

Laws, Policies and Procedures

Supporting Your IIS Operations

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June 15, 2023



Learning Objectives

- Increase understanding about how your jurisdiction's laws, policies, and procedures can impact IIS and Immunization program goals.
- Explore important benefits and risks of modifying laws, policies, and procedures
- Discuss how federal initiatives and related policy requirements affect state and local IIS implementation and IIS data



Overview of this Session

- Discuss the difference between law and policy
- Discuss the landscape of jurisdictional IIS laws and policies
- Discuss the impact of law and policy on technical and operational program components
- Discuss the challenges and reasons to consider modifying laws or policies
- Explore policy impacts to the following national initiatives:
 - Inter-jurisdictional data sharing
 - Sharing immunization data with the federal level
 - Data Dashboards
- Review the current policy documents required for national initiatives

Difference Between Laws and Policies

Definitions

Laws

Laws describe the principles and regulations established in a community by some authority and applicable to its people, whether in the form of legislation (statutory law) or of custom and policies recognized and enforced by judicial decision (case law).

Administrative Rules

Administrative rules (sometimes called *regulations*) are officially promulgated agency regulations that have the force and effect of law. Generally these rules elaborate the requirements of a statute.

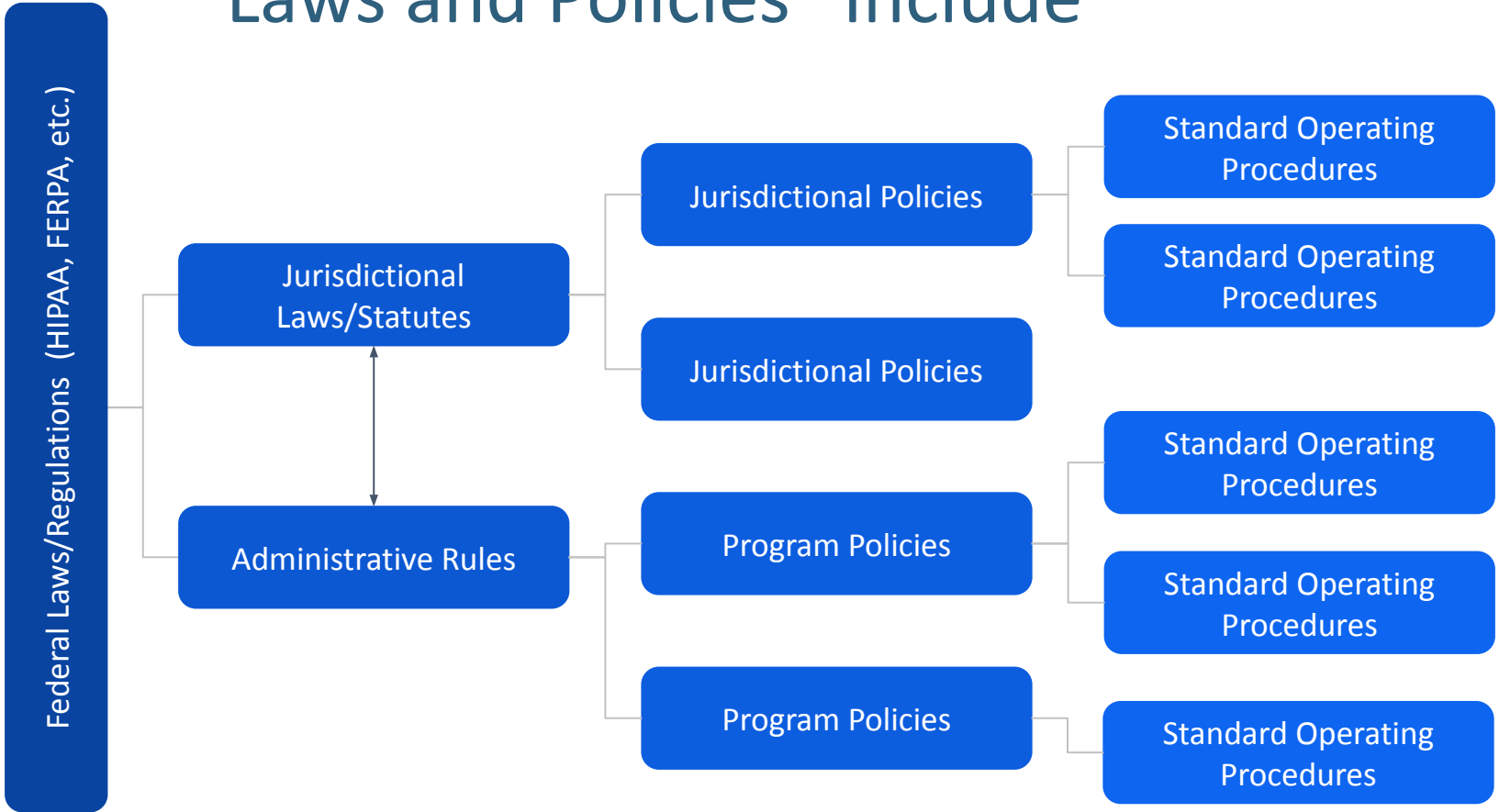
