



# Intersection of Policy and Immunization Information Systems (IIS)

**American Immunization Registry Association (AIRA) 2021  
National Meeting**

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# Robust IIS are Essential to Support a Resilient Vaccine Ecosystem

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The COVID-19 pandemic underscores the importance of robust IIS at the point of clinical care as well as population health level.

At the point of clinical care, a well-integrated IIS can **improve identification of patient vaccination needs** and facilitate data sharing across health systems.

At a population health level, IIS can be used to **monitor vaccination rates in communities** and better target vaccination initiatives.

From a vaccine equity standpoint, a robust IIS can be used to help **address disparities** and identify those that have disproportionately been affected.

The Community Preventive Services Task Force recommends the use of IIS based on strong evidence of effectiveness in increasing vaccination rates and reducing vaccine-preventable diseases.

# Progress has been made in strengthening IIS, but further action is needed across the United States to fully realize their benefits across the life-course

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## Actions include...



Ensuring all providers are consistently entering vaccination data for all patients across the life-course



Enabling schools and childcare facilities to access and input data into IIS, compliantly



Appropriately enforcing policies in place for reporting through oversight



Allowing patients direct access to their data and others to access de-identified data, as appropriate

# Study Objectives

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There is wide variability in IIS policies that can impact technical and programmatic capacity and a comprehensive legal assessment of IIS laws has not been completed in 10 years.

The objective of this study was to obtain up-to-date data and assess trends relating to jurisdictional laws (statutes and regulations) that enable, support or constrain the ability of an IIS to receive, store, or disclose vaccination information across the life-course.

We sought to:

- ✓ Develop a database of current IIS policies across all 50 states and Washington, DC
- ✓ Determine whether and how jurisdictions changed these laws in the last decade
- ✓ Identify potential policy barriers that may impact IIS data quality and completeness
- ✓ Identify examples of state policy that promotes data completeness

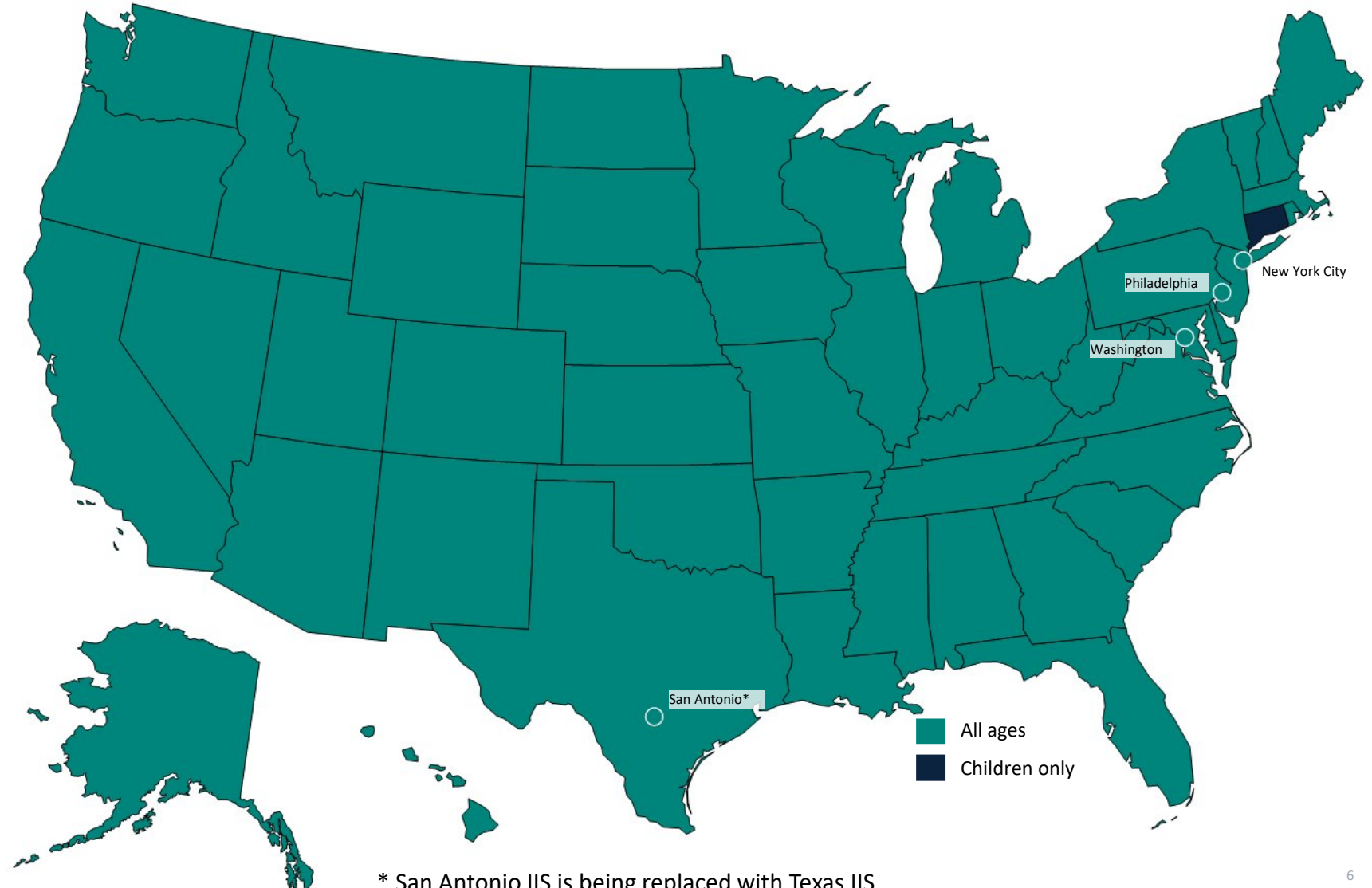
# Methods

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- Used legal epidemiological research methods to complete a cross-sectional analysis of IIS laws (statutes and regulations) across all 50 states and Washington, DC, Philadelphia, and NYC (n=53 jurisdictions)
- Collected state laws between July 05 – 16, 2021 using the WestlawNext® legal database
- Developed 12 parent questions and child questions, where appropriate, to capture nuances within the laws. Attribute themes included were:
  - Ages included in the IIS
  - Reporting requirements (by provider type and by pediatric and adults)
  - Consent required (pediatric and adults)
  - Data sharing provisions (intra- and inter-state)
  - Use of IIS for school and childcare entry
  - School and childcare access to data
  - Inclusion of demographic data (e.g., race/ethnicity)
- Examined state health websites as secondary sources to support validation of data
- Compared findings to the 2015 study<sup>1</sup> by Martin et al, which was a legal assessment of jurisdictional laws as of 2011, which was supplemented by an online survey of immunization program managers and follow up interviews.

# All jurisdictions assessed, except for Connecticut, have IIS across the life-course

Since the 2015 study by Martin et al, Rhode Island has expanded their IIS to include all ages and New Hampshire now has an operational IIS.

