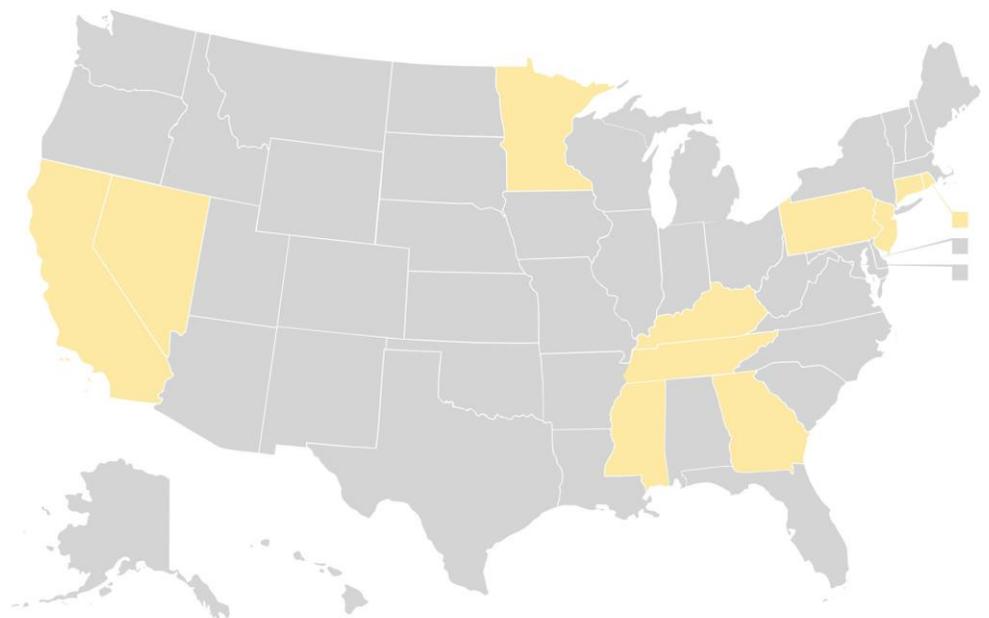


# Research Protocol for Pharmacist Vaccination Laws

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RESEARCH PROTOCOL  
January 2016

## *Pharmacist Vaccination Laws*

- I. **Date of Protocol:** January 1, 2016
- II. **Scope:** This legal dataset consists of state statutes and regulations enacted on or before January 1, 2016, relating to the authority of pharmacists to administer vaccines to patients. The statutes and regulations were accessed through the Westlaw legal databases.
- III. **Primary Data Collection**
  - a. **Project dates:** Legal research was conducted from July 19, 2013, through July 2, 2014, and updated March 29, 2016.
  - b. **Dates covered in the dataset:** The dataset includes laws in effect on or before January 1, 2016. Although data prior to January 1, 1990 exists in the full data (the complete data is presented in the “Full data – all variables” tab in the data extract), only data between January 1, 1990 and January 1, 2016 can be explored using the maps at [LawAtlas.org](http://LawAtlas.org). This date range was selected because fewer states had enacted Pharmacist Vaccination laws prior to January 1, 1990, yielding searches with blank data for a majority of states. The earliest effective date for laws included in the dataset varies by jurisdiction, depending on a number of factors, including:
    - i. Limitations of the Westlaw databases (i.e., how far back in time the Westlaw digital archives extend for a jurisdiction)
    - ii. Frequency of updates to the law (e.g., a Westlaw state archive may only extend back to 2002, but if the law was not changed between 2004 and 1984, then the version of the law in the 2002 archive reflects the version of the law in effect in 1984)
    - iii. The earliest discovered instance of relevant law (e.g., if a law came into effect in 2008, there are no previous versions of that law to collect)<sup>1</sup>

**c. Data Collection Methods:**

The WestlawNext database was used to identify current statutes and regulations using selected search terms (detailed below). The “Historical Notes” and “Credits” sections contained in the Westlaw annotations were used to identify the legislative

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<sup>1</sup> The earliest effective date for laws included in the dataset ranges by jurisdiction from 1971 (New York) to 2010 (South Carolina).