Policies

Policies are detailed guiding principles to put laws and rules into practice.

Procedures

Procedures are detailed steps for compliance with policies.

“Laws and Policies” Include



The Landscape of IIS Laws and Policies

Federal Laws Relevant to IIS

Health Insurance Portability and Accountability Act (HIPAA)

- Are you a covered entity? A hybrid?

Family Educational Rights and Privacy Act (FERPA)

- Protects the privacy of student education records but indirectly affects data exchange between schools/IIS

21st Century Cures Act

- Health information reform, includes provisions around TEFCA (Trusted Exchange Framework and Common Agreement)

Jurisdictional Laws Relevant to IIS

- IIS enabling legislation
 - Or your law/statute may be silent
- Immunization data sharing
 - Among whom, for what purposes, and under what conditions
- Reporting mandates
- Individual Consent Mandates
 - Mandatory Inclusion
 - Opt-out
 - Opt-in
- Interjurisdictional exchange
- Federal partner-IIS exchange of data
- Sharing with CDC

The National Picture

- Public health law largely and constitutionally originates at the state level
- As a result, statutes and policies vary across the U.S and there are few national policy frameworks

Policies Impacting IIS Data

- Individual Consent
- Provider Reporting
- Data Sharing



Activity #1: Pick Your Policy Status



Which number best describes your status? Select that number.

1. We love our laws/rules – they're rock solid!



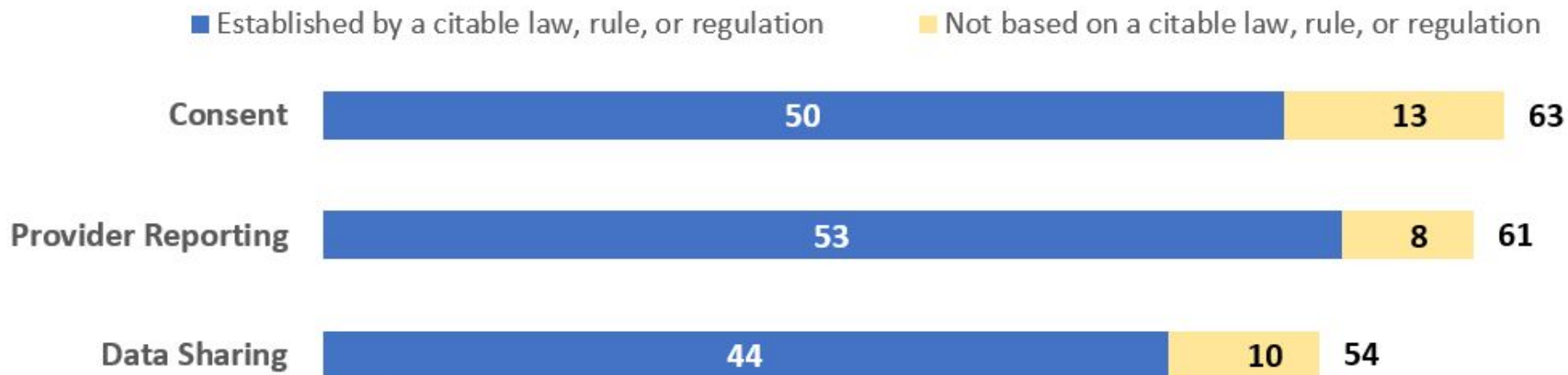
2. Program is pursuing changes – stand by to hear more...



