

POCKET GUIDE TO

# Pennsylvania's Regulatory Review Process



**HAP**

THE HOSPITAL & HEALTHSYSTEM  
ASSOCIATION OF PENNSYLVANIA

The regulatory review process creates an open forum through which regulations are critically examined by the public, the General Assembly, and the Independent Regulatory Review Commission.

The Regulatory Review Act, initially enacted in 1982, established the regulatory review process and created the Independent Regulatory Review Commission (IRRC). The reenactment of the act in 1989 established the current two-step process for reviewing regulations. This two-step process includes the proposed rulemaking stage and the final-form rulemaking stage. During the proposed rulemaking stage, the public, the standing committees of the General Assembly, and the IRRC submit comments on a regulation that has been developed by a state agency. During the final stage, the standing committees and the IRRC take final action on a regulation. Slight modifications to the review process were made in 1997 to strengthen its oversight elements.

This booklet provides a ready reference to the regulatory review process. It is intended to help members of the Pennsylvania hospital and health system community participate in the regulatory review process.

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Adapted from “The Regulatory Review Process...,” a publication of the Independent Regulatory Review Commission.

## ■ Development of Regulations

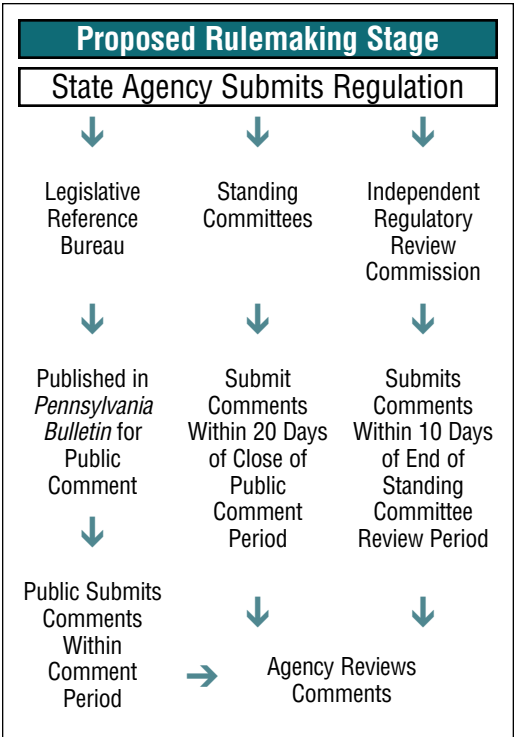
A state agency, (i.e., Department of Health) may introduce a new regulation for a variety of reasons: to add, amend, or repeal a regulation so that it does not conflict with a recently enacted or amended statute; to make changes to comply with federal law or a decision of a state or federal court; to update an existing regulatory scheme to improve the way it implements an existing statute.

Three state statutes simultaneously affect the regulatory review process. They are the Commonwealth Documents Law, the Commonwealth Attorneys Act, and the Regulatory Review Act. The first prescribes the steps in the preparation of a regulation. The second provides for review and approval as to form and legality. The third delineates the oversight and review undertaken by the Independent Regulatory Review Commission and the General Assembly.

## ■ Proposed Regulations

Proposed regulations are submitted to the Legislative Reference Bureau for publication in the *Pennsylvania Bulletin*, which is distributed every Saturday. This public notice lists a deadline for interested parties to submit comments to the state agency proposing the regulation. Except in very limited circumstances, at least a 30-day public comment period for proposed regulations is required. The agency also may schedule public hearings to receive comments or schedule information sessions to explain the regulation and entertain questions. State agencies are required to forward all comments to the IRRC and to the standing committees of the General Assembly.

After the close of the public comment period, the review process mandated under the Regulatory Review Act commences. The standing committees have 20 days from the close of the public comment period to file comments or recommendations with the promulgating state agency. The commission has 10 days following the expiration of the standing committee review period to submit its comments.



## ■ Formal Comments to a State Agency

In developing its comments, the IRRC conducts independent research on the regulation's subject matter, discusses issues with the state agency and the standing committees of the General Assembly, and solicits input from potentially affected parties, such as HAP and hospitals and health systems. The IRRC also looks at comments submitted to the state agency by the public. Such a comprehensive review is necessary, as the Regulatory Review Act permits disapproval of a final regulation based only on (1) unresolved issues raised by the IRRC to the proposed regulation, (2) new provisions included in the final-form regulation that were not included in the proposed regulation, or (3) comments made by the standing committees. Filing comments on proposed

rulemakings is optional for the standing committees, as they do not forfeit their ability to later disapprove the final-form version of the regulation. Many committees, however, routinely file comments, which is why it is important for organizations like HAP and individual hospitals and health systems to communicate concerns or support for a proposed regulation to members of these standing committees.