or regulatory history for each current law. Past versions of laws and regulations were obtained by using the Westlaw Classic database archives.<sup>2</sup> Effective dates in the archived versions of the law were cross-checked with the legislative history to verify that the correct version of the law was collected and to verify that no intermediate legislative actions took place between statutory versions. Whenever the legislative or regulatory history was not included in the Westlaw annotations for a law, the archived versions of the law were pulled consecutively in reverse chronological order from the Westlaw Classic annual archives. If an effective date could not be found for a law, the law was assigned a default effective date. For this research, the default effective date was 02/02/YYYY<sup>3</sup> (with YYYY reflecting the year associated with the Westlaw Classic annual archive used to obtain the text of the law).<sup>4</sup>

In some instances, a law would be reconstructed based on the text found in the legislative or rule-making history. For example, if 1) more than one legislative action impacted a law in a given year, 2) the actions had differing effective dates, and 3) Westlaw did not provide the alternate versions of the law for the different effective periods of the legislative actions, then the text of the enacted legislation (i.e., bill(s) passed by the legislature) was used to reconstruct the law as it existed during a date range.

When possible, the earliest relevant law was identified. In many cases, Westlaw Classic archives were adequate to check whether a law existed prior to the earliest effective date indicated in legislative history. In those cases, the archive of the year preceding the earliest listed effective date was used to verify that no prior versions of the law were relevant to the study. If the Westlaw archives were insufficient to verify the existence of a law prior to the earliest known version, legislative and regulatory history was checked to verify whether the enacting language reflected an amendment of an existing law or adoption of a new law.

**Databases used:** Westlaw Classic® and WestlawNext®

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<sup>2</sup> The WestlawNext and Westlaw Classic databases contain historical archives for state statutes and regulations. These historical archives are maintained on an annual basis. Each year, Westlaw archives the statutes and regulations in effect in two separate annual archives (i.e., one annual archive for a state's statutes and one annual archive for the state's regulations). This archiving process usually occurs in December or January. If the archiving process occurred in December, the year associated with the annual archive is the year the archiving process occurred. If the archive process occurred in January, the year associated with the archive is the preceding year (i.e., an annual archive created on January 1, 2008, would be associated with the year 2007).

<sup>3</sup> February 2 was chosen as the month and day of the default effective date primarily because the month and day combination, "02-02," is easily identifiable.

<sup>4</sup> For example, the text of a Massachusetts regulation changed between April 15, 2009 and October 27, 2010. The text of the changed regulation was found within the Westlaw archive titled "Massachusetts Administrative Code - 2010." The precise effective date for this regulatory change could not be found, so it was assigned the default month and day (February 2), and assigned the year 2010 to correspond with the annual archive where the text was obtained. See *supra* note 2.

**Search terms:** “vaccin!,” “pharmac!,” “immuniz!,” “administ!,” “protocol,” “prescription!,” “standing order,” or other key words likely to be named in the statute based on trade organization data, such as “influenza” or “zoster.”

## IV. Coding

### a. Development of coding scheme

- i. The coding scheme was developed through an iterative process. There were four stages to this process: 1) development of a question set, 2) testing the questions on a batch of legal provisions, 3) analysis of question adequacy, and 4) revision of questions. This iterative process was repeated for all state legal provisions. There were 10 revisions to the coding questions.
- ii. Questions were designed to capture the scope of the authority of pharmacists to administer vaccines. There are four broad categories of questions:
  1. Questions addressing the legal authority of pharmacists to administer substances (i.e., legal authority to administer drugs or vaccines)
  2. Questions addressing limitations or requirements for pharmacists who administer vaccines (e.g., training requirements, patient notifications, or state registration)
  3. Questions addressing specific types of authorizations (i.e., authorization to administer vaccines without prescription, to administer to a group of patients, or to administer only to named patients)
  4. Questions addressing limitations that are specific to a type of authorization (e.g., limiting the use of patient-specific immunization prescriptions to certain vaccines, certain patient age groups, or certain modes of administration)

### b. Coding methods

- i. The coding methodology had two phases. In the initial phase, legal provisions were coded without reference to other legal provisions within the same jurisdiction. For example, statutes and regulations within the same jurisdiction were coded separately in this first phase to help identify any inconsistencies.
- ii. In the second phase, laws within the same state that were in effect at the same time were coded together. The result of this second phase was that each state would have exactly one coded answer to each question for a given time period.
- iii. Dividing the coding methodology into two phases served three purposes. First, it helped researchers develop coding questions (outlined above) because examining the laws separately helped identify new coding questions or nuances within existing coding questions that needed refinement in protocol. Second, coding each law separately helped identify possible contradictions and inconsistencies within a jurisdiction’s

laws. Finally, it added redundancy in coding; laws would be reanalyzed collectively after they were analyzed separately.

