

**Data Use and Sharing Agreement to Support the United States Government's
COVID-19 Emergency Response
Jurisdiction Immunization and Vaccine
Administration Data Agreement**

This Data Use and Sharing Agreement (DUA) is made between **the New Mexico Department of Health** (Jurisdiction) and the Centers for Disease Control and Prevention (CDC), an agency of the Department of Health and Human Services (HHS), to describe the data use and sharing parameters for certain immunization and vaccine administration data, as further described herein. This DUA: 1) describes the data needed for the monitoring of COVID-19 vaccine uptake; 2) describes the methods and parties within CDC, HHS, and other users who will be authorized to access, display, or share these data; 3) describes platforms for the rapid collection, transmission, use, storage, and maintenance of vaccine administration data available to jurisdictions; 4) establishes the terms and conditions for the sharing, protection, and use of these data with CDC, HHS, and other federal partners; and 5) sets forth the roles and responsibilities of each party.

The DUA is effective as of December 4, 2020 ("Effective Date").

Background and Purpose

Access to immunization and vaccine administration data is critical to the whole of government response to the Coronavirus Disease 2019 (COVID-19) public health emergency. In furtherance of federal government response efforts, HHS and CDC seek to obtain and utilize these data from various immunization and vaccine data sources, including a jurisdiction's immunization information system (IIS), pharmacies, federal provider organizations, and other relevant parties for a range of purposes, including but not limited to, rapidly assessing patterns of vaccination among the population; identifying pockets of undervaccination; assisting in determining vaccine resource allocation to address the needs of jurisdictions; monitoring vaccine effectiveness and safety; assessing spectrum of illness, disease burden, and risk factors for severe disease and outcomes; and helping to understand the impact of COVID-19 on the healthcare system and communities.

To support these purposes, HHS and CDC, working with partners, have developed a technical architecture to facilitate the transmission of jurisdictional vaccine administration data from various sources to CDC, and then to HHS's Tiberius analytic platform, to generate a comprehensive picture of COVID-19 vaccine uptake nationally. HHS and CDC 1) have developed specifications to describe critical demographic and vaccination elements for COVID-19 vaccine administration to be reported to CDC; 2) have made available a series of platforms and tools for use by data sources to manage, share, and store their immunization data in furtherance of the response; 3) will, consistent with applicable law, enable the secure transmission of extracted data from and across these platforms for further use by jurisdictions, CDC, HHS, and other federal partners in furtherance of the response; 4) as applicable, will assure compliance of these platforms with the Federal Information Security Management Act (FISMA) and other federal data security policies; and 5) will provide operational support to the data sources and other authorized users of the various platforms, as appropriate.

To ensure comprehensive monitoring of vaccine administration, HHS and CDC are requesting the following types of COVID-19 vaccine administration data. A detailed description of these elements, data submission specifications, and relevant systems can be found in Appendices A–D.

1. **Record-Level, Identifiable Dataset:** This dataset, which will reside in the Data Clearinghouse (DCH), contains identifiable data elements, as defined in Appendix D, and is being requested for specific purposes, including to assess and verify second-dose vaccination, to assess vaccine safety, and to allow for critical vaccine effectiveness monitoring. Identifiable elements are also needed to ensure proper deduplication of information for analytic purposes. Neither HHS nor CDC will have access to or release such identifiable data, including but not limited to names and other identifying information of persons who are the subject of such data, either during the term of this DUA or longer, except as consistent with this DUA or as may be allowed or required by applicable law. Jurisdictions that are unable (due to legal or regulatory restrictions) to submit identifiable data to CDC will be provided with the alternative option of implementing Privacy-Preserving Record Linkage (PPRL) technology when it is available (see Appendix E).
2. **Record-Level, Redacted Dataset:** This dataset, which, after submission, will reside in the Immunization Data Lake (IZ Data Lake) is a condensed version of the identifiable dataset and does not include 16 of the 18 identifiers as defined under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). These data will also be used to monitor vaccine uptake, but a jurisdiction may be unable to fully assess the second-dose vaccination needs of its population, particularly in a case when individuals are vaccinated in multiple states. Therefore, jurisdictions submitting record-level, redacted datasets because of legal or statutory prohibitions against submitting identifiable data to CDC will be provided with the alternative option of implementing Privacy-Preserving Record Linkage (PPRL) technology when it is available (see Appendix E).