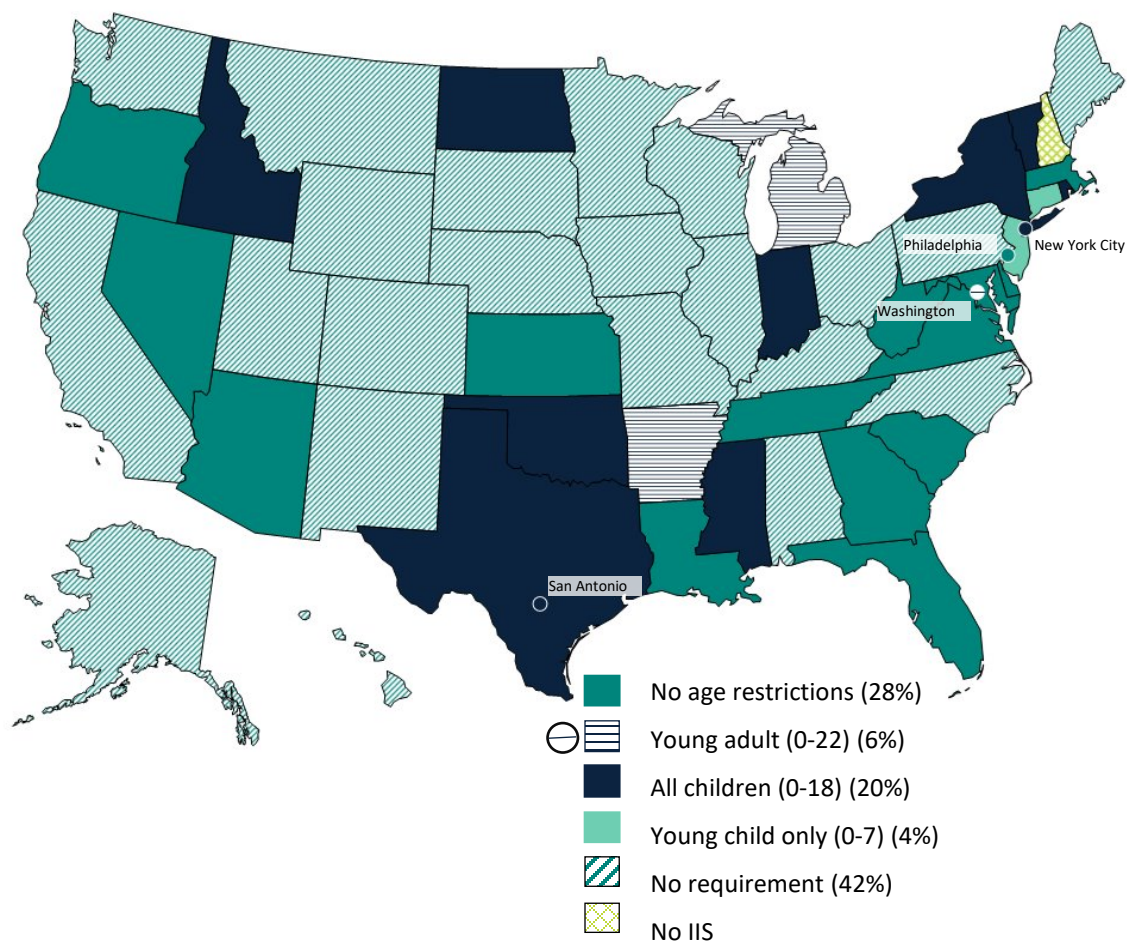


## Express consent is not required to record vaccination information into the IIS in the majority of jurisdictions (81% childhood and 70% adult)

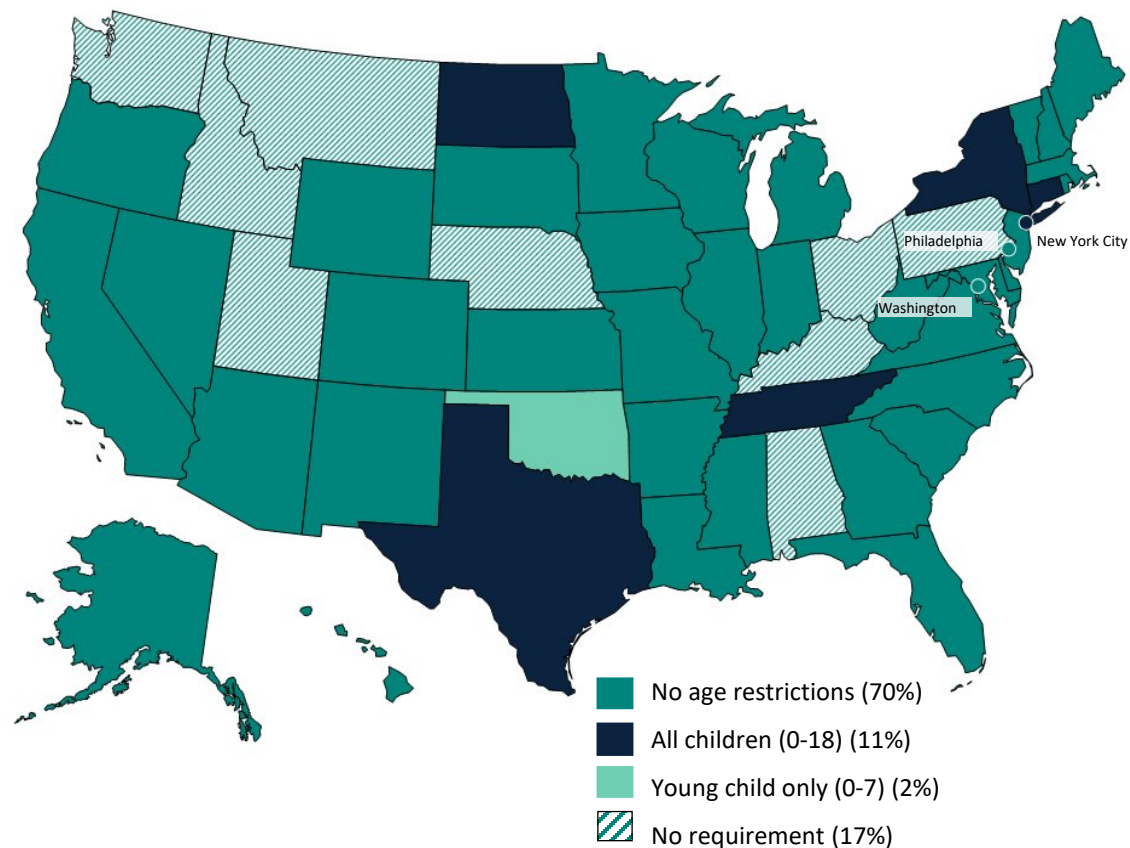
<b>% out of 53 Jurisdictions</b>	<b>Mandated (no opt out)</b>	<b>Implied Consent (with opt out)</b>	<b>Expressed consent (written)</b>	<b>Expressed consent (verbal or written)</b>	<b>Law is silent</b>
<b>Birth Record-Vital Statistics (by parent)</b>	26%	13%	4%	2%	55%
<b>Childhood Vaccination Info (by parent)</b>	30%	51%	4%	2%	13%
<b>Adult Vaccination Info</b>	19%	51%	7%	6%	17%

# Since 2011, the percentage of jurisdictions that have reporting requirements with no age restrictions increased from 28% to 70%