**c. Coding criteria**

**i. Coding Definitions:**

1. “Y” or “Yes” means the law clearly satisfies the coding criteria.
2. “N” or “No” means the law clearly rejects the coding criteria.
3. “AB” or “Ambiguous” means the law could either satisfy the coding criteria or not, depending on differing reasonable interpretations of the terms of the law.
4. “NM” or “Not Mentioned” means the law does not address the coding criteria.
5. “N/A” or “Not Applicable” means the question is not relevant given the response to another question, such as in “parent”-question and “child”-question relationships where a child question might not be applicable given a particular answer to the parent question.

**d. Question coding instructions:**

**i. May a pharmacist administer substances to a patient?**

1. Code “yes” if the law clearly states that pharmacists may directly administer substances to patients.
2. Code “yes” if the law says that practice of pharmacy includes “drug administration” (including all reasonably synonymous terms) or includes a term the state defines as including “drug administration” (including all reasonably synonymous terms).
3. Code “ambiguous” if the state’s definition of “practice of pharmacy” lists administration without using the term “drug.”
4. For the purposes of this question, include reasonable variations of “practice of pharmacy” within the scope of this question. For example, code this question “yes” if the law includes drug administration within its definition of “pharmaceutical services.”

**ii. Are pharmacists explicitly authorized to vaccinate?**

1. Code “yes” if there are any circumstances in which a state will allow a pharmacist to administer a vaccine, and if the law clearly describes the authority.
2. Code “yes” if the law allows pharmacists to administer biologics or biologicals.
3. Code “no” if the law allows drug administration but an included definition of “drug” does not expressly include immunizations, vaccines, biologics, or biologicals.

**iii. What is the youngest age of a patient a pharmacist may vaccinate under any authority (not including emergencies)?**

1. Record the lowest age allowed for vaccination in any nonemergency circumstance.
2. Code “not mentioned” if the law does not limit vaccinations by age.
3. Note: Unless otherwise indicated, an adult is interpreted to be a person at least age 18 years.

**iv. Does the state require specific qualifications beyond general licensing requirements, including, but not limited to, training or education?**

1. Code “yes” if the law requires specific qualifications pharmacists must have before vaccination. Examples of qualifications beyond general licensing requirements include education in administering vaccines, education in emergency response to adverse reactions to vaccine administration, training in administering emergency epinephrine, certification in cardiopulmonary resuscitation, or certification from a nonstate entity, such as a trade organization.
  2. Code “no” if the only qualification required to administer vaccines, in addition to general licensing, is certification with a state entity (e.g., state pharmacy board). See question below relating to registration/certification requirements. However, code the question “yes” if the state entity requires specific education, training, or experience for vaccination beyond general licensing for the certification.
- v. Does the state have a prior notification requirement for a pharmacist to administer vaccines, such as state registration or state certification requirements?**
1. Code “yes” if the state requires that a pharmacist do something to notify the state prior to administering vaccines to patients, such as submit practice information, copies of vaccination orders or protocols, or registration.
  2. Note: Requirements that a pharmacist provide documentation of vaccination qualifications to a state on request of a state entity does not by itself indicate that this question should be coded “yes.”
  3. Code “no” if the only registration or certification requirements involve nonstate entities.
- vi. Are there specific vaccine reporting requirements for vaccine administration?**
1. Code “yes” if the law requires pharmacists to report vaccinations under some circumstances. Examples: requirements that pharmacists report vaccinations to a patient’s primary physician or the pharmacist-authorizing physician, that pharmacists report adverse reactions, and that pharmacists report vaccinations to an immunization registry.
- vii. Are there specific record-keeping requirements for vaccine administration?**
1. Code “yes” if the law requires specific record keeping for vaccination distinct from general pharmacist record-keeping requirements.
  2. Note: Requirements that a pharmacist be trained in record keeping as a prerequisite to vaccine administration does not by itself indicate that this question should be coded “yes.”
- viii. Does the state require specific patient notifications (e.g., a Vaccination Information Statement)?**
1. Code “yes” if the state expressly requires patient notifications beyond general requirements of consent.
  2. Note: Requirements that pharmacists provide patients with a record of the vaccination are not relevant to this question because

they relate to records of treatment rather than patient education or counseling.