Information regarding all variables requested for submission to CDC, Data Security, and Data Access are described throughout this DUA. If a state law or regulation prohibits the submission of identifiable data, jurisdictions will be required to provide legal documentation.

Authority

HHS and CDC are authorized by Sections 301 and 319D of the Public Health Service Act [42 U.S.C. §§ 241 and 247d-4], as amended, to maintain active surveillance of diseases through epidemiologic and laboratory investigations and data collection, analysis, and distribution.

The jurisdiction entering this DUA agrees that it is authorized under NMSA 1978 Section 24-5-9 to send the Covered Data to and through the Vaccine Administration Management System (VAMS), COVID-19 Data Clearinghouse (DCH), Immunization Data Lake (IZ Data Lake), and HHS Tiberius (Tiberius), as those platforms and systems are further defined herein, and/or will obtain consent from any external entities or individuals from whom it collects data to allow for such sharing and use. The parties agree that consistent with Appendix B, jurisdictions, including New Mexico, and federal agencies, who are data sources, are only authorized to view identifiable portions of the data they provide to the DCH. CDC, HHS, or other federal entities will not have access to identifiable data in the DCH. A redacted dataset will be transferred to the IZ Data Lake. For the redacted dataset, where CDC has requested date of birth as a data element, New Mexico will instead provide year of birth. The parties agree that this limitation controls throughout this DUA.

In addition, HHS and CDC each is a “public health authority,” as defined under 45 C.F.R. §164.501 and as used in 45 C.F.R. §164.512(b), Standards for Privacy of Individually Identifiable Health Information, promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and, as such, covered entities are authorized by 45 CFR 164.512(b) to disclose Protected Health Information (PHI) to CDC and HHS for the public health purposes described herein.

As applicable, the Parties acknowledge that the jurisdiction may be a covered entity or hybrid entity for purposes of HIPAA. As HHS and CDC each is a public health authority for purposes of this DUA, the Parties expressly do not intend to create a HIPAA business associate relationship.

Definitions

For the purposes of this Agreement, the following definitions shall apply and may be used in the main body of the DUA and/or in relevant appendices:

“Authorized User,” for purposes of this DUA, means an individual who, as part of directly supporting the whole of government response efforts, has a need for data stored in the DCH, the IZ Data Lake, and/or the Tiberius platforms in furtherance of the purpose, and uses set forth herein. Authorized Users will generally be employees, contractors, and/or other agents specified by jurisdictions or federal agencies engaged in the response for purposes of addressing critical public health and emergency response activities, including assessing infrastructure needs and resource allocation. Authorized Users must adhere to applicable federal law and to any applicable provisions set out in this DUA with respect to the data stored in the respective platforms, which are further defined herein and described in Appendices A–D.

“Covered Data” means the information that is being shared by the jurisdiction with each relevant platform as further described in Appendices A–D, but that is generally categorized into four primary datasets: the IIS data (coming directly from an IIS or through VAMS), the DCH data, the IZ Data Lake data, and the Tiberius data. HHS and CDC acknowledge that the Covered Data to which each agency will have access is the minimum amount of information necessary to accomplish public health or emergency response needs. A list of Covered Data elements for each dataset is provided in Appendices A–D.