2011

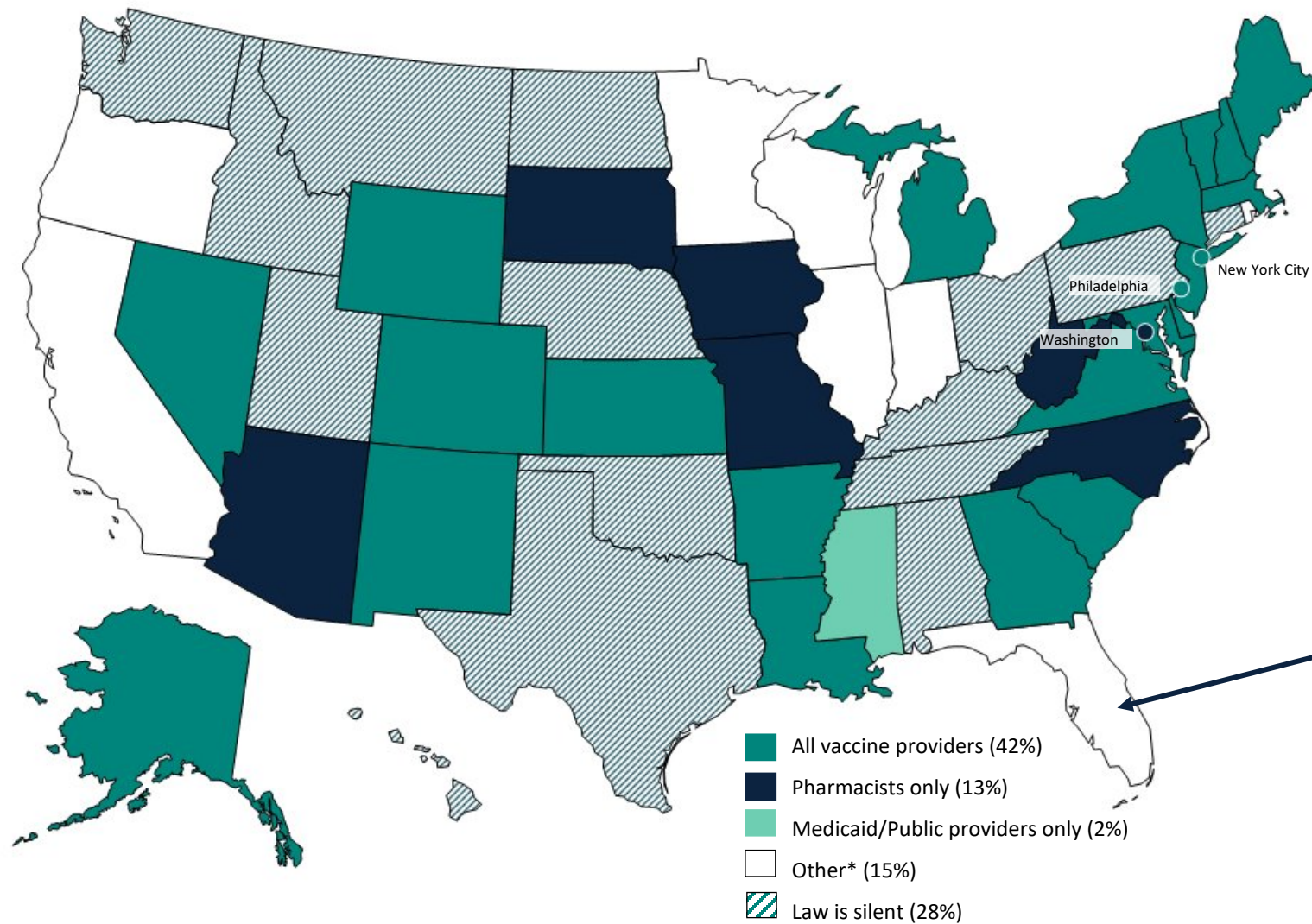


2021





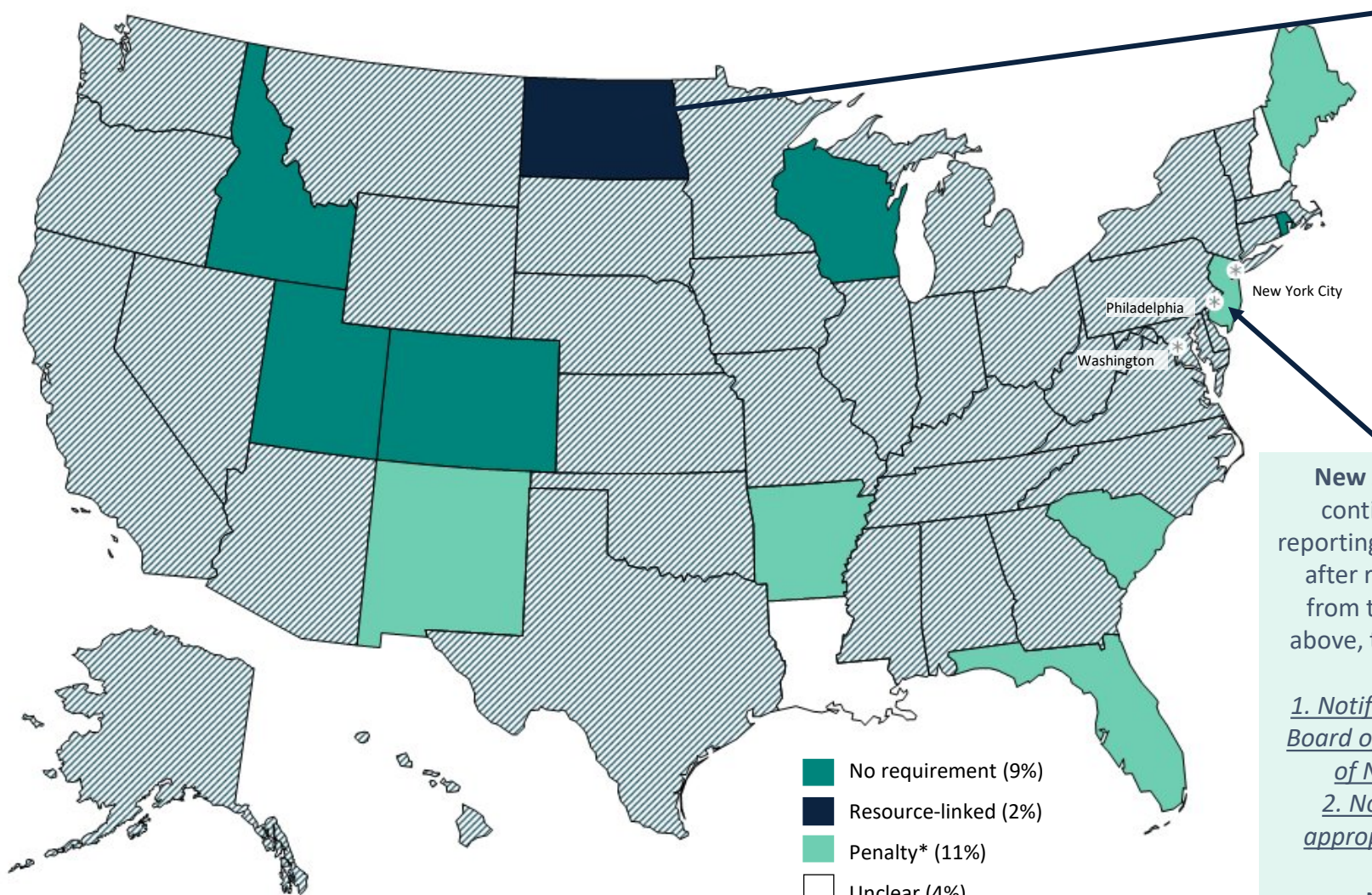
# 42% of jurisdictions require all vaccine providers to report **adult** vaccinations to the IIS