- ix. **Does the state have specific requirements for the physical facility where pharmacists vaccinate?**
  1. Code “yes” if the law requires that the pharmacist vaccinate in a specific type or types of physical facility.
  2. Note: The location of a facility within a designated geographic area, such as a designated “healthcare shortage area,” may be a facility requirement under this question.
- x. **Does the state allow pharmacists to choose not to vaccinate as part of their practice of pharmacy?**
  1. Code “yes” if the state provides an express provision allowing pharmacists to opt out of vaccine administrations.
  2. Code “no” if the state forbids an authorized pharmacist from refusing to administer a vaccine.
  3. Note: Allowed professional discretion by itself should not be coded “yes.” Uncertainty regarding this question should be coded “ambiguous” or “not mentioned.”
- xi. **Does the state permit exceptions to grant pharmacists the authority to vaccinate in an epidemic or emergency?**
  1. Code “yes” if the law lessens or expands the requirements for pharmacists to vaccinate under certain circumstances where public health is at heightened risk.
- xii. **Does the state have an exception for state-declared emergencies?**
  1. Code “yes” if the law has an exception during emergencies as declared by a state entity.
- xiii. **Does the state have an exception for epidemics declared by non-state public health organizations (CDC, WHO)?**
  1. Code “yes” if the law has an exception for epidemics declared by a nonstate public health entity, such as the Centers for Disease Control and Prevention (CDC) or the World Health Organization (WHO).
- xiv. **Does the state require pharmacists to carry malpractice insurance to vaccinate?**
  1. Code “yes” if the law requires pharmacists who vaccinate to obtain insurance (e.g., malpractice coverage) in addition to what is normally required to practice pharmacy.
- xv. **If able to administer vaccines, does the law grant pharmacists prescriptive authority?**
  1. Code “yes” if the law gives pharmacists unilateral authority to administer vaccines under some circumstances.
  2. Code “yes” if the law allows pharmacists to administer vaccines without a physician’s approval and without a standing order or protocol from the state.
  3. Code “yes” if the only restrictions on the pharmacist’s ability to administer vaccines are requirements that pharmacists follow guidelines established a nonstate public health entity (e.g., CDC) or guidelines established by a trade organization.

4. Code “no” if there is no circumstance where a pharmacist can administer a vaccine without physician approval or without an order from the state.
  5. Note: A collaborative agreement between a physician and pharmacist that gives the pharmacist authority to prescribe should be interpreted as a third-party authorization, not as a grant of prescriptive authority, because the basis of the prescriptive authority is the third-party agreement.
- xvi. Are there patient age limitations for the pharmacist’s prescriptive authority (general authority, patient-specific authority)?<sup>5</sup>**
1. Code “yes” if the law limits a pharmacist’s prescriptive authority (general authority, patient-specific authority) to certain patient age groups in some circumstances.
  2. Code “no” if the law does not limit a pharmacist’s prescriptive authority (general authority, patient-specific authority) to certain age groups.
  3. Note: Record minimum patient age permitted under a pharmacist’s prescriptive authority (general authority, patient-specific authority). Legal citations for the specific age limitation recorded are equivalent to the citations for this question.
- xvii. If there are age limitations on prescriptive authority (general authority, patient-specific authority), does it vary by vaccine type?<sup>5</sup>**
1. Code “yes” if the law allows pharmacists to administer more than one type of vaccine, and at least two vaccines are limited to patient groups with different age ranges. For example, “Pharmacists may administer influenza vaccines to patients at least 14 years old and administer all other vaccines to adult patients.”
  2. Code “no” if the law specifies a single age range for all vaccines authorized under the law for a pharmacist to administer.
  3. Code “no” if the law authorizes pharmacists to administer only one vaccine.
  4. Code “no” if the only age variations listed in the law are under different types of authorization. For example, “Pharmacists may administer any vaccine to adult patients under a standing order or patient-specific prescription and influenza vaccines to patients at least 14 years old under a patient-specific prescription.” This example contains two different types of limitations (age limitations and vaccine limitations) within the context of two different types of authorizations (general authorizations and patient-specific authorizations). The question (do age limits vary for different vaccines?) only addresses variations within a specific authorization type, so variations in age and vaccine limitations between authorization types are not relevant. In this example, the

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<sup>5</sup> The coding instructions for the prescriptive authority questions mirror instructions for the general authority and patient-specific authority questions. Parentheses are used to indicate where “general authority” or “patient-specific authority” are interchangeable with “prescriptive authority” for some questions.

age limits for general authorizations do not vary by vaccine type; pharmacists may administer any vaccine to adult patients. In contrast, the age limits on patient-specific authorizations do vary by vaccine type because the pharmacists have different age limitations for influenza and noninfluenza vaccinations authorized under a patient-specific prescription.

