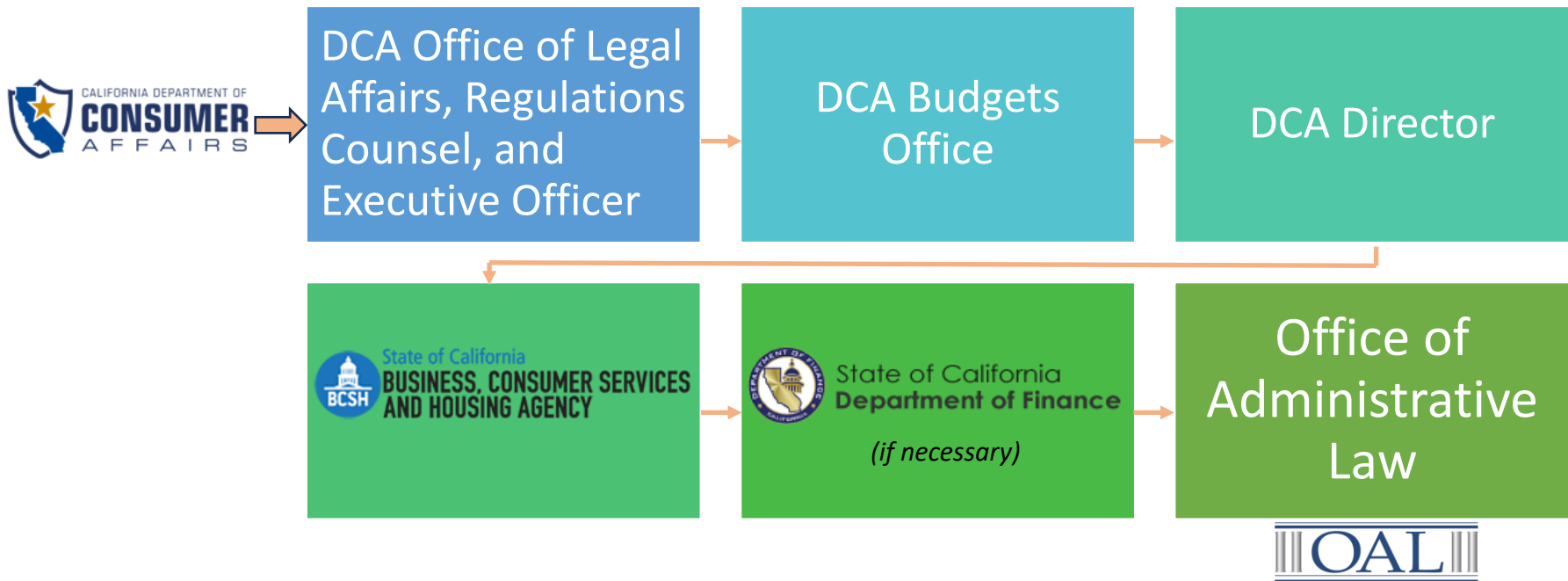
# Board Concept Approval

1. Board reviews and approves text for initiation of the rulemaking process at noticed Board meeting
2. Delegates to the Executive Officer: production of the rulemaking file, including: preparation of initial statement of reasons, setting the matter for a public hearing, and authority to make non-substantive or technical corrections

# Staff Production Phase

1. Initial Package includes:
2. Part A portion of the Std. Form 400
3. Notice of Proposed Action (“Notice” or “NOPA”)
4. Board-Approved Proposed Text/Language
5. Any forms incorporated by reference in the proposed text/language as approved by the Board
6. Initial Statement of Reasons (ISOR)
7. Underlying Data (Materials Relied Upon) enumerated in the ISOR (including SRIA if applicable)
8. Completed Std. Form 399 – Economic and Fiscal Impact Statement (Note: additional docs for major regulation required)

# Rulemaking Package Review Process



Staff Initiates Rulemaking:  
Filing with and review by  
OAL, Publication and  
Notice to Interested Parties

1. Package filed with OAL by staff
2. OAL reviews Notice
3. Staff corrects any deficiencies identified by OAL
4. Publication in Notice Register
5. Mail notice to interested parties and post Notice, Text, and ISOR on web site

## Initial Phase: Board Oversight

1. At Board meeting: Board reviews and votes on proposed responses to all comments received during public comment period and at any hearing







2. Authorizes all modifications to proposed text



3. Retains authority to review all adverse comments received by staff in response to text modifications



# Final Phase

- The Board approves the final proposed text at a noticed Board meeting 
- Approval includes delegations to Executive Officer: authority to complete the rulemaking file, including preparation of Final Statement of Reasons, make any non-substantive or technical changes and take “all steps necessary to complete the rulemaking” 
- Staff files the final package with OAL per the Board’s motion 
- If OAL or DOF indicates problem areas, the package may be withdrawn and discussed at a future Board meeting. 

# Board Member Action on Regulations

How to prepare:

- Review the memo(s), text, and supporting documentation
- List questions
  - *If possible, seek clarification prior to meeting*
  - *Consider whether legal standards are met and alternatives considered*

# Considerations

When reviewing the text, suggest considering the following:

1. Review the memo(s), text, and supporting documentation
2. Are there unintended consequences?
3. Is this the least restrictive alternative or interpretation that your agency can choose to implement the law?

# Considerations (cont.)

When reviewing the text, suggest considering the following:

4. Is it necessary?
5. Do you have the authority to adopt regulations on this subject matter?
6. Does the proposal make specific or interpret a law under your jurisdiction?
7. Is it clear?
8. Is it in harmony with or does it conflict with California or federal statutes or other regulations?
9. Does it duplicate something already required in state or federal law or regulations?

# Any Questions?

Raise your hand to ask

-OR-

Type in the chat box