**Florida:** “A health care practitioner . . . who administers vaccinations or causes vaccinations to be administered to college or university students from 18 years of age to 23 years of age at a college or university student health center or clinic is required to report vaccination data to the immunization registry,”  
FL ST § 381.003

\* Laws may require specific provider types to report such as optometrists, student health clinics, dentists, midwives, VFC depending on state and patient age

# In 87% of jurisdictions, there is **no express enforcement mechanism for compliance** with reporting requirements



**North Dakota:** "2. If a health care provider fails to submit an immunization report required under this section within four weeks of vaccination:

- a. That health care provider may not order or receive any vaccine from the North Dakota immunization program until that provider submits all reports required under this section.
- b. The department of health and human services shall make a report to that health care provider's occupational licensing entity outlining that provider's failure to comply with the reporting requirements under this section.

N.D. Cent. Code Ann. § 23-01-05.3 (West)

**New Jersey:** "If a health care provider continues to be deficient in required reporting of vaccination information 30 days after receiving notification and warning from the Department as set forth in (b) above, the Department may impose other actions, such as:

1. Notification of the violation to the State Board of Medical Examiners or State Board of Nursing, as appropriate; and/or
2. Notification of the violation to the appropriate hospital medical director or administrator."

N.J. Admin. Code § 8:57-3.22

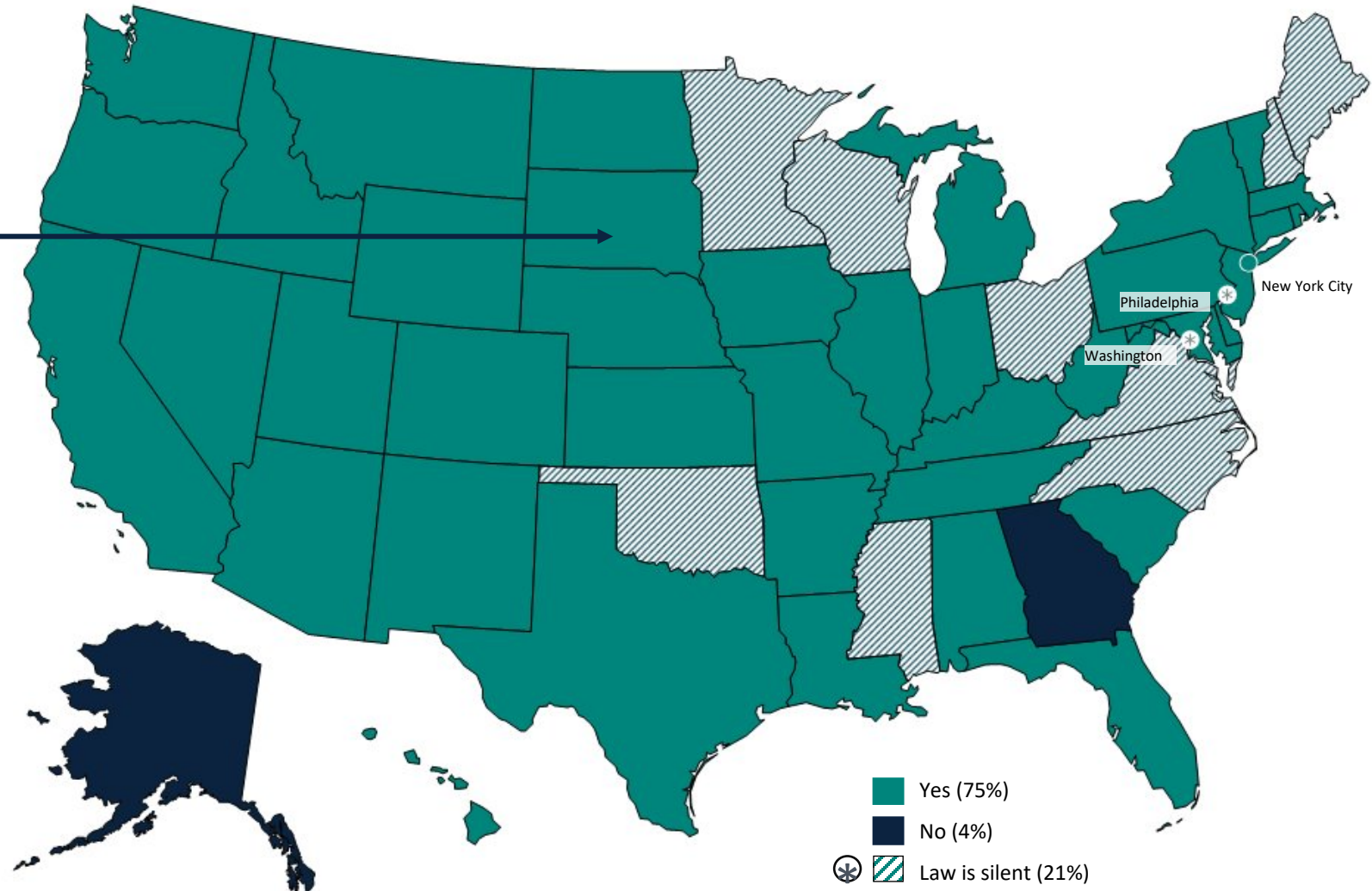
\* Penalties can include: reporting to authorities, civil penalties, removal/suspension from VFC program

- No requirement (9%)
- Resource-linked (2%)
- Penalty\* (11%)
- Unclear (4%)
- Law is silent (74%)



# Most jurisdictions (75%) expressly accept IIS-generated certificates as proof of vaccination for school and childcare entry

**South Dakota:** “ . . . Acceptable proof is a signed Immunization Record from SDIIS, a vaccination card from the parent or guardian, or a Certificate of Immunization. If a card is presented, the immunizations shall be entered in to SDIIS or a Certificate of Immunization form shall be completed.  
S.D. Admin. R. 44:81:04:02



# While most jurisdictions allow schools and childcare facilities access to IIS, only 35% expressly permit school and childcare staff to enter data

% out of 53 Jurisdictions	Access Only	Edit Rights
Yes	81%	35%
No	0%	19%
Unclear	2%	8%
Law is Silent	17%	38%