Covered Data may be used by Authorized Users within the parameters set forth in this DUA. The data elements listed in Appendices A–D will be updated periodically as more information on COVID-19 immunization is available. The overall DUA will remain unaffected by subsequent updates to the Appendices; jurisdictions will be notified of any such updates as soon as practicable and be afforded an opportunity to coordinate with HHS and CDC on implementation of the updates. Appendices A–D also provide the mode and method of secure transmission of the data from the jurisdiction’s IIS or similar system(s) directly to the DCH; from the DCH to the IZ Data Lake; and from the IZ Data Lake to Tiberius. This information includes the potential availability and use of a privacy-preserving record linkage (PPRL) tool, which may be made available by HHS or CDC, either directly or by and through a contractor (Appendix E). Of note, data entering the DCH through the Immunization (IZ) Gateway will be governed by agreements between the IIS jurisdiction and the Association for Public Health Laboratories (APHL).

“Immunization Information System” or “IIS” are confidential, population-based, computerized databases that record all vaccine doses administered by participating healthcare providers to persons residing within a given geopolitical area.

“Jurisdiction” means the state, territorial, or local health jurisdiction operating under either statutory or regulatory authority to obtain and use health-related data for population health protection. For the purposes of this document, jurisdictions are funded under CDC-RFA-IP19-1901 317 Notice of Funding Opportunity. For the purposes of this DUA, the jurisdiction is the data source that, by and through an IIS and/or similar system(s) created to serve a range of administrative functions related to vaccines, provides Covered Data as set forth herein. Generally, the IIS or similar system(s) will collect data from public and private health care provider organizations (e.g., electronic health records [EHRs], health information systems [e.g., vital statistics, state Medicaid agencies, etc.], and pharmacies).

“Redacted Dataset” means the exclusion of direct identifiers of an individual, but with minimum necessary elements related to vaccine administration management as further defined in Appendix D.

“Party” means a state, territorial, or local jurisdiction or CDC; **“Parties”** means state, territorial, or local jurisdictions and CDC.

“Privacy-Preserving Record Linkage (PPRL)” means the process whereby personally identifiable information (PII) is redacted from a patient/customer record using a one-way, irreversible encryption algorithm to create one or more unique tokens that replace PII elements and allow data systems to match patient/customer records. PPRL is an industry standard that has been implemented and integrated across several data collection sectors where an individual’s privacy must be maintained (e.g., health care, biomedical research, payment and claims, retail, intelligence, social research, and public health). For COVID-19 vaccination reporting, PPRL offers jurisdictions a mechanism to meet applicable jurisdiction regulations where data sharing with partners such as HHS and CDC may be limited (Appendix E).

“Provider” means an individual health professional or health facility organization licensed to provide healthcare diagnosis and treatment. For the purpose of this DUA, a provider is also a health professional who administers COVID-19 vaccine.

“Vaccine Administration Management System” or “VAMS” means the CDC-provided and supported web-based application that provides an option for a jurisdiction to plan and execute COVID-19 vaccine administration in temporary, satellite, or mobile vaccination settings.

“Vaccine Ordering Data” are data from the Vaccine Tracking System (VTrckS), CDC’s vaccine order management system, which supports routine vaccination and will also be used for all COVID-19 vaccine ordering (Appendix B). VTrckS receives data from jurisdiction IISs and from providers.

“Vaccine Inventory Data” are data reported to CDC’s VaccineFinder website, which helps: 1) the public find providers who offer select vaccines-2) healthcare providers to list their vaccination locations in a centralized, searchable database, and 3) collects vaccine supply data from providers. Jurisdictions have the ability to choose to report on behalf of all providers in the jurisdiction.

“Vaccine Administration Data” are demographic and vaccine-related data elements collected by vaccination providers at the point of vaccination. The primary purposes of these data include (but are not limited to): 1) monitoring the number of COVID-19 doses administered among populations; 2) assessing national COVID-19 vaccination coverage; and 3) assessing vaccine safety and effectiveness. IISs

are the primary source of vaccine administration data for many jurisdictions, providing information on an individual's first dose of vaccine to inform the appropriate second dose. **The provisions outlined within this DUA specifically address vaccine administration data and its transmission from the jurisdiction to the DCH, transmission from the DCH to the IZ Data Lake, and to the Tiberius platform.**

Description of Data Requested and Transmission Specification

COVID-19 Vaccine Reporting Specification (CVRS) Document (Appendix D)

The jurisdiction agrees to provide record-level (line list) data for all persons receiving a COVID-19 vaccine in the jurisdiction, subject to the terms and conditions included in this DUA and applicable to that platform. Data elements required for submission by the jurisdiction include all variables as outlined in the current CDC COVID-19 Vaccine Reporting Specification (CVRS) document.