5. Note: Any differences in age limitations must be for the same type of administration authorization (prescriptive authority, general authority, patient-specific authority) for a “yes” code to be appropriate.
6. Note: Record age limitations that vary by vaccine. Legal citations for the specific age limitations recorded are equivalent to the citations for this question.

**xviii. Does the law limit which vaccines a pharmacist may prescribe and administer (general authority, patient-specific authority)?<sup>5</sup>**

1. Code “yes” if the law limits a pharmacist’s prescriptive authority (general authority, patient-specific authority) to certain vaccines.
2. Code “no” if the law allows a pharmacist to administer any vaccine under a prescriptive authority (general authority, patient-specific authority).
3. Note: The following example is representative of an age limitation and not a vaccine limitation because all vaccines are allowed under the authorization type: “A pharmacist may administer influenza vaccine to a person 6 years of age or older or may administer vaccine other than influenza vaccine to a person at least 18 years of age.”
4. Note: Record all vaccines specifically authorized.

**xix. Under a prescriptive authority (general authority, patient-specific authority), is a pharmacist limited to certain modes of vaccine administration?<sup>5</sup>**

1. Record all modes of vaccine delivery by mode of delivery (e.g., injection, ingestion) if the law limits the vaccines a pharmacist may administer under the pharmacist’s prescriptive authority (general authority, patient-specific authority).
2. Code “no” if the law includes a nonexhaustive list of modes of administration. For example, a law that says “pharmacists can administer vaccines by injection, inhalation, or other means” is an example of a nonexhaustive list that does not limit the modes of vaccine administration available to pharmacists.
3. Code “not mentioned” if the statute does not enumerate specific modes of delivery.

**xx. Are there other limitations to a pharmacist's prescriptive authority (general authority, patient-specific authority) besides limitations on patient age, vaccine, or mode of delivery?<sup>5</sup>**

1. Code “yes” if the law includes a limitation to prescriptive authority (general authority, patient-specific authority) that is not a limitation by patient age, vaccine, or mode of delivery.
2. Code “no” if the only other limitations listed are the general limitations and restrictions for all authority types that were

previously covered by other questions (e.g., training requirements, reporting requirements, record-keeping requirements).

3. Note: Record other limitations.

**xxi. If the state allows pharmacists to vaccinate, does a pharmacist need third-party authorization in certain circumstances?**

1. Code “yes” if the law requires a third party to authorize the pharmacist to administer vaccines in certain circumstances. Examples of third-party authorizations include prescriptions, standing orders from physicians, standing orders from a state entity, or an authorizing protocol.
2. Note: Standing orders can be patient-specific or general.
3. Note: Some states use the term “protocol” to imply an authorizing instrument. Other states use “protocol” to imply a set of instructions to follow when so authorized.
4. Code “no” if the only limitation on a pharmacist is to use professional judgment in administering vaccines or to follow guidance established by nonstate entities, such as CDC. See [Prescriptive Authority Questions](#) above.

**xxii. Is the third-party authorization to vaccinate required to be patient-specific?**

1. Code “yes” if the pharmacist must have a patient-specific authorization in nonemergency settings.
2. Code “no” if an authorizing instrument allows a pharmacist to administer vaccines to more than one patient. For example, a “no” code is appropriate for a law specifying that an authorizing instrument can allow a pharmacist to administer a vaccine to any patient who fits certain criteria, such as an adult patient without contraindications for immunizations. In this example, the authorizing instrument grants a general authorization to administer vaccines.
3. Note: Standing orders can be patient-specific or general.
4. Code “ambiguous” if law does not use specific language with regard to a third-party authorization, e.g., “physician’s order.”
5. Note: Some states use the term “protocol” to imply an authorizing instrument. Other states use “protocol” to imply a set of instructions to follow when so authorized.