Following its review of the proposed rulemaking, the IRRC submits formal comments to the promulgating state agency. The Regulatory Review Act requires the state agency to respond to these and any comments it has received from the public and the committees in preparing the final-form regulation. In addition, state agencies must mail a copy of the final-form regulation or a summary of the changes made to the proposed regulation to every party that submits a request for information concerning the final-form regulation. Commenting in the proposed stage, therefore, is one way to assure being kept in the “review loop” from proposed through final-form stage.

## ■ **Regulatory Review Act Criteria**

The Regulatory Review Act sets forth criteria for the IRRC to consider in determining whether a regulation is in the public interest. These criteria serve as the cornerstone of the IRRC’s review of all regulations. As such, comments submitted by hospitals and health systems should follow these criteria to be useful and relevant in the regulatory review process.

Statutory authority and legislative intent are the primary criteria. If the IRRC finds that the state agency has statutory authority, the IRRC then must determine whether the regulation is consistent with the legislative intent of the enabling legislation.

Once it completes this analysis, the IRRC then considers the remaining five criteria contained in Section 5.1(i) of the Regulatory Review Act. These five criteria are used to determine whether the regulation is in the public interest.

## Regulatory Review Act Criteria

**Primary Criteria:** Determination of statutory and legislative intent.

**Five Secondary Criteria:** Determination if a regulation is in the public interest.

1. Economic impact of the regulation.
  - Direct and indirect costs to the Commonwealth, to political subdivisions, and to the private sector.
  - Adverse effect on prices, productivity, or competition.
  - Nature and costs of paperwork requirements and legal, consulting, or accounting services.
  - Exemptions or lesser standards for small businesses or individuals when lawful and feasible.
2. Protection of public health, safety, and welfare and effect on natural resources.
3. Reasonableness and feasibility.
  - Possible conflicts with or duplication of statutes or existing regulations.
  - Clarity and lack of ambiguity.
  - Need for the regulation.
  - Reasonableness of requirements, procedures, and timetables for compliance.
4. Substantial policy decision that requires legislative review.
5. Approval or disapproval by a standing committee of the General Assembly.

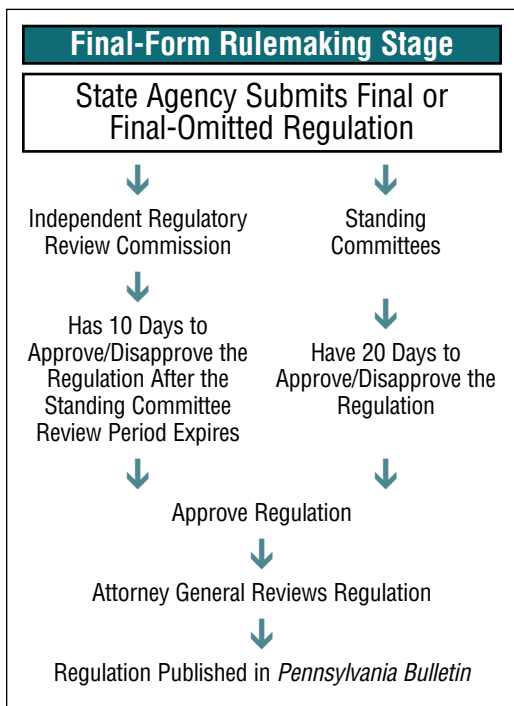
## ■ Final-Form Regulations

The Regulatory Review Act requires an agency to submit its final-form regulation to the IRRC and the standing committees within two years following the close of the public comment period on the proposed version of the regulation. If a state agency does not submit the final-form regulation within the two-year

time frame, it must re-publish the regulation as a new rulemaking and conduct a new public comment period.

Upon receipt of a final-form or final-omitted regulation, the standing committees have 20 days to meet and either approve or disapprove the regulation. If a committee fails to disapprove the regulation during the 20-day period, it is deemed to have approved the regulation.

Likewise, the IRRC must hold a public meeting and take formal action to approve or disapprove the regulation within 10 days of the end of the standing committees' review period, or at its next regularly scheduled meeting, whichever is later. If the IRRC does not act within that time frame, it is deemed to have approved the regulation.



