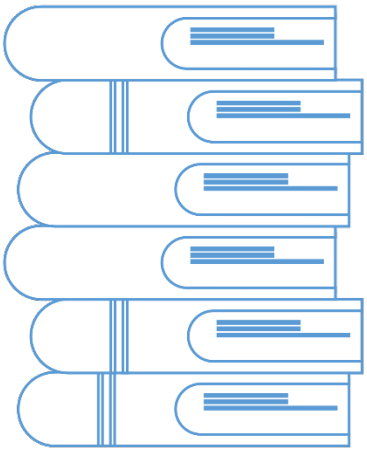

A State Law and Regulatory Searchable Database and Analysis of Legislative and Regulatory Strategies to Identify Best Practices Among Central Cancer Registries

March 2021

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Project Goals

1. Create a searchable database of central cancer registry laws and regulations.
2. Provide access to critical elements of the laws and regulations that support improved central cancer registry (CCR) completeness and timeliness.
3. Understand the legal and regulatory processes that central registries use to change laws and rules.
4. Identify practices to improve CCR operations through legal and regulatory strategies.

Background and Significance

Historically, most CCRs were legislatively created state entities, and state laws define the authority, roles, and responsibilities of the CCRs. As a result, most registries are either direct state agencies—as in the case of programs embedded within state departments of health—or are empowered by states to function as agents for them, such as registries located in academic centers, independent health organizations, or medical centers. In either case, all CCRs are subject to these laws and must follow the directives and language included in them. Registry laws vary from state to state; some are very broad in scope, others more detailed and explicit, and still others embedded within more general health surveillance or public health laws. In addition, CCRs may be affected by a range of related state laws, including privacy, confidentiality, and budgetary legislation. As such, laws and the legal environment have an important impact on CCRs' structure, resources, and function.

Administrative codes and regulatory rules are developed in the executive branch of government and usually interpret, implement, or prescribe the requirements of the law.[1] These have the force of law but must be authorized within the statutes related to them and must follow the scope defined in that law. In the case of central registries, authority to develop administrative codes and rules is usually designated to the commissioner, director, or leader of the department or board of health or another associated state department. State departments follow very specific procedures to create and maintain codes and rules. In some states, review by either a legislative body or an attorney general also may be required. Administrative codes and regulatory rules help CCRs define terms; identify who must report data; describe what data may be collected and reported and how; lay out privacy and confidentiality protections; enumerate how data may be used for research; enable interstate exchange of data; and delineate fees, penalties, or reimbursement of costs for failure to comply. For these reasons, codes and rules hold significant influence for CCRs and may contribute to successful operations.

Although some states created cancer registries in the 1930s and '40s, most were established in the 1970s and '80s as a result of growing public concerns surrounding cancer. With the enactment of the National Cancer Registry Act in the 1990s, all states either initiated or updated legislation related to central registries with support from the Centers for Disease Control and Prevention (CDC). A three-to-one (federal-to-state) funding match was required to apply for CDC funding. As a result, state funding for CCRs often is provided as state appropriations, either within general funds or as special line items. A review of legislative activity since the 1990s indicates that only nine states have changed or amended their laws in the past 10 years. Regulations are updated either on a schedule stipulated by their department or as needed by the agency. Twenty-six states updated regulations in the past 10 years. It also appears that state funding for many cancer registries has stagnated with either stable 1990s funding levels

maintained despite inflation and increased workloads, or cuts and decreases to budgets occurring.

As part of the project entitled *Identify and Implement Best Practices for Cancer Registry Operations*, funded by CDC to the National Association of Chronic Disease Directors (NACDD) in collaboration with the North American Association of Central Cancer Registries, Inc. (NAACCR), several states indicated that strategies to strengthen laws would be desirable, especially around penalties or fines for reporting deficiencies and improving reporting timeframes.[2] This led to a discussion among the National Program of Cancer Registries (NPCR), NACDD, and NAACCR to find ways to offer more resources and support to CCRs that need to deal with the challenges and opportunities that exist within the legal and regulatory environment. NPCR requested a searchable database of central registry laws and regulations to help states track any changes or updates to such laws and regulations and provide model language or best practices for adoption. NAACCR accepted responsibility for this project and launched the initiative. As the project developed, it also was decided that more in-depth analysis would help elucidate the legal and regulatory processes that registries follow and identify strategies that some states use to address legal and regulatory issues. As a result, expert interviews with 10 states were organized and implemented by NAACCR.