3. Jurisdiction (e.g. governor/legislators) is pursuing changes



The Current Landscape Assessment



Consent Policies

Consent is whether or not an individual has the right to decide if their demographic and immunization data is included in the IIS

Types:

- Mandatory inclusion, meaning that an individual is included in the IIS with no possibility to opt out
- Implicit consent, meaning that an individual is included in the IIS unless they choose to opt out
- Explicit consent, meaning that an individual must give consent, or opt in, to be included in the IIS

63 Known Consent Policies for Children

Child Vaccine Recipients

14	Include vaccine recipients in the IIS with no possibility for their parent(s)/guardians to opt them out
43	Include vaccine recipients in the IIS unless their parent(s)/guardian(s) opt them out
6	Must obtain explicit consent from vaccine recipients' parent(s)/guardian(s) to participate in the IIS

63 Known Consent Policies for Adults

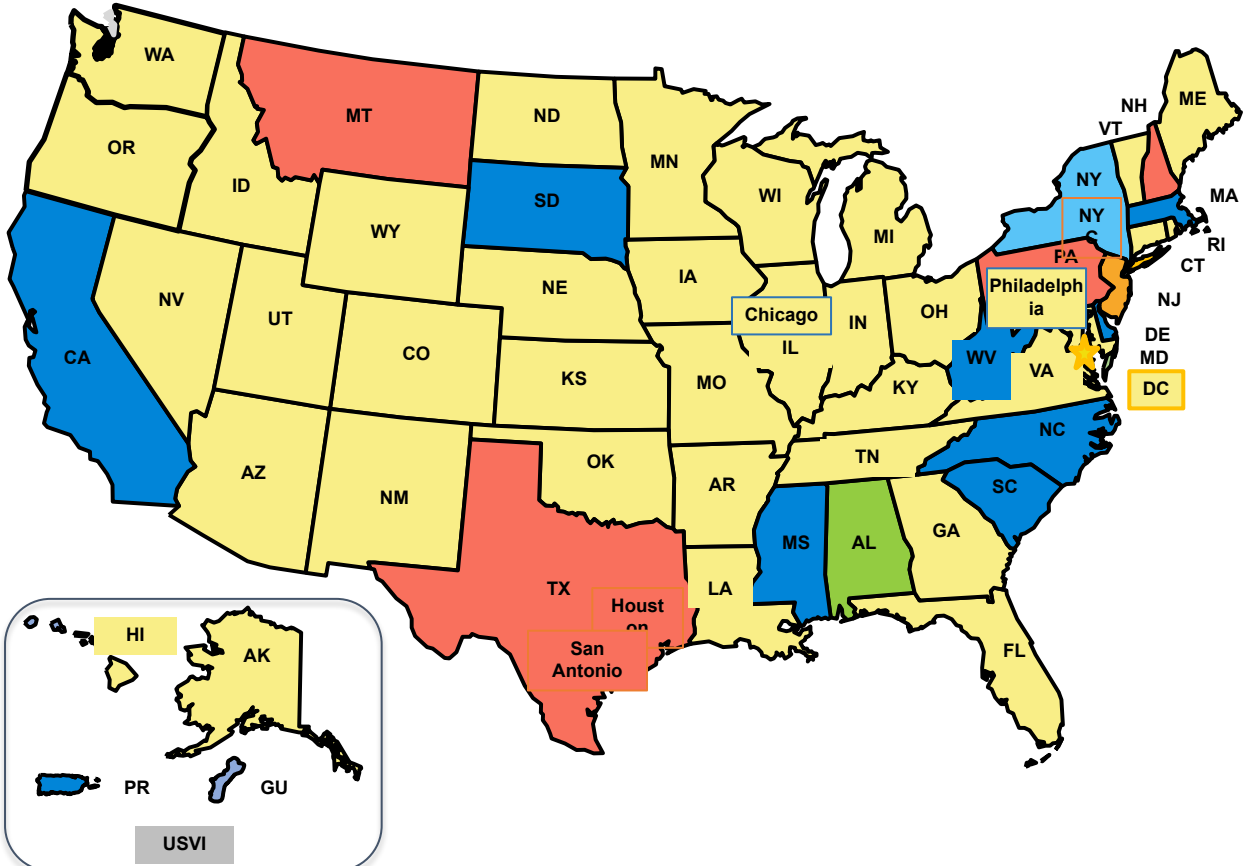
Adult Vaccine Recipients

12	Include vaccine recipients in the IIS with no possibility for them to opt out
42	Include vaccine recipients in the IIS unless they choose to opt out
9	Must obtain explicit consent from vaccine recipients to participate in the IIS