## ■ **48-Hour Blackout Period**

The Regulatory Review Act prohibits the IRRC and its staff from discussing a regulation with or receiving comments from anyone except the standing committees during the 48-hour period prior to its public meeting. This grace period was established to insulate the IRRC from lobbying efforts for a short period of time before the public meeting. It is important for parties wishing to provide comments on a regulation to take note of the beginning of the blackout period, because any comments received by the IRRC are embargoed until the public meeting.

## ■ **IRRC Public Meetings**

The IRRC usually holds public meetings twice a month, on Thursdays. These meetings may be rescheduled, however, to accommodate the flow of regulations. All regulations submitted to the IRRC are discussed and voted on at a public meeting.

At the public meeting, a commissioner will summarize the regulation and make a motion for approval or disapproval. The chair then will invite the promulgating agency to make remarks and answer any questions the commissioners may have. Members of the General Assembly and other interested parties, such as HAP, also are invited to comment on the regulation. This discussion enables the commissioners to resolve any unanswered questions concerning the agency's intent or the regulation's impact on the regulated community.

Following this discussion, IRRC commissioners can vote only to approve or disapprove a final regulation; they may not amend or modify a regulation. If the IRRC or one of the standing committees disapproves a regulation, the review process continues until the regulation is either approved, withdrawn, or permanently barred.

If the IRRC and both standing committees approve the regulation, the agency submits the regulation to the Attorney General for review for form and legality.

Upon the Attorney General's approval, the regulation is published in the *Pennsylvania Bulletin*. The regulation becomes effective either on the date of publication or on a later date specified by the state agency in the order adopting the regulation.

## ■ Other Types of Regulations

Two types of regulations may be adopted without prior publication as proposed rulemakings. These regulations are known as final-omitted regulations and emergency certified regulations. Use of these regulations is permitted only in certain situations.

“Final-omitted” is a shorthand name for a final regulation with proposed rulemaking omitted. This type of regulation is promulgated without publication of the proposed regulation in the *Pennsylvania Bulletin* and without a formal public comment period.

An emergency certified regulation is a regulation that is certified by either the Governor or the Attorney General as necessary to meet either a fiscal crisis, satisfy the order of a court or mandate of a federal law or regulation, or ward off a danger to the public health, safety, or welfare.

## ■ Final-Omitted Regulations

Final-omitted regulations are permitted under three very limited circumstances:

- where comments from the public are not appropriate, necessary, or beneficial (e.g., military affairs, Commonwealth property);
- when all persons subject to the regulation are named or have been given personal notice (e.g., fees for professional licensure examinations); and
- when the state agency for good cause finds that notice is impracticable, unnecessary, or contrary to the public interest (e.g., regulations that have a significant and immediate fiscal impact, regulations that are prepared in response to exigent circumstances such as a measles outbreak, and regulations that are being rescinded due to a statute that has since been repealed or amended).

By eliminating the public comment period, the state agency somewhat is able to expedite the adoption of the regulation. However, the final-omitted process does not eliminate the review of a regulation. A final-omitted regulation cannot take effect until it has been approved by the Attorney General, the designated standing committees, and the Independent Regulatory Review Commission. The review process for final-omitted regulations is the same as it is for final-form regulations.

## ■ **Emergency Certified Regulations**

Emergency certified regulations take effect immediately upon publication in the *Pennsylvania Bulletin* and remain in effect for a minimum of 120 days. If they ultimately are approved pursuant to the Regulatory Review Act, they achieve permanent status.

To date, the Attorney General has not certified any regulation as an emergency. The Governor has, however, issued several emergency certified regulations. These include a regulation from the Pennsylvania Emergency Management Agency responding to the drought conditions a few years ago, and five emergency regulations from the Department of Public Welfare dealing with the General Assistance program's pharmaceutical services and hospital reimbursements.

As the emergency certified regulation proceeds through the channels for review under the Regulatory Review Act, it is treated like a final-form regulation. Within 30 calendar days after the receipt of the regulation, which occurs during the 120-day period, the IRRC holds a public meeting to either approve or disapprove the regulation. Likewise, the standing committees may take action on the regulation within 20 calendar days after receipt of the regulation.

If both the IRRC and the standing committees approve the regulation, the regulation continues in effect after the 120 days expires. If the IRRC or one or both of the standing committees disapprove the regulation, the regulation is suspended at the end of the 120-day period.

## ■ Existing Regulations

Hospitals and health systems may want to take advantage of the Independent Regulatory Review Commission's authority to review existing regulations that have been in effect for at least three years. This review occurs upon request or by the IRRC's own initiation. If the IRRC determines that an existing regulation does not meet the criteria of the Regulatory Review Act, it may recommend changes to the state agency. The IRRC also may submit a report to the appropriate standing committees in the General Assembly. If one of the committees concurs with the IRRC's report, it may initiate legislation to change the regulation in question.