Methodology

1. *Create a searchable database of central registry laws and regulations and provide access to critical elements of the laws and regulations that support improved central registry completeness and timeliness. (Goals 1 & 2)*

A searchable database of central registry laws and regulations was created for use by registry staff, related policymakers, and the interested public. After discussion, it was agreed to modify an existing NAACCR database called the Cancer Registry Information (CaRI) Database because it offered the structure and flexibility desired for this project. CaRI is designed to capture, and make available in a single location, helpful information for researchers interested in using CCR data; it was built several years ago at the request of NPCR to maintain such data. Information available in the CaRI Database for each registry includes the following: Registry and Institutional Review Board review requirements, data request process, consent requirements, fees for requests, and general information about the registry contacts, available data, and participation in various types of studies. Information on and links to state laws and regulations were added to this database for this project. The system is populated by cancer registry staff and reviewed annually at a minimum. The CaRI Database is housed on the NAACCR website, and the data are publicly accessible. For this project, student interns from the Edward J. Bloustein School at Rutgers, The State University of New Jersey were recruited to research all state laws and regulations related to CCRs. A draft design of the database was embedded in the CaRI query system. It was structured to capture links to all relevant laws, current regulatory rules, and administrative codes. Such database components as legal citation, year data collection began, central registry location, reporting deadline, and reporting entities were incorporated. Data elements were organized for filtering and searchable queries. Information from 65 central registries was uploaded into the system. The structure was then activated in CaRI and pre-tested by registry staff to ensure understandability and ease of use. The advantage of this system is that the database will be updated as part of the annual *Call for Data* in which all registries participate, allowing continued currency of information. The Central Cancer Registry State Laws & Regulations section of the CaRI database will be available to the public using the following link: CaRI Database.

2. *Conduct expert interviews aimed at understanding the legal and regulatory processes that central registries follow and identifying best practices and success stories that improve registry operations. (Goals 3 and 4)*

Expert interviews were completed with 10 state registries with various levels of legislative and regulatory activity over the past 5 years: California, Colorado, Illinois, Louisiana, Kansas, Minnesota, Mississippi, New York, Oregon, and Tennessee. CCRs were chosen based on how often their laws and regulations were updated, geographical diversity, and whether they were located in government agencies or academic centers. Five states were identified as proactive based on the number of amendments to their laws or updates to their rules or administrative codes (two or more in past 5 years). Three were deemed as average in their legislative and regulatory activity (one update to either in past 5 years), and three were inactive (no updates in past 5 years). CCRs were offered a small stipend for participation.

A standard question set was developed based on input from central registry directors, operations staff, and NAACCR staff. In addition, an analysis of each state's laws and regulations was undertaken to identify any innovative elements that might be worth exploring, and individualized questions were designed to address these. General overarching topics included the legislative and regulatory processes in place within the state; major strengths and weaknesses of the state-specific laws and regulations; state funding and budgetary processes; approaches to fees, penalties, and reimbursements; partnerships with external partners; risks and benefits of using laws and regulations to improve registry reporting along with legal and regulatory factors that contributed to the overall success of central registry operations; and finally, threats that interfered with central registry effectiveness. Designated representatives were invited to participate using a Zoom meeting format. Qualitative/content analysis was then applied across all interview transcripts. Each offered insights into the processes required to amend laws or update administrative codes and regulatory rules, their attitudes toward and perceptions of the risks or benefits of amending laws or updating regulations, and what strategies they use to streamline or proactively approach using regulations and administrative codes to address the changing cancer surveillance field.

Findings and Results

Goal 1: Create a searchable database of central cancer registry laws and regulations.

The CaRI Database is complete with CCR state laws and regulations embedded for user-friendly search capability and is currently available to any interested party. It was updated by registry staff as part of the Call for Data in November 2020, and the process worked smoothly. Public access to the database is available using the link above.

Goal 2: Provide access to critical elements of the laws and regulations that support improved central cancer registry completeness and timeliness.