CVRS defines the COVID-19 vaccine administration data reporting requirements for the DCH. This specification addresses how a jurisdiction, by and through its IIS and/or similar system, will report vaccine administration data to the DCH. The jurisdiction is expected to include all variables as listed in the CVRS document as specified (e.g., in the same order as listed in the data dictionary, Appendix C). Columns should be present for all variables, including those variables that are not populated. If values for a variable(s) are not captured and stored at the jurisdiction at the record level, the jurisdiction should not try to derive this information to complete the field prior to submitting data to the DCH. The jurisdiction should follow all parameters as outlined in the CVRS file specifications, including reporting requirements.

The CVRS document and comprehensive data dictionary documents will be updated periodically to incorporate revisions to code sets, such as when new vaccines are introduced. In the future, the specification will also be expanded to include additional mechanisms for reporting (e.g., data transport via the IZ Gateway). All mechanisms will use the same file format but will vary in what identifying information is provided. The jurisdiction agrees to comply with all specifications as defined in the CVRS document and implement changes outlined in the CVRS as expeditiously as possible. Jurisdictions will be notified of changes or updates to the CVRS document as soon as possible, and such changes will be updated online and can be accessed at the following [location](#).

Data Access and Use

HHS and CDC, working with their partners, have created a technical architecture (Appendix A) containing various platforms to facilitate the management, sharing, storage, and analysis of vaccine administration data. In accordance with this agreement, the Jurisdiction acknowledges and agrees that HHS, CDC, and Authorized Users may use the Covered Data transmitted through the technical architecture, including the DCH, IZ Data Lake, and Tiberius platforms, in furtherance of response activities related to the COVID-19 pandemic. This includes, at a minimum, the following activities, which jurisdictions shall complete as applicable to the platform and consistent with this DUA:

- a. As applicable to the platform and consistent with this DUA, analyze and visualize the Covered Data, to which they have access, to improve the monitoring of vaccination and vaccine-related activities for the COVID-19 pandemic response, including vaccine safety and assessment of vaccine effectiveness;

- b. As applicable to the platform and consistent with this DUA, share the Covered Data and/or analyses thereof with official federal, state, local, tribal, and territorial government health agencies or their agents and/or entities collaborating with them, as the health agencies conduct their public health and vaccination response responsibilities consistent with their statutory authorities;
- c. Develop analytic methods using the Covered Data to identify immediate public health events or concerns at the federal, state, territorial, and local level that warrant further public health investigation or immediate public health intervention actions;
- d. Enable Authorized Users, including public health and emergency response officials, to query the Covered Data within the HHS- and CDC-provided data platforms as may be necessary to carry out critical public health functions
- e. Share specified data elements with Tiberius for the visualization of vaccine administration data; and
- f. Publish findings and conclusions related to their analyses of the data provided. As appropriate, publications will acknowledge Jurisdiction as the source of the data in any such publication. Given the emergent nature of the response, HHS and CDC may not be able to inform or seek approval from Jurisdiction for such publications but will coordinate as soon as possible and practicable. Information will be reported and published in aggregate.

Data access and permissions for all Covered Data as described in this DUA are further described in Appendix B. This includes data access and permissions for Authorized Users at CDC and HHS. In addition, data that are transmitted from the IZ Data Lake to Tiberius will adhere to all aspects of a signed Memorandum of Agreement (MOA) between CDC and HHS (Appendix F). The MOA: 1) describes the framework through which HHS and its platform partners will rapidly obtain, integrate, use, store, and maintain a local copy of data provided by CDC into the Tiberius platform; 2) establishes the terms and conditions for sharing, protection, and use of CDC COVID-19 vaccine distribution, administration, and inventory data in Tiberius provided hereunder and further described below; and 3) sets forth the roles and responsibilities of each party.