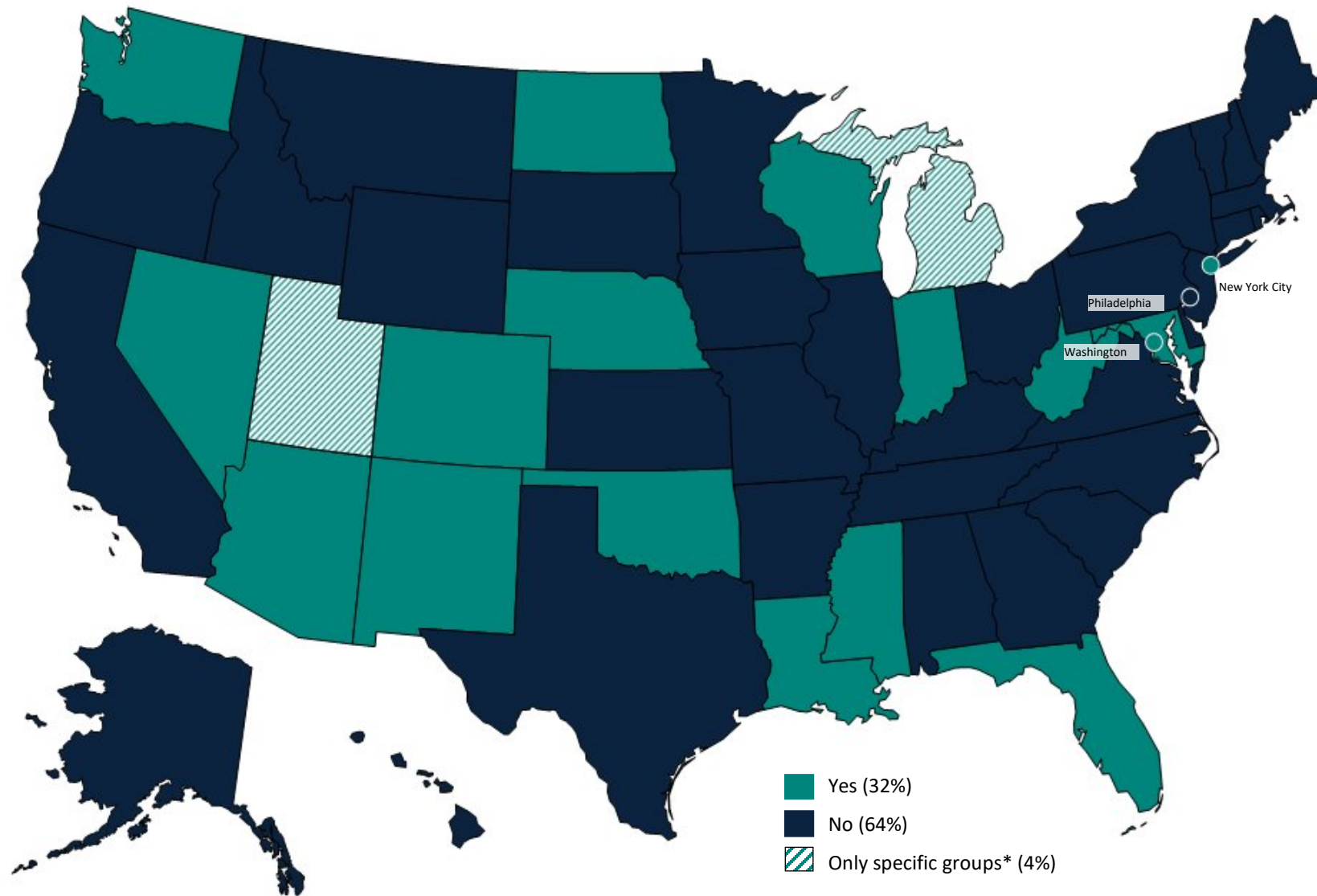


**New York:** “Allowable access levels and permitted uses of NYSIIS and/or CIR data by authorized users specific to the organization they are representing.  
 (ii) Read-only access. Authorized users . . . such as schools are permitted read-only access to NYSIIS and/or the CIR,”  
 N.Y. Comp. Codes R. & Regs. tit. 10, § 66-1.2

**West Virginia:** The information shall be entered into WVSIIS in order to ensure that updated immunization information is readily available to health officials in the event of a communicable disease outbreak that presents an imminent danger to students or other members of the community.  
 W. Va. Code R. 126-51-6



# 32% of jurisdictions provide patients direct access to personal vaccination data from the IIS



Direct access means through portal, app, or other digital tool.

# Capturing demographic characteristics in the IIS is critical to support addressing vaccine disparities among population groups

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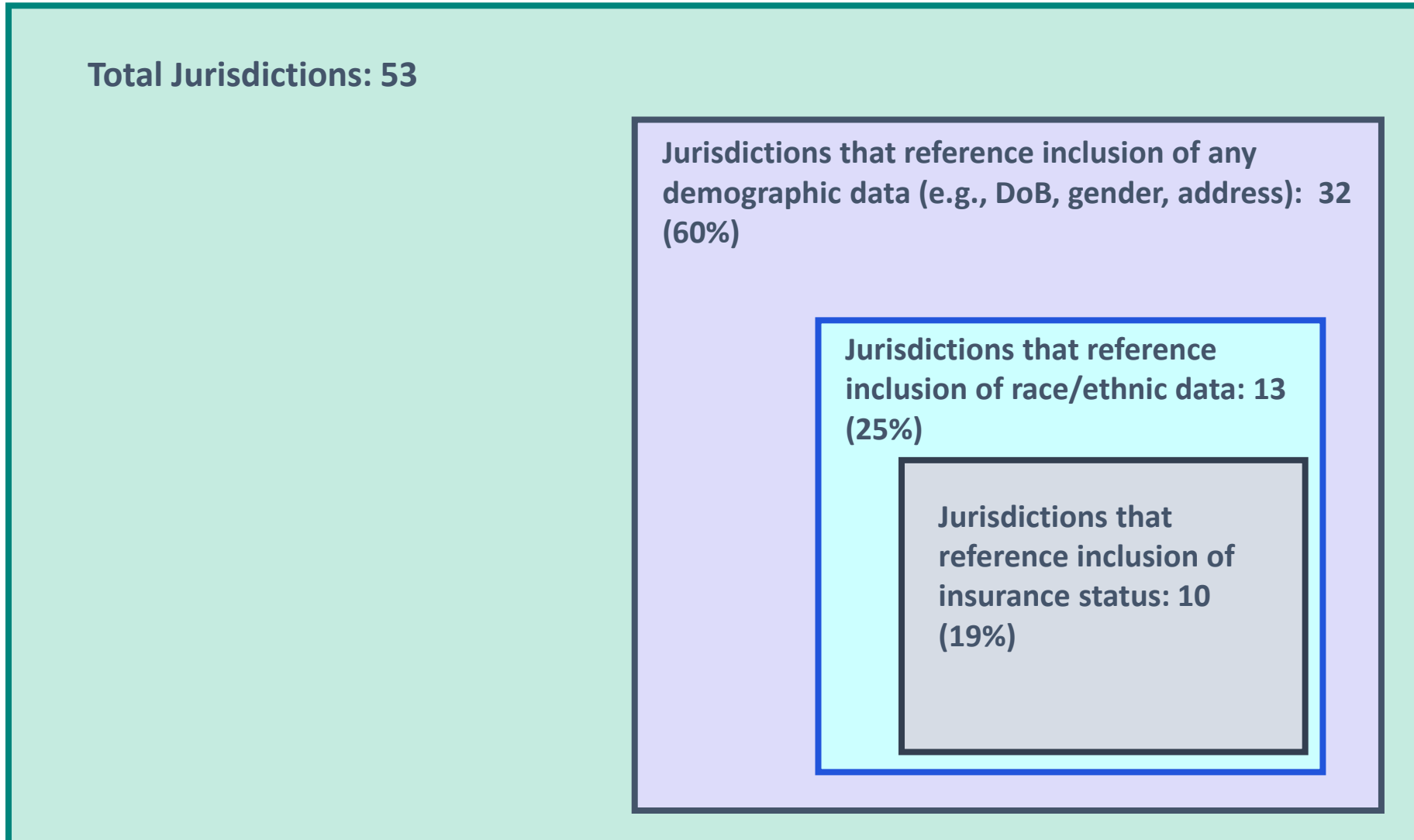
**The Centers for Disease Control and Prevention (CDC) designed functional standards that describe the operations, data quality, and technology needed by IIS's to support immunization programs, vaccination providers, and other immunization stakeholders.** This covers 4 key areas:

- Policy Framework
- Essential Infrastructure
- Data Quality
- Use and Terms of IIS

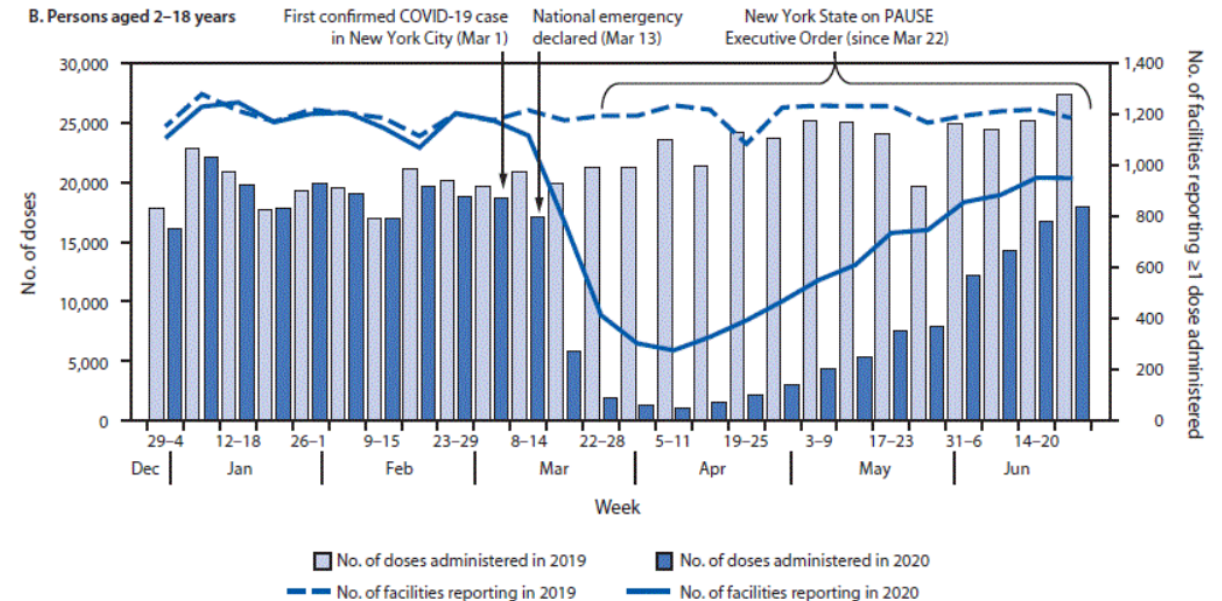
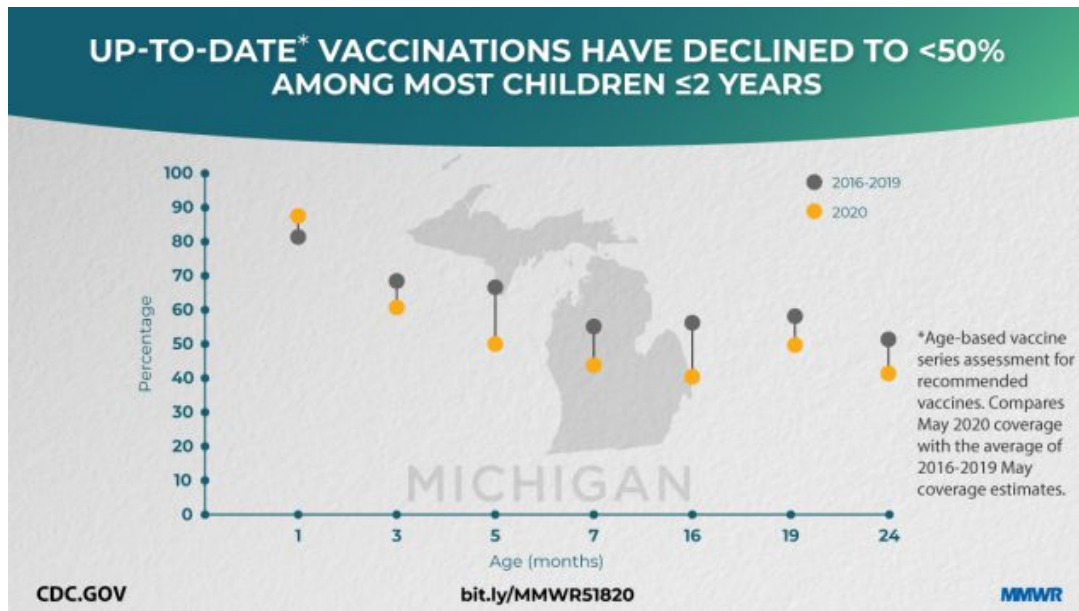
**Demographic data are included as CORE elements in the Essential Infrastructure.** This includes data elements such as: race, ethnicity, address, birthplace, gender, insurance status, and VFC eligibility.

**Jurisdictions may include option for inclusion of demographic data elements in their IIS.** We were interested in identifying which states required inclusion of certain demographic criteria in the IIS within their IIS policies.

# Only 25% of jurisdiction's policies detail race/ethnicity as mandatory patient demographics for inclusion in IIS



Policies that support the ability of an IIS to receive, store, or disclose vaccination information across the life-course are critical to appropriate oversight of individual, community, and population health.



**Examples of how IIS data is being used during the COVID-19 pandemic to demonstrate the changes in routine vaccination**

Source: Bramer CA, Kimmins LM, Swanson R, et al. Decline in Child Vaccination Coverage During the COVID-19 Pandemic — Michigan Care Improvement Registry, May 2016–May 2020. MMWR Morb Mortal Wkly Rep 2020;69:630–631. DOI: <http://dx.doi.org/10.15585/mmwr.mm6920e1>

Source: New York City Department of Health and Mental Hygiene Citywide Immunization Registry (CIR); data are as of July 14, 2020.

# Key Takeaways

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## **The COVID-19 pandemic has illustrated the following:**

- Importance of complete and quality patient vaccination data to record and monitor COVID-19 vaccination.
- Understanding the impact of COVID-19 on routine vaccination rates and efforts to recover.