The research undertaken to create the searchable database for CaRI offers an opportunity to identify, analyze, and assess novel approaches, strategies, or language that states may adopt to either their laws or regulations. Registries or interested policymakers may use the database to see what other states are doing with the laws and regulations for major areas, such as reporting entities, reporting frequency and deadlines, required electronic reporting, required pathology reporting, and penalties or fees. Because the legal language is already in use within a

central registry, states interested in similar requirements or changes can be more confident that adapting model wording to their circumstances will reduce any risks of negative impact on operations or stakeholders.

Goal 3: Understand the legal and regulatory processes that central registries use to change laws and rules.

Each state varies in how laws are created, but most follow a similar process that, while not uniform, includes common steps. First, a bill requires a sponsor(s) who will introduce it for passage. It is assigned to one or more committees for intensive legislative review and public hearing where it needs to be approved by most of the committee members. During committee hearings, amendments or changes may be proposed. Once approved by all committees, it is then moved to the floor for a first reading, where legislators can again voice concerns or request amendments. A second reading is then completed, and the bill is posted for a vote. If approved, it then moves to the second house where the same procedures occur. Although the registry staff are not directly involved in most of this process, they nonetheless must deal with any consequences that might arise during it.

The process is complex, fraught with risks, and very time consuming. For example, a recent change to one registry law took more than 2 years to pass. Some health departments have strong policies that do not allow programs to initiate legislation. Advocates demanding more privacy and confidentiality protections have gained strength in recent years and argue tenaciously for stronger safeguards, proposing amendments that hinder access to data. Lobbyists for special interests can recommend language that might harm registry operations. Legislators might raise concerns about privacy or cancer clusters in their district or question the timeliness of registry data. One state does work with its law when changes are required, because the regulatory rules process is so long and tedious. However, the consensus of the CCR interviewees was that the risks were generally too high to make amending laws worthwhile.

Registry respondents were more open to using administrative codes and regulatory rules proactively to address reporting problems and maintain currency in a rapidly changing cancer surveillance field. Although variations exist among states in how regulations are updated, most follow similar processes. Some state registry rules expire and need renewal for a specific term. Most registries review rules annually but make changes on an as-needed basis. If a need is identified, the registry director usually works with his or her department's legislative services office to write the necessary language. It then is moved for review to the director/commissioner, attorney general's office, or other appropriate legal entity. It then undergoes a public comment period and/or public hearings. Negotiations may then occur in which problems are resolved, and a second public comment period may be required. Finally, the new codes or rules are either accepted or voted upon by the authorized body. In most instances, this process is less onerous than legislative change, but still takes 6–9 months and considerable work on behalf of the registry. One state does have a more time-consuming regulatory process, so it relies more on specificity in its law and amendments than on rules for any changes.

For registries housed in such nongovernmental organizations as universities, cancer centers, or freestanding health programs, the regulatory authority usually remains with its associated government partner, e.g., the department of health. This situation requires more communication and collaboration, but the overall process follows the same steps.

The state funding process varies depending on the state, but most registries are housed in or partner with a government agency, so an established appropriations process is followed. State budgets are proposed by the executive branch and submitted to the legislature for review and approval in the form of a law. Hearings are held and modifications either up or down to various programs may be occur. Special interests, advocacy groups, and lobbyists actively engage in promoting their cause. Because state budgets are under significant pressure, increases or new budget items usually need justification and receive serious scrutiny. A final budget is usually voted on very close to the end of the fiscal year. Of serious concern, many registries have faced stagnant or decreased state funding in recent years despite increasing costs, and many are forced to rely upon in-kind support for any federal matching requirements.

Goal 4: Identify practices to improve central cancer registry operations through legal and regulatory strategies.

Despite the challenges associated with legislative and regulatory changes, many registries work with their laws and rules to advance strategies to improve reporting and timeliness and keep registry operations current in a changing environment. In most instances, registry staff avoid amending laws and rely on updates to administrative codes and regulatory rules to move their agendas forward. Several overarching themes were identified through the interviews:

1. **Embrace the value of laws and regulations:** States that are most active in making changes to rules tend to have a positive attitude toward the regulatory process, having embraced a more proactive approach to updates. Registry directors in such states understood the regulatory process, developed strong relationships with their legislative liaisons, established timelines, and worked to meet any deadlines. They paid particular attention to the language used in the regulations and did background research to understand any barriers and opposition in advance. They laid the groundwork with stakeholders, explaining why changes were required and listening carefully to any concerns raised. Most were able to make changes successfully.