**xxiii. If the law permits a pharmacist to administer vaccines under a general authority, does the law have limitations for general authorizations to vaccinate based on the age of the patient, the type of vaccine, or the mode of vaccine delivery?**

1. Note: The coding instructions for the general authorization questions mirror instructions for the prescriptive authority questions. Please see [Prescriptive Authority Questions](#) above for coding and interpretation guidance.
2. Note: General requirements and limitations such as record keeping, reporting certification, etc. that are captured by other questions do not factor into the coding of this question.

**xxiv. If the law permits a pharmacist to administer vaccines under a patient-specific authority, does the law have limitations for patient-**

**specific authorizations to vaccinate based on the age of the patient, the type of vaccine, or the mode of vaccine delivery?**

1. Note: The coding instructions for the patient-specific questions mirror instructions for the prescriptive authority questions. Please see [Prescriptive Authority Questions](#) above for coding and interpretation guidance.
2. Note: General requirements and limitations such record keeping, reporting certification, etc. that are captured by other questions do not factor into the coding of this question.

**V. Quality Control**

**a. Redundant coding**

The validity of data collection, coding, and data entry was checked in two different phases. In the first phase, after the first researcher finished coding all laws, a second researcher selected 10 states at random and duplicated the collection and coding of laws while blind to the first researcher's coding. The second researcher then verified that the results were consistent between researchers.

The second phase occurred after the data were loaded into the LawAtlas platform. During the second phase validation check, the first researcher selected 10 states at random and verified that text of the law supported each code for all entries for the 10 states.

Coder divergence rates were calculated for laws in effect between January 1, 2014 and January 1, 2016.

The average divergence rate for blind coders was 5.3%, with a range of 0% – 23.3%.<sup>6</sup> In other words, blind coders agreed on 94.7% of questions on average.

**b. Secondary source comparison**

Two secondary sources were identified<sup>78</sup>, which were used to verify the accuracy of the data on a limited basis. These sources each contained one variable included in the data at specific points in time, corresponding to when these secondary sources were most recently updated:

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<sup>6</sup> Divergence rate calculations excluded questions requiring free text answers and other “detail” questions relating to specifics of a “parent” question because of the difficulty in measuring divergence in these questions. Calculations also did not distinguish between “no,” “not mentioned,” and “not applicable” answer choices because differences among these responses were typically the result of data entry error rather than substantive differences in legal interpretation.

<sup>7</sup> “States Authorizing Pharmacists to Vaccinate” *Immunization Action Coalition*, 7 Mar. 2016. Web. 1 Nov. 2016. <http://www.immunize.org/laws/pharm.asp>

<sup>8</sup> “Pharmacist Administered Vaccines” *American Pharmacists Association*, 1 Oct. 2013. Web. 1 Nov. 2016. <http://www.pharmacist.com/sites/default/files/PharmacistIZAuthority.pdf>

The ExplicitVx variable was verified on March 7, 2016. As this data is current until January 1, 2016, and the secondary source's data was current as of March 7, 2016, any divergences in this check triggered a verification that the law had not been updated between those two dates, to ensure that the divergence was not due to a change in law.

GAAgeLim was verified on October 1, 2013 against the same point in time in this data.

Using SAS 9.4, two random samples of data for the specified points in time were selected. ExplicitVx was coded in 51 records total on January 1, 2016, a 50% random sample (25 records) was selected for this variable. GAAgeLim was coded in 51 records total on October 1, 2013, a 50% random sample of records (25 records) was selected for this variable.

In the check on the ExplicitVx variable, one divergence was identified. The divergence was analyzed and it was concluded that it was due to a difference in the coding scheme between the secondary source and this dataset.

In the check on the GAAgeLim variable, one divergence was identified. The divergence was analyzed and it was concluded that it was also due to a difference in the coding scheme between the secondary source and this dataset.

## VI. Updates

The 2016 update followed sections 1-3 of the above protocol with the addition of a second researcher for data collection and coding. For the 2016 update, two researchers blind-coded each jurisdiction's laws that were in effect between January 1, 2014 and January 1, 2016. After each blind coding session, coding discrepancies were analyzed and corrected in peer-review meetings. The consensus codes for each jurisdiction's laws were determined by peer review and recorded in the final dataset.

In a few cases, the researchers' consensus decision on the codes for laws in effect between January 1, 2014 and January 1, 2016 indicated a possible coding error for a jurisdiction's codes for laws in effect prior to January 1, 2014. In these situations, researchers re-evaluated that jurisdiction's laws for consistency with the consensus decision.