Legend

Mandatory inclusion for all individuals in the IIS 11
Mandatory inclusion for children; explicit consent for adults 2
Mandatory Inclusion for specific vaccine recipients 1
Implicit consent for all individuals 42
Implicit consent for children; explicit consent for adults 1
Explicit consent for all individuals 6
Policy developed and under legal review 2

Consent Policies



- Palau
- North Mariana Islands
- Micronesia
- American Samoa
- Marshall Islands



Reporting Policies

Requirements for vaccination providers to report immunizations to the jurisdiction's IIS

Types:

- All providers are mandated to report to the IIS
- Specific providers are mandated to report to the IIS
- Mandatory with age requirements
- Specific vaccines are mandated to report to the IIS
- No mandatory reporting to the IIS

Note: Jurisdictions may have a combination of reporting policy types

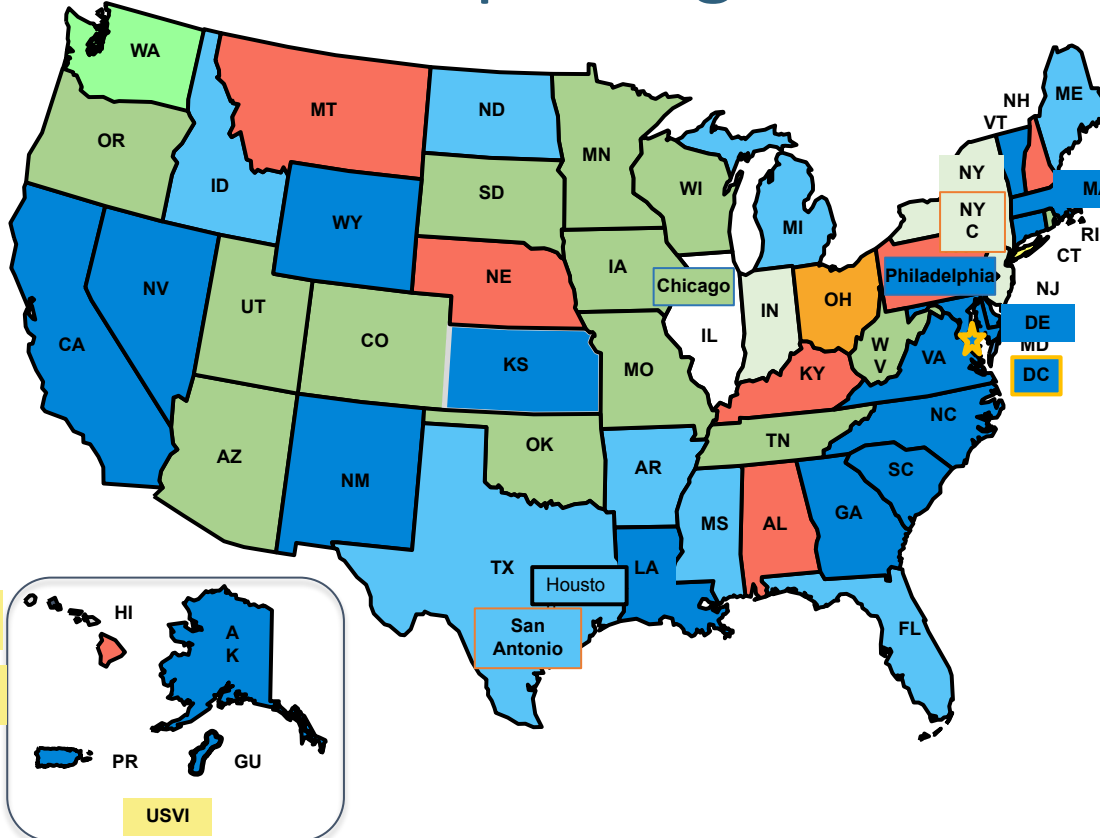
61 Known Reporting Policies

† An individual jurisdiction may be represented in more than one category.