## ■ Statements of Policy

The IRRC also is authorized to review policy statements, guidelines, bulletins, and other published and unpublished nonregulatory documents to determine whether they should be promulgated as regulations. Because policy statements and other types of directives do not have the force of law behind them, these nonregulatory documents are not subject to the rigorous review statutorily mandated for regulations. If the IRRC finds that the agency is enforcing such directives as regulations, it may bring the matter before the Joint Committee on Documents for resolution.

## ■ Glossary

**Agency**—As defined in the Regulatory Review Act (71 P.S. § 745.3), an executive or independent board, commission, or department.

**Commonwealth Attorneys Act**—Provides for review and approval of a regulation's form and legality by the Office of General Counsel and the Office of Attorney General.

**Commonwealth Documents Law**—Requires publication of proposed regulations, solicitation of comments, and review and approval for form and legality.

**Deemed Approved**—The approval of a regulation by operation of law when the Independent Regulatory Review Commission and the standing committees have not formally disapproved the regulation.

**Emergency Certified Regulation**—A regulation certified by the Attorney General or the Governor as necessary for compliance with a court order or statutory mandate, or to respond to an emergency. Becomes effective immediately and remains in effect for up to 120 days.

**Existing Regulation**—An enforceable regulation contained in the *Pennsylvania Code*.

**Final-Form Regulation**—The final version of a proposed regulation that a state agency submits to the Independent Regulatory Review Commission and the standing committees for review and approval. Before submitting final-form regulations, agencies must wait for the close of the public comment period and must respond to all comments received.

**Final-Omitted Regulation**—A regulation adopted without prior publication in the *Pennsylvania Bulletin* and without a formal public comment period. Must be approved by the Independent Regulatory Review Commission, the standing committees, and the Attorney General. Permitted only in certain circumstances.

**IRRC Comments**—A public document containing recommendations, suggestions, or objections relating to a proposed regulation that the Independent Regulatory Review Commission prepares for the promulgating state agency.

**IRRC Order**—A public document containing the IRRC's findings and reasons for approval or disapproval of final-form, final-omitted, or emergency certified regulations.

**IRRC Public Meeting**—The second public session at which the IRRC takes formal action on a regulation.

**IRRC Staff Review Session**—The first public session at which the IRRC staff brief the commissioners on the regulations scheduled for action at the public meeting.

***Pennsylvania Bulletin***—The official gazette of the Commonwealth of Pennsylvania. It is published every Saturday.

***Pennsylvania Code***—The official codification of Pennsylvania’s administrative rules and regulations.

**Policy Statement**—An announcement to the public of a policy that an agency intends to implement in a future rulemaking or an adjudication.

**Proposed Regulation**—An agency’s draft regulation that is published in the *Pennsylvania Bulletin* with a request for public comments. Also submitted to the Independent Regulatory Review Commission and the standing committees of the General Assembly for review.

**Public Comment Period**—The period of time following an agency’s publication of a proposed regulation in the *Pennsylvania Bulletin*, during which the public may submit recommendations or objections to the agency.

**Regulation**—A state agency statement designed to implement, interpret, or prescribe law or policy or to describe the organization, procedure, or practice requirements of a state agency. Has the force of law and is binding on both the state agency and anyone affected by the rule.

**Regulatory Analysis Form**—A form containing information about a regulation, including the state agency’s statutory authority, title of the regulation, a description of the regulation, a cost/benefit analysis, an impact analysis, and time frame for the adoption of the regulation.

**Regulatory Review Act**—Provides for the review and approval of state agency regulations by the Independent Regulatory Review Commission and the standing committees of the General Assembly.

***Sine Die***—The final adjournment of the House of Representatives and Senate by November 30 of even-numbered years. A new legislative session, including newly elected legislators, begins the following January.

**Standing Committee**—A House or Senate committee charged to develop expertise in a particular area. One function is to review and approve or disapprove the regulations of selected state agencies.

**Statutory Criteria**—The requirements that a regulation must satisfy for the Independent Regulatory Review Commission to determine that the regulation is in the public interest.

**48-Hour Blackout Period**—A provision that prohibits the Independent Regulatory Review Commission from receiving any written documents or oral communications about a final regulation during the two days prior to the IRRC's staff review session.

*The Hospital & Healthsystem Association  
of Pennsylvania is an affiliate of  
The Health Alliance of Pennsylvania  
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- PHICO Group, Inc.
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