This MOA between HHS and CDC is effective as of September 29, 2020. Additional information about data use terms, asset protection, data disposition, terms of agreement, amendment, and termination of the agreement are further described in Appendix F.

Data Confidentiality and Security

Data confidentiality, security, and access processes specific to the DCH, IZ Data Lake, and Tiberius are further described in Appendix B. However, as a general matter, HHS and CDC agree to the following:

Confidentiality: Where Covered Data provided pursuant to this DUA are identifiable or potentially identifiable, HHS and CDC agree to maintain the confidentiality of the Covered Data to the fullest extent required by federal law, which includes, as applicable, the Privacy Act of 1974; standards promulgated pursuant to HIPAA, and the Freedom of Information Act (FOIA), including exemptions provided thereunder.

HHS and CDC further agree to not disclose such Covered Data, including but not limited to names and other identifying information of persons who are the subject of such Covered Data, either during the term of this DUA or longer, except as consistent with this DUA or as may be allowed or required by applicable law. Where required by law and/or where practicable, HHS and CDC agree to notify the

Jurisdiction before releasing Covered Data to a third party pursuant to a judicial, governmental, or other request under law, to allow the Jurisdiction the opportunity to state any objection to the disclosure of the Covered Data.

Security: As applicable to the platform, HHS and CDC will establish appropriate administrative, technical, procedural, and physical safeguards to ensure the confidentiality and security of Covered Data in their custody and control, consistent with federal requirements under FISMA and other applicable federal laws. The safeguards shall provide a level and scope of security that is not less than the level and scope of security established by applicable law for the type of data provided under this DUA and are intended to protect Covered Data from unauthorized access, disclosure, use, or modification. This includes setting permissions to access or edit data commensurate with the level of sensitivity of the data. Should there be a data breach and unauthorized disclosure of Covered Data, consistent with applicable legal requirements, an Authorized User must notify appropriate response teams within CDC, which will, in turn, will notify the relevant jurisdiction of the incident as soon as practicable, and, to the extent allowed by federal law, will coordinate with Jurisdiction in responding to the incident.

Transfer: Transfer or transmission of the Covered Data by and through the various platforms in a the control of HHS and CDC shall be done in accordance with acceptable practices for ensuring the protection, confidentiality, and integrity of the contents, commensurate with the level of sensitivity of the Covered Data. The Parties may coordinate to implement methods to achieve these outcomes consistent with procedures already in place for similar data exchanges. If encrypted identifiable information is transferred electronically through means such as the Internet, then said transmissions will be consistent with the rules and standards promulgated by applicable legal requirements regarding the electronic transmission of identifiable information.

Storage: Covered Data will be maintained and stored in compliance with the HHS and CDC security policies and procedures and consistent with applicable federal law. Where Covered Data are identifiable or potentially identifiable or are privileged, sensitive, or confidential, such records and data shall be secured in an encrypted, password-protected electronic folder with access restricted to Authorized Users for purposes as set forth in this DUA.

Access: HHS and CDC may provide Covered Data access to appropriate employees, contractors, and other Authorized Users, as further provided in this DUA. HHS and CDC agree to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized access to the Covered Data. Where Covered Data provided pursuant to this Agreement are identifiable or potentially identifiable or are privileged, sensitive, or confidential, HHS, CDC, and their Authorized Users shall access Covered Data on secured devices only.

Data Maintenance, Deletion, or Storage Requirements after Termination

Unless explicitly stated otherwise in the DUA, ownership of Covered Data shall remain with the Jurisdiction. However, the Parties agree that the Covered Data provided under this DUA and in the custody and control of HHS and CDC are subject to applicable federal law.