Reporting Requirements†

20	Mandate by law that all providers must report immunizations for all vaccine recipients
16	Mandate reporting of immunizations for only a subset of vaccine recipients (e.g., children age 18 or younger)
15	Mandate reporting of immunizations by only certain providers (e.g., pharmacists, registered nurses)
10	Mandate reporting of only specific immunizations (e.g., COVID-19, VFC vaccines)
4	Mandate reporting of immunizations only under specific circumstances (e.g., a declared disaster)
3	Require by operational policy that all providers report immunizations for all vaccine recipients
7	Do not mandate reporting by providers

IIS Reporting Policies



Legend
Mandated reporting for all providers 20
Mandated reporting for specific ages 11
Mandated reporting for specific providers and specific ages 4
Mandated reporting for specific providers 15
Mandated reporting of specific vaccines 1
Required to report through an operational policy 3
Not required to report through an operational policy 1
No mandated reporting to the IIS 7

- Palau
- American Samoa
- North Mariana Islands
- Marshall Islands
- Micronesia

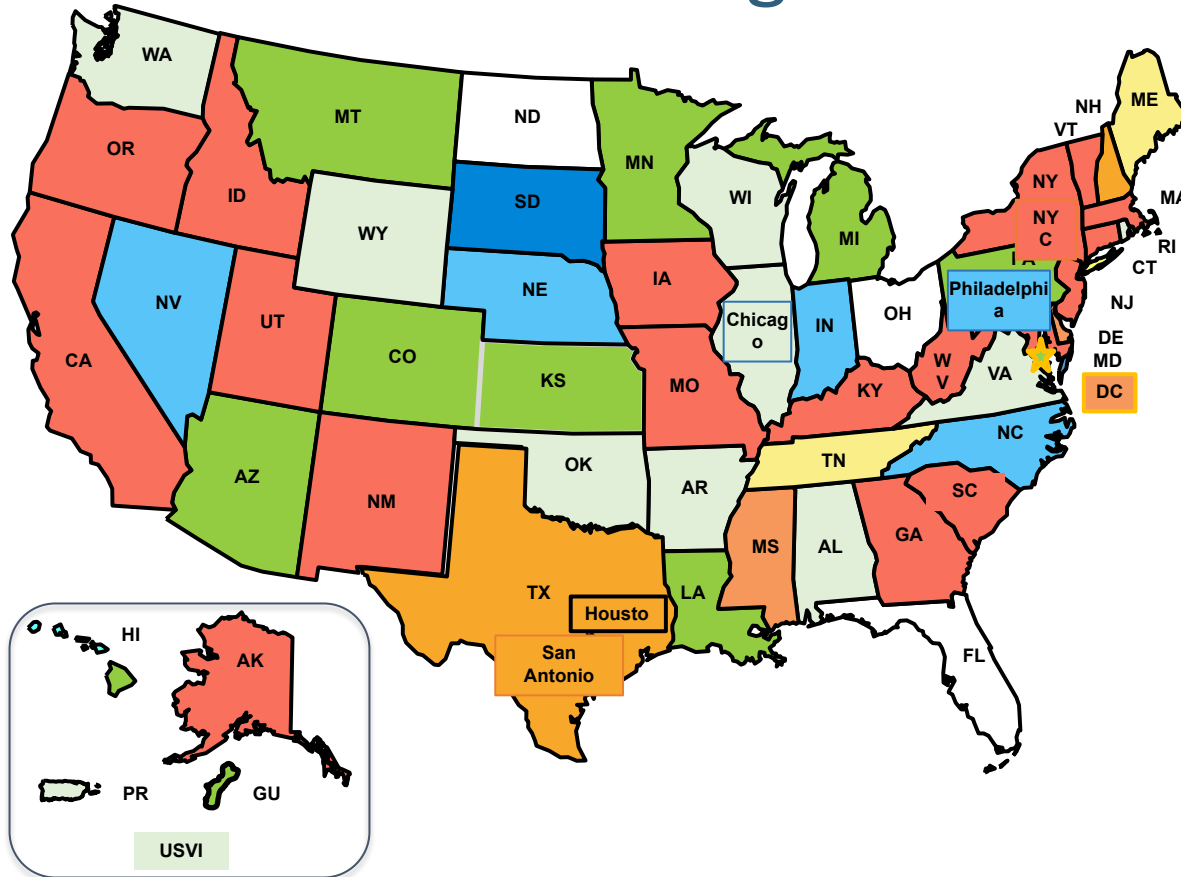
54 Known Data Sharing Policies

†† An individual jurisdiction may be represented in more than one category.