## **By two years of age, over 20% of the children in the U.S. typically have seen more than one healthcare provider, resulting in scattered medical records.<sup>1</sup> IIS reporting requirements may help consolidate fragmented data.**

- Over the last decade, our research shows a 42% increase in provider reporting requirements for all ages when compared to Martin et al's 2015 study.
- Yet, while nearly all IIS collect data across the life-course, only 57% require all providers to report pediatric vaccinations and even fewer (42%) require all providers to report adult vaccinations.

## **Due to vaccination requirements for entry, schools and childcare facilities often hold the most complete vaccination records.**

- Only 35% of jurisdictions expressly permit school or childcare staff to enter data into IIS, and in some cases only school nurses are provided these rights. Family Educational Rights and Privacy Act (FERPA) restrictions on student record data-sharing may pose a barrier to this.

# Demonstrating value of IIS at the State-level will be key to enhancing utility and promoting uptake more broadly

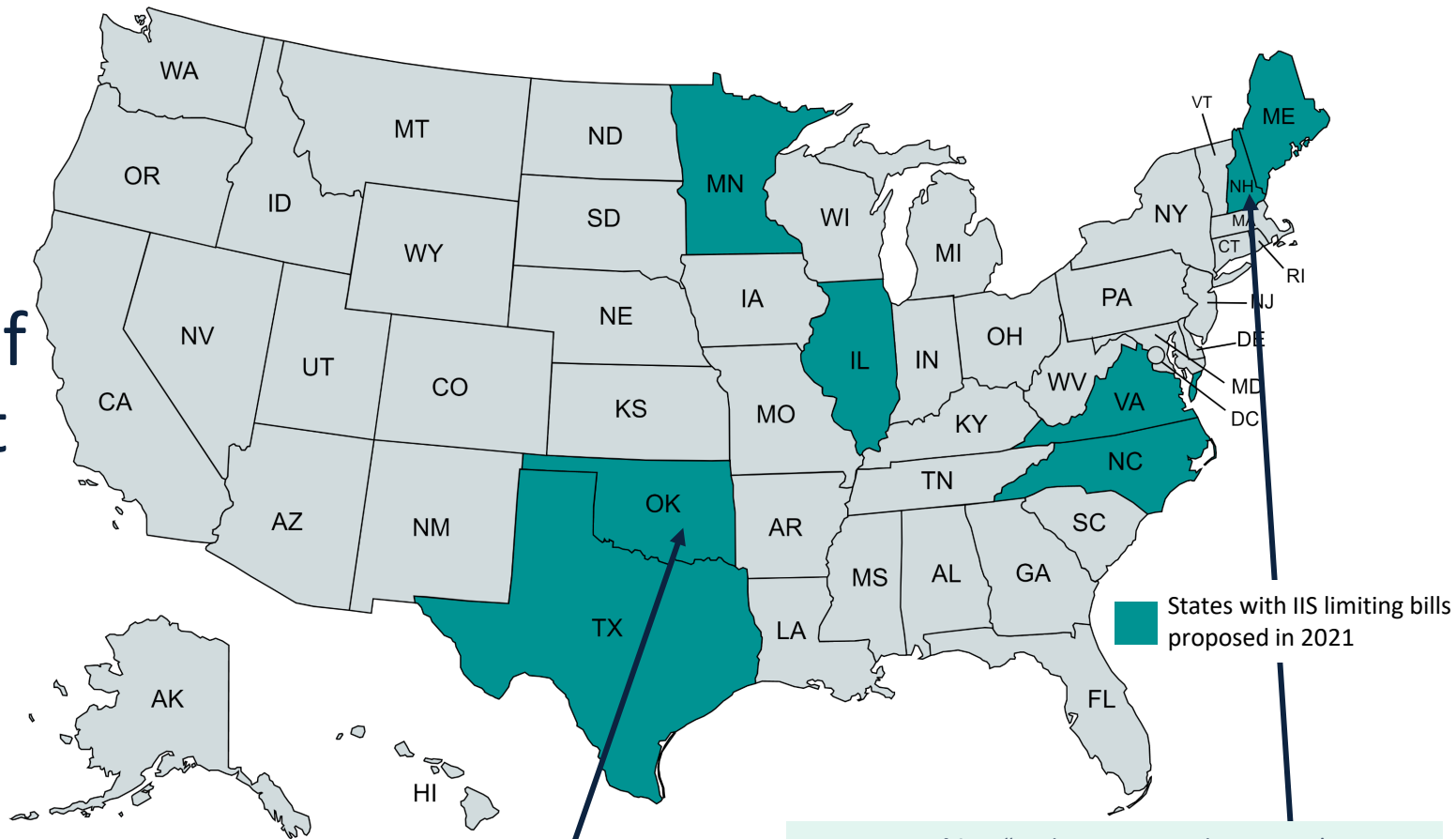
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## Why is advocacy for IIS at the State-level important right now?

- Widespread adoption can significantly reduce disease burden, unnecessary health care costs, and optimize quality improvement
- Demonstrating value of IIS through real-world examples can help State-level policymakers and public health officials better understand their utility
- Integration with EHRs is critical to streamlining provider workflows, increasing IIS adoption, and providing real-time retrieval and delivery of information
- Improving data quality can enhance and create more robust IIS overall

# Demonstrating the value of IIS is also critical to protect progress from emerging threats

While the COVID-19 pandemic has demonstrated the critical importance of IIS as a centralized repository of vaccination data across the life-course with the capacity to securely share with other health data systems, concurrently **we have seen an emerging threat to IIS in the recent 2021 legislative session.**



**Oklahoma:** “The State Department of Health or an agent of the Department *shall not enter immunization records or other data of an individual into any database or system* including, but not limited to, the Oklahoma State Immunization Information System *without the prior written informed consent* of the individual or, in the case of a minor child, the prior written informed consent of the minor child’s parent or guardian . . . .”

**New Hampshire:** “Each patient, or the patient’s parent or guardian if the patient is a minor, *shall be given the opportunity to opt-in to the immunization registry*. No patient’s immunization or vaccination information shall be entered into the registry without the explicit, written, opt-in consent of the patient, or the patient’s parent or guardian.”

# Study Limitations

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- This study was comprehensive legal assessment of IIS laws and did not include surveys of relevant stakeholders or self-reported data. The previous Martin et al study was based on both a legal assessment as well as self-reported data from IIS programs.
- There may be programmatic policies in place that impose additional requirements and have not been considered.
- Local rules, policies, and municipal ordinances were not used unless included on jurisdiction's state law or state health department website.
- San Antonio IIS was excluded as it is in the process of being replaced by Texas IIS. At present, San Antonio residents are currently able to opt-in to either IIS.
- Previous analyses did not assess school and childcare related IIS provisions nor demographic related provisions, as such, those are not included in the comparative analysis.