> ***"Laws and rules are the backbone of central registries, and we need to learn to be more comfortable working with them. Change is coming, and we cannot move forward if we are locked down by outdated laws."***
>
> Participating Registry Director

2. **Broad laws with authorization to the executive branch allow flexibility:** Broader laws that did not delineate requirements in detail are easier for registries to implement and allow much more flexibility in improving operations and reporting. Registries used their administrative codes and regulatory rules to lay out the exact language they wanted to work with reporters effectively, establish reporting schedules, and add new requirements as needed. One state has very specific laws and relies on its regulatory

codes less often because laws are easier to change than regulations. However, this still requires more time and energy than in states whose laws are broad.

> ***"Broad laws that empower the Executive Branch to promulgate regulations allow central registries to make changes as needed without opening the door to legislative scrutiny and unanticipated consequences."***
>
> Participating Registry Staff

3. **Non-cancer registry laws around hospital licensing and certificates of need may be helpful:** If language within the law require a hospital to follow all state laws and requirements to be eligible for a certificate of need or license, CCRs may use this to their advantage. Putting this language in correspondence or warning letters to reporters or hospital compliance officers is often enough to motivate improved reporting.

> **"*Our planning board laws include a requirement that hospitals not in compliance with all state laws could have their certificate of need held. It is a wonderful tool to motivate reporters."***
>
> Participating Registry Director

4. **The ability to use your administrative codes and regulatory rules proactively keeps you nimble:** CCRs can stay ahead of changes to the field using codes and rules strategically. Criteria most often included are requiring electronic reporting, allowing remote access to medical records, changing rapidly expanded data fields, and requiring electronic pathology reporting, to name a few. However, states must be strategic and thoughtful in how laws and regulations are written to produce ones that are not rigid but fluid. For example, genetic privacy is an emerging issue that may require changes to registry confidentiality laws. Respecting the interests of advocates while protecting access to data for research requires carefully crafted language and consensus building to be successful.

> ***"The modern cancer registry is so much more complex and clinically detailed than when our laws were passed. It becomes impossible to operate effectively using those old ways."***
>
> Participating Registry Director

5. **Stakeholder relationships are still critical for success:** Although registries use laws, codes, and regulations to strengthen their authority for reporting, nearly all participants pointed out that it was their strong relationship with stakeholders that is the most important tool in their success with reporting. To update a law requiring pathology reporting, one state needed to work with a consortium of stakeholders who served as arbitrators among different parties to come to consensus allowing an amendment to successfully pass. Many fees and penalties, although written into laws, may not be as useful as they appear. Interviewees reported that noncompliant reporters were rarely fined, and reimbursement costs were not retrieved. It was better to rely on good working relationships and provide support when needed; these approaches brought the most success when working with such challenging situations.

> ***"In the end, it is still your relationship with stakeholders that is most important to encourage better reporting. Laws and regulations can lay out expectations, provide clear and concise direction, and even offer some enforcement, but in the end, it all depends on strong relationships with all your stakeholders."***
>
> Participating Registry Director

Success Stories and Best Practices

Adding New Data Items

Using the regulations to allow frequent and continual updates for new data items is a top common strategy to improve reporting operations. For example, including language that allows registries to "publish a list of required data elements once a year" keeps data items current with changes that standard setters might make.

Reporting Timelines and Deadlines

Most states include reporting timelines and/or deadlines in either their laws or regulations. Deadlines vary, with the majority requiring reporting within 6 months, and timelines vary from monthly to annually, for example, "Each patient's cancer report form shall be sent within six months after the date of diagnosis or within four months after the date of discharge from the reporting facility, whichever is sooner. Reporting facilities shall report by letter to the Department, each year by July 1, the status of the completeness of reporting of cancer incidence cases diagnosed through December of the preceding year. All reporting facilities shall submit the report forms monthly.[2]"

Electronic Submissions

Several states have added a requirement for electronic reporting to their regulations, such as, "Health care entities shall report information concerning all patients diagnosed as having cancer

[2] TITLE 77: PUBLIC HEALTH CHAPTER I: **Section 840.110**
https://www.ilga.gov/commission/jcar/admincode/077/077008400B01100R.html

in a standard electronic format designated by the Department.[3]" These changes were generally well received, reduced manual workloads, and improved operations significantly.