Data Sharing Policies††

21	Require a data use/sharing agreement or memorandum of understanding
14	May share data upon request or with approval/authorization
15	Require that data are only used for public health or other specific purposes (e.g., disease surveillance, IIS management)
15	Require protecting the data's confidentiality
7	May only share deidentified data or nonidentifying summary statistics
3	Allow vaccine recipients to request to limit sharing of their data that are stored in the IIS
2	May only share data during a declared state of emergency
1	Has no specific data sharing requirements or restrictions
3	Have not yet established data sharing policies

IIS Data Sharing Policies



Legend

No data sharing restrictions 1

Data can be shared upon request or with approval/authorization 4

Data sharing allowed with public health entities if an MOU or DUA is in place 14

Data can be shared for public health purposes of treating, control, investigating and preventing vaccine preventable diseases 10

Data sharing allowed with other jurisdictional IIS and Federal Entities if data confidentiality is maintained 2

Data may be shared for public health purposes at the aggregate level 4

No current data sharing policy 3

Data sharing policy has ≥ 2 features 18

- Palau
- North Mariana Islands
- Micronesia

American Samoa

Marshall Islands

USVI

Policy Changes since 2015 Landscape Assessment

Consent

- 12 jurisdiction changed the consent policy applying to all constituents
- 2 jurisdictions changed their childhood consent policy
- 4 jurisdictions changes their adult consent policy

Reporting

- 10 jurisdictions established universal reporting mandates
- 22 jurisdictions added some type of reporting mandate (e.g. for an age group or specific providers)



Activity #2: Discussion

What is your current jurisdictional policy configuration? Is it changing?
Share what's happening in your jurisdiction?

Consider:

- Jurisdiction trends focused on privacy
- Impact on what a jurisdiction shares and what it receives
- Managing expectations and gatekeep on data needs

IIS Program Policies and Procedures

Example IIS Policies

Jurisdictional-level examples

- Requirements to inform public on personal data handling
- Consent requirements*
- Security policies
- Vital records information
- Data uses: summary data/reports, research, evaluation
- Record retention
- Linking VFC vaccine distribution to IIS reporting



Procedures

- Documented and updated regularly, procedures are as critical as the policies themselves
- IIS procedures help ensure compliance with policies
- The most common kind of procedure document used across the IIS community is the Standard Operating Procedure (SOP)
 - Documents how things get done operationally, and by whom

Why Maintain SOPs?

- Consistency, ensuring a procedure is done accurately each time
- Accountability, so that you and your team can demonstrate how your program complies with applicable laws
- Turnover, since staff will inevitably change over time
- Onboarding of new staff, so that you have documents to orient and train them with
- Support cross-training among current staff

SOP Topics

The topics that need to be covered will be specific to your jurisdiction, but consider starting with the most common procedures:

- Common Helpdesk issue responses
- Requests for data
- Onboarding tasks
- Data Exchange tasks - importing or extracting
- Data quality tasks

SOP Tracking

Consider developing an index that can help you track policies in need of development, as well as the cycle of review

- As a general rule, SOPs and policies should be reviewed at least annually
- They don't need to be updated each time, but they should be reviewed and dated to ensure they are still current

Leveraging an SOP template and tracking index can streamline drafting and review

SOP Tracking Tool and Template

A	B	C	D	E
SOP Tracking Tool - Sample				
SOP #	Topic Area	SOP Title	SOP Author(s)	SOP Reviewer
ADV001	Advisory Council	Advisory Council Planning/Support		
ANL001	Analysis	Interoperability Benchmarking Processes		
DEX003	Data Exchange	HL7 Real-Time Data Exchange		
DR001	Data Requests	Data Requests - Ad-Hoc Internal		
ENT001	Data Entry	Incoming Mail		
EXT001	Data Extracts	Extract for HEDIS		
FOR001	Forecaster	Forecaster set-up/Updates		
HLP001	HelpDesk	Troubleshooting		
IMP004	Data Imports	Vital Records Upload		
INV001	Ordering & Inventory	Managing NDC Codes		
MGM001	Data Management	Locking and Purging/modifications		
MRG001	Merging	Merge Rules (patient and vaccine)		
QUA001	Data Quality	EDRS data loads		
REC001	Recall	Statewide Reminder Recall		
SYS001	System Maintenance	Updating Vaccine Codes		
TEAM001	Team Management	After-hours/Emergency Communication		
IMP005	Data imports	Medicaid Interface/data exchange		
IMP006	Data imports	WIC Interface		
IMP007	Data imports	Other Public Health Data sets linkages (lead, NBS, NBH)		
DEX004	Data exchange	Emergency Preparedness (pandemic Response)		
QUA003	Data Quality	Ongoing Data Quality Plan		