# Next Steps for Legal Analysis

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Perform in-depth analysis over last 20 years of IIS policy data

Compare policy findings to CDC functional standards and core elements of IIS

Develop manuscript (to be finalized by Nov/Dec 2021)

Incorporate suggestions from YOU on how this data can be leveraged

# Opportunities for Future Efforts to Enhance IIS

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**Sharing best practices and lessons learned at the state-level can help support future research to examine policies, programmatic features, and technical capabilities that are essential drivers to data quality and completeness (e.g., sharing of state-level best practices that enable school staff to enter data into IIS).**

This can be done by:

- Developing case studies on high-performing, robust registries
- Qualitative analysis: semi-structured interviews to understand facilitators and barriers for enhanced IIS and how IIS can be utilized to support high vaccination coverage rates (including demographic data to address vaccine disparities and promote equity)
- Quantitative analysis: Understand impact of policies and programmatic features on IIS usage, and potentially health outcomes such as vaccination rates

# Thank you!

**For questions, please contact:**

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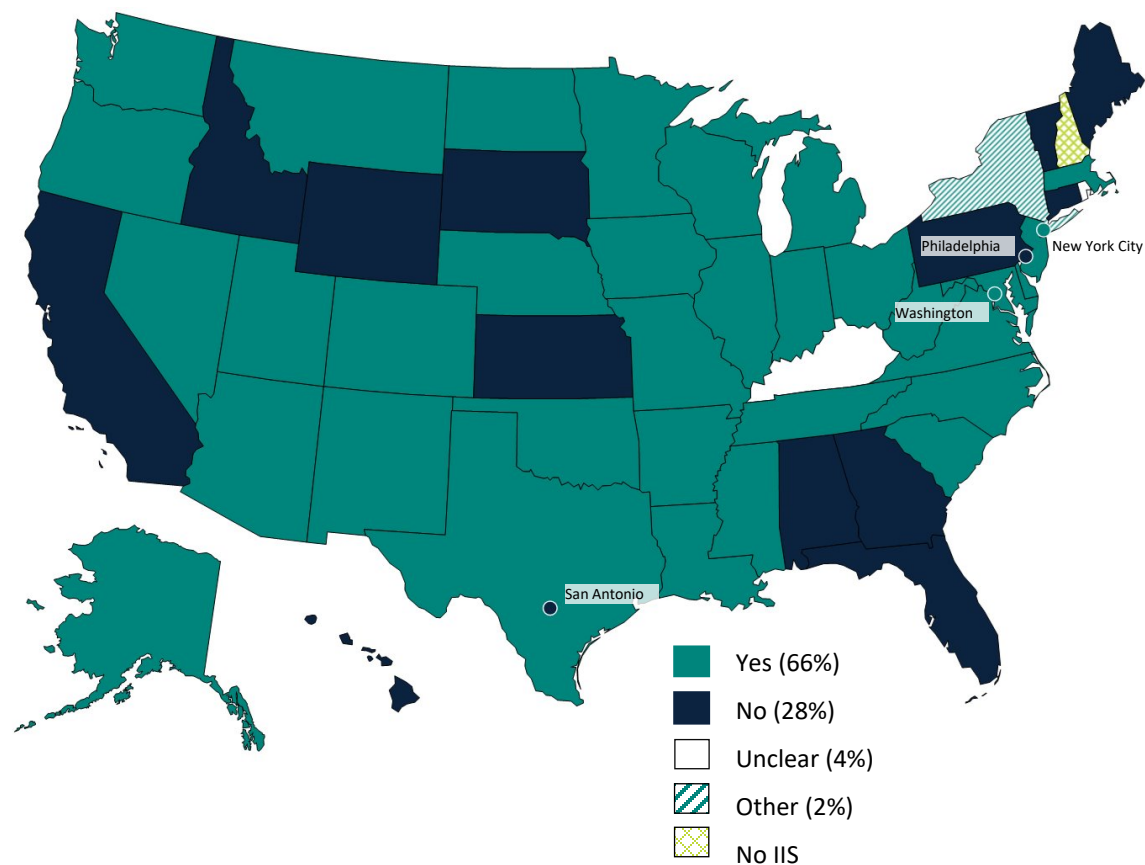
Lara Heersema, PhD, MSc

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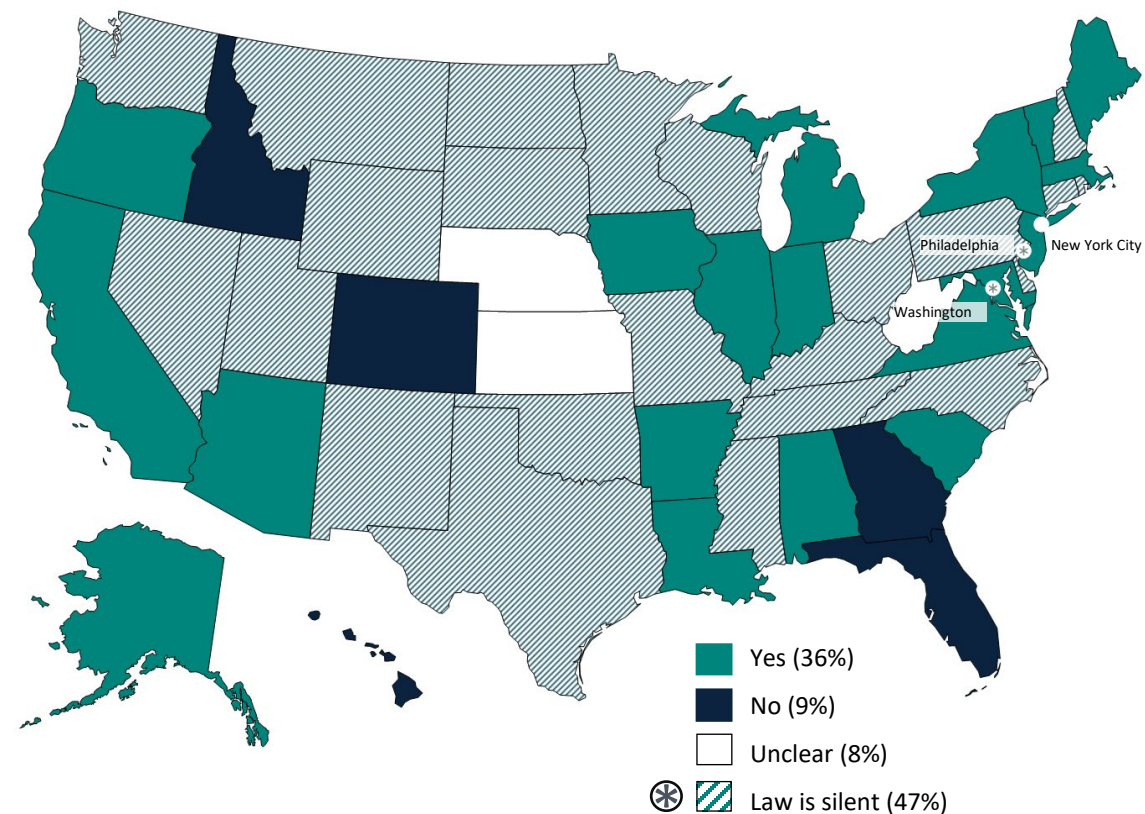
Alex Ervin, JD candidate

# In nearly half of jurisdictions assessed, the law is silent regarding inter-state data sharing

2011



2021



Adapted from Martin et al. 2015