Access to Medical Records

Engaging in follow-up to find missing data is both time consuming and inefficient. Several interviewees included language in their regulations to permit remote access to reporters' medical records, allowing missing data to be retrieved quickly. For the most part, this approach has been successful, especially with smaller facilities, with compliance as high as 85 percent for one state. Some hospitals create onerous approvals prior to allowing access to medical data, but most readily comply. Health information exchanges (HIEs) are also useful in gaining access to medical records.

Increasing Fees or Penalties for Noncompliance

Several states decided to increase reimbursement rates for work that the registries undertook for noncompliant reporters. Generally, such fees had not been increased for many years and the increases reflected inflation and basic cost-of-living adjusted levels. It remains too early to determine whether this strategy will be successful, because collecting such fees often depends on the willingness of senior management to take appropriate action. One state tried to increase penalties through its regulations but experienced resistance from hospitals and physician groups, resulting in legislators' intervening on behalf of the opposition.

Collaborate with Health Care Facilities Regulators

Several states use a more innovative strategy—language offered in related laws from facilities oversight or licensing programs within the state departments of health allows registries to remind reporters that licenses or certificates of need could be in jeopardy in the event of late or incomplete reporting. For example, one state included the following in its administrative rules form Illinois:

> "The Certificate of Need approval is necessary in Illinois to establish a new category of service, allow a substantial increase in a facility's bed capacity, have a substantial change in the scope or functional operation of a facility, move forward with closure or change of ownership of a health care facility, or discontinue a category of health care service. Each Certificate of Need submitted to IDPH must be reviewed for cancer reporting compliance by the registry before it can proceed and be approved. This requirement is codified in the Administrative Rules (77 Illinois Administrative Code 1130) governing the Health Facilities and Services Review Board which states: Section 1130.620, c.1.H "all HFSRB requests and questionnaires for information or data for all Illinois facilities owned or operated by any applicant, such as but not limited to the Annual Hospital or Long-term Care Questionnaire (77 Ill. Adm. Code 1100.60 and 1100.70) **or Cancer Registry (77 Ill. Adm. Code 840.110(d) and 840.115(i)) have been received and are complete;[4]"**

[3]Department of Public Health and Environment, Regulations 6 CCR 1009-3: sec. III

[4] TITLE 77: PUBLIC HEALTH CHAPTERI I: Section 1130 C1:H http://www.ilga.gov/commission/jcar/admincode/077/077011300F06200R.html.

Legislative and Regulatory Challenges

High Political Risks When Amending Laws

Most interviewees reported great hesitancy to amend laws. The risks are considered very high because special interests or legislators who might not understand the complexities or value of population-based cancer registries could oppose changes or even introduce requirements that hinder the ability of central registries to function.

> **"I do not want to take the risk of opening that door!"**
>
> **"It would take an act of God before we would risk changing our law."**
>
> Participating Registry Directors

Time-Consuming Cumbersome Processes

Participating interviewees also pointed out that the process to change laws usually takes at least 2 years; some rural states may even take longer. Regulations can take 6 months to a year to update. Both processes are cumbersome, requiring multiple reviews by various legal entities, public hearings, or comment periods, and/or approval by various boards or committees.

Lack of Political Will to Enforce Penalties

Interviewees reported that even when penalties or fees were included in laws, implementation was almost never enacted. Senior leadership in most health departments is hesitant to damage relationships with health care facilities or make constituents angry by applying penalties or fees. Although the threat of action may be enough to motivate some reporters to respond, many simply ignore the threats.