Standard Operating Procedure (SOP) Template

Project Phase 3: Execute Project Phase 4: Monitor

SOP Title	<Name of SOP>		
Topic Area	<Topic Area>		
SOP #	<#>	Version #	<version>
Implementation Date	<XX/XX/XXXX>	Last Revision Date	<XX/XX/XXXX>
SOP Owner	<Name of Owner>	Approver	<Name of Approver>
Document Path	<File path>		

1. Purpose and Background

[Describe the overall purpose for this procedure. Describe relevant background information.]

2. Scope

[Identify the intended audience and/or activities where the SOP might be relevant.]

3. Prerequisites/Related Resources/Documents

[Outline information required before proceeding with the listed procedure, or resources/documents related to this procedure; for example, any needed worksheets, documents, etc.]

4. Responsibilities

[Identify the personnel that have a primary role (and, if relevant, personnel who are cross-trained for a backup role) in the SOP and describe how their responsibilities relate to this SOP. If necessary, include contact information.]

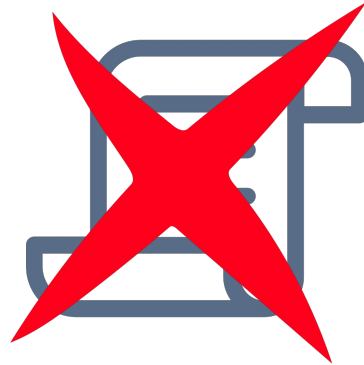
5. Procedure

Explore Risks to Modifying Laws or Policies

Laws can be changed, but there is risk...



Bill passes, get what you want

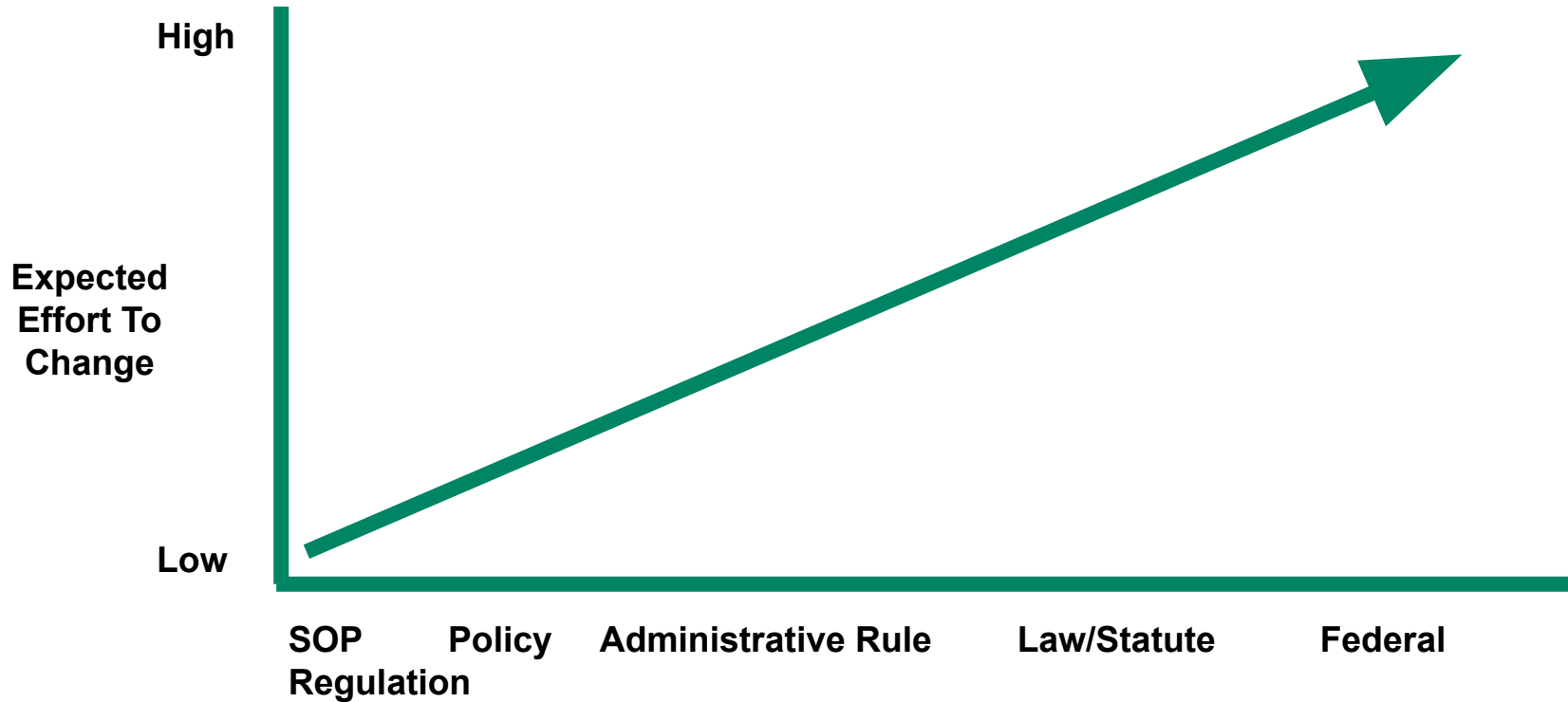


Bill fails, get nothing



Legislature changes bill, may include conditions you don't want

Consider Level of Effort to Change



Support

CDC, AIRA, and AIM all try to amplify the IIS/Immunization Program voice in policy/law, to ensure laws and policies continue to support our work:

- Representation on the Adult Vaccines Access Coalition
- Collaboration with HIMSS Government Relations
- Support for state laws/policies through testimony
- Comments on emerging federal laws/policies





Activity #3: Discussion Questions (select one)

1. Are there any changes to your laws or policies that you would like to make or ones being made that you find challenging to ensure complete data within your IIS?
2. What are some major challenges you might expect in making a change to your existing law/statute?

National Initiatives Impacted by the Policy Arena

IZ Gateway

- Inter-jurisdictional data exchange
- National Provider data exchange

Sharing Data with CDC

Public Data Dashboards

Policy Documents in 2023

Data sharing policy documents

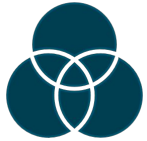
- CDC Data Use Agreement (DUA) for submission of vaccination data to federal level
 - COVID Only
 - All Routine and Flu Immunizations
 - Implementation of PPRL Business Associate Agreement (BAA)

IZ Gateway Legal documents

- Association of Public Health Laboratories (APHL) Data Use Agreement (DUA)
 - Share Task Order, Appendix A of APHL DUA
 - IIS-CDC Task Order, Appendix B of APHL DUA (See above)
- CDC Jurisdictional Provider Agreement (Immunization Gateway)
- Interjurisdictional Memorandum of Understanding (MOU)



Summary and Wrap Up



Policy is a complex area that affects IIS work at multiple levels (federal, state, local, law, procedures, etc.)



As an immunization Leader, you are in control of some of these levels, able to influence others, and simply responsible for implementing others



However, it is critical you understand and can speak to the impacts and intersections at all levels

Questions/Comments/Discussion?



Laws, Policies, and Procedures Resources

[Awardee Sharepoint Site Policy Document Folder](#)

- APHL DUA
- Interjurisdictional MOU
- Share Task Order, Appendix A of APHL DUA
- IIS-CDC Task Order, Appendix B of APHL DUA (see above)
- IZ Gateway Multi-Jurisdiction Vaccine Provider Jurisdiction Data Exchange Agreement (JPA)
- CDC COVID-19 DUA (current)
- CDC Routine and Seasonal Flu Immunization DUA
- Business Associate Agreement (BAA)

[AIRA Repository](#)

- [AIRA Confidentiality and Privacy Considerations for IIS](#) - assists IIS as they develop policies and procedures to meet legal requirements for protecting the privacy of individuals and the confidentiality of information in IIS
- [Public Health Inter-jurisdictional IIS MOU Template](#) - provides a fillable form for a MOU for secure, electronic exchange of immunization information among governmental entities that operate a population-based IIS
- [IIS Policies to Support Pandemic and Routine Vaccination One-Sheet](#) - highlights areas to focus on strengthening policy related to data exchange, vaccine reporting and consent to achieve more uniform, consistent policies
- [Immunization Program Policy Toolkit](#) - designed to equip members of the Association of Immunization Managers (AIM) and their staff with the tools and information necessary to appropriately and effectively engage with elected officials