Confidentiality and Privacy

A major concern of central registry directors involves confidentiality and privacy protections contained in laws and regulations. These often are subject to serious scrutiny and legal review that may curtail a registry's ability to share data across states or with researchers. In other instances, language creates patient notification requirements that are onerous for staff. More recently, laws dealing with data sharing and genetic privacy have gained momentum. Although these are not directly related to CCRs, language contained within them may affect the registry operations. Finally, privacy advocates have gained strong voices in recent years and are

> **"We have tried to introduce amendments to our laws to allow data sharing with other states, but it has not gained any momentum, and the privacy advocates are very politically connected."**
>
> Participating Registry Staff

applying political pressures that are difficult to negate. Finding a balance between protecting the privacy of individuals and supporting important research is a challenge that registries will increasingly have to deal with.

Funding and Budgetary Concerns

Another very serious concern for central registries is stagnant or reduced state funding. Most states have some funding to cover the CDC three-to-one matching requirement for states. These funds usually are included in state general appropriation budgets, which are submitted by departments that are often under pressure to cut costs. In some instances, line items specifically designating funds to registry programs may be included in budgets. However, funding has been stagnant for many CCRs, often not increasing since the program was created. In other instances, CCR state budgets have been cut significantly. Federal dollars are also static, and registries are being asked to do more with less. Little to no progress appears to have been made to overcome this problem that threatens the very existence of some registries.

> **"Very little of our match is covered by the State. Most comes from in-kind services."**
>
> **"We cannot hire staff anymore, our resources have not changed in years, and we are holding on by a thread."**
>
> Participating Registry Directors

Recommendations for Best Practices

1. State central registries can benefit from understanding the legislative and regulatory process in more depth. Establishing working relationships with legislative liaisons, legal departments, and other related programs can be useful when making necessary changes.

2. Administrative codes and regulatory rules offer opportunities for central registries to keep reporting requirements updated and stay current with the changing cancer surveillance field.

3. Adapting language and reporting requirements from other states to state laws or rules increases the likelihood of successful implementation because they are already field tested.

4. Central registries should consider working with managers in state health departments who regulate compliance and undertake oversight to identify ways to use licensing or certificate-of-need requirements to encourage timely reporting to the registry.

5. Central registries housed in universities or health care settings might benefit from working with their government relations offices to promote their needs to both state departments and legislators.

6. Advocacy remains critical to central registries. Although registry staff may be unable to speak for themselves in legislative settings, cancer advocates and organizations are often well positioned to take up the cause. Their voices are loud and effective.

7. Strong relationships with researchers, cancer control organizations, and public health professionals also can help legislators and policymakers understand and appreciate the value that central registries bring to the fight against cancer.

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[1] USLegal.com (https://definitions.uslegal.com/r/regulations/)
[2] *Identify and Implement Best Practices for Cancer Registry Operations,* NAACCR, August 2019

Tips for Understanding the Legislative and Regulatory Process

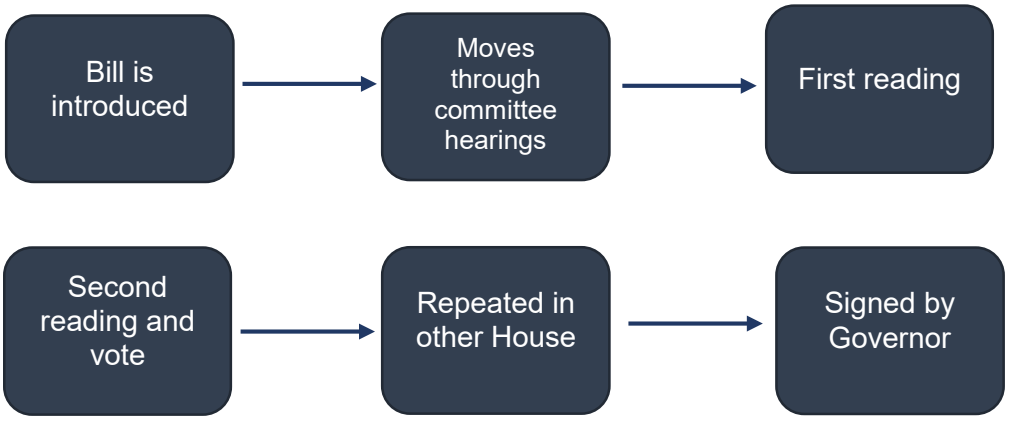
The legislative and regulatory procedures can be lengthy and complex, but it is important for registry directors to develop a basic understanding of these processes to ensure cancer registry requirements are appropriate and enforceable. Amendments to laws require specific actions. Regulatory rules need another set of steps. Learn about both.

Contact your department's office of legal and regulatory affairs or your legislative liaison to request training on procedures specific to your state.

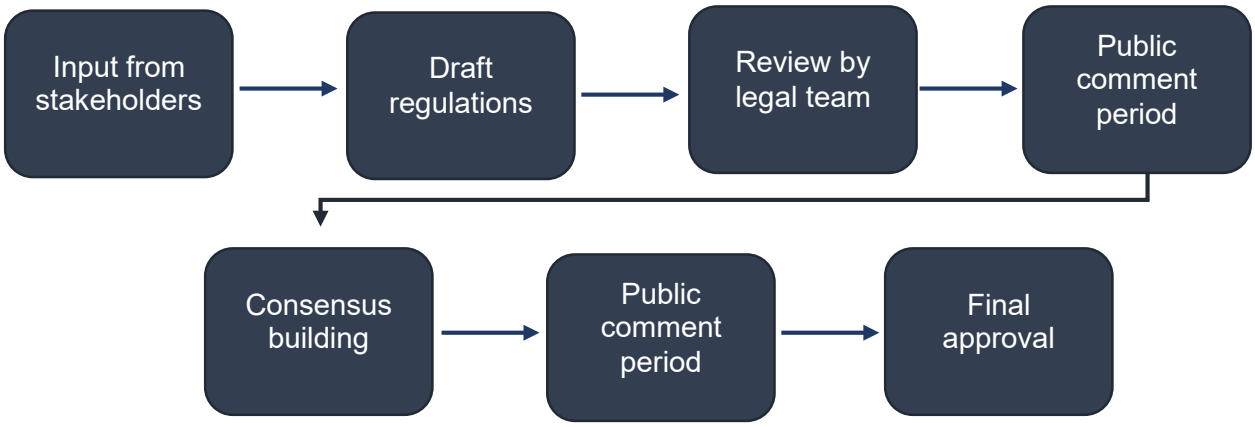
Registry staff may be prohibited from participating in the legislative process directly, but stakeholders or advocacy groups may act on the registry's behalf.

Work with stakeholders to review the CaRI database for language to include in the law.

How to Change a Law



How to Work with Regulations



These tip sheets are not meant to lay out a specific methodology, but rather, are meant to serve as a starting point for more in-depth discussions, development of tools, and the establishment of new processes or practices within individual registries as appropriate.

Tips to Strengthen Central Cancer Registry Laws and Regulations

Discussions during interviews with registry directors resulted in the following tips to help you strengthen central cancer registry laws.

> *"Laws and rules are the backbone of central registries, and we need to learn to be more comfortable working with them. Change is coming, and we cannot move forward if we are locked down by outdated laws."* — **Participating Registry Director**

USE THE CaRI DATABASE: It allows registries to see what other states are doing with their laws and regulations. Because the legal language is already tested, you can be more confident when adapting model wording to your circumstances, reducing the risk of negative impact on operations or stakeholders.

PLAN STRATEGICALLY: Think carefully about the types of changes needed and how you will put them in place.

BE FLEXIBLE AND BROAD: Broad laws that provide regulatory power to the Executive Branch are best. Update and revise regulatory codes to improve operations and reporting.

CONSIDER LICENSING AND CERTIFICATE OF NEED REGULATIONS: Laws and regulations that require hospitals or health facilities to comply with all state requirements to be eligible for certificates of need or licenses may give you an opportunity to strengthen compliance. See if you can include registry reporting requirements under this umbrella.

WORK WITH YOUR STAKEHOLDERS: Strong relationships are critical to your success. Work with advocates and supporters. Listen to the opposition carefully. Build consensus and be willing to compromise. NACDD, ACS, and Komen are excellent sources for help with advocacy support.

SUCCESS STORIES: Registries have changed laws and regulations to simplify edits to reporting fields, require electronic reporting, improve access to medical records, require pathology reports, increase penalties or fees, and require CTRs.