Accordingly, HHS and CDC agree to maintain, store, protect, archive, and/or dispose of Covered Data in accordance with federal law. When HHS and/or CDC acts as an Authorized User, as federal agencies, the disposition of records in their custody and control is governed by the Federal Records Act and may only be accomplished in accordance with schedules for destruction as provided under law. At a minimum,

the Jurisdiction agrees that an archival copy of the Covered Data may be retained by HHS and CDC to comply with relevant records retention requirements and/or for the purposes of research integrity and verification. Obligations under law to maintain and secure Covered Data will survive termination of this DUA.

IT and Data Architecture

HHS and CDC are expanding the capacity of the following secure, certified, cloud-based data management platforms:

Vaccine Ordering and Inventory Systems (Appendix B)

- a. **Vaccine Tracking System (VTrckS):** The Vaccine Tracking System (VTrckS) is the Centers for Disease Control and Prevention's (CDC) vaccine order management system, which will support:
 - i. Vaccine allocation
 - ii. Ordering
 - iii. Reporting throughout the vaccine distribution process, from vaccine order placement through distribution
 - iv. Tracking vaccine shipments
- b. **VaccineFinder:** The VaccineFinder website helps the public find providers who offer select vaccines; allows healthcare providers to list their vaccination locations in a centralized, searchable database; and collects vaccine supply data from providers

Vaccine Administration and Reporting Systems (Appendix B)

- a. ***Vaccine Administration Management System (VAMS):*** Vaccine Administration Management System (VAMS) is a web-based application that supports planning and execution for temporary, mobile, or satellite COVID-19 vaccination clinics. Use of VAMS is optional.
- b. ***IZ Gateway:*** The IZ Gateway is a cloud-based message routing service intended to enable data exchange between IISs, other provider systems, and the IZ Data Lake. The IZ Gateway enables centralized data exchange and eliminates the need for multiple, individual, point-to-point connections. Use of the IZ Gateway is encouraged but not required and is further set out in agreements between a jurisdiction and APHL.
- c. ***COVID-19 Data Clearinghouse (DCH):*** The DCH is a cloud-hosted data repository that receives, deduplicates, and redacts COVID-19 vaccination data that are then used to populate the IZ Data Lake with a limited dataset for analytics. The DCH may also be used by the Jurisdiction and/or healthcare providers to enable appropriate administration and dosing for individuals receiving vaccines. For example, if populated with identified data or identified data that have been redacted using privacy-preserving record linkage (PPRL) software, then the DCH would allow healthcare providers to search for a patient, see what brand of COVID-19 vaccine they received, and see when they received their first dose of COVID-19 vaccine to ensure dose matching and appropriate vaccination intervals to complete the vaccination series.
- d. ***Immunization (IZ) Data Lake:*** The IZ Data Lake is a cloud-hosted data repository to receive, store, manage, and analyze a limited dataset for COVID-19 vaccination data.

Miscellaneous

1. **Data Disposition:** As noted above, Covered Data that have been provided to HHS and CDC under this DUA will be archived, stored, protected, or disposed of in accordance with relevant federal records retention requirements.
2. **Funding:** This DUA is not an obligation or a commitment of funds or a basis for a transfer of funds. This DUA does not create an obligation or commitment to transfer data, but rather is a statement of understanding between the parties concerning the sharing and use of Covered Data. Expenditures by each party are subject to its budgetary processes and to the availability of funds and resources pursuant to applicable laws, regulations, and policies. To the extent funds provided by CDC under a cooperative agreement are used by a jurisdiction in furtherance of these activities, the terms of that cooperative agreement will be read, consistently with the terms of this DUA. Any conflict discovered must be raised with CDC for resolution.
3. **Settlement of Disputes:** Disagreements between the parties arising under or relating to this DUA will be resolved by consultation between the parties and referral of the dispute to appropriate management officials of the parties whenever possible.
4. **Applicable Laws:** U.S. federal law shall govern the construction, interpretation, and performance of this DUA.

Term of Agreement, Amendment, and Termination:

1. The term of this DUA shall be one year commencing from the date of the final signature or shall last for the duration of the national emergency, whichever is longer. The DUA may be renewed upon mutual written consent of the Parties.
2. Except as otherwise expressly provided herein, this DUA may be amended only by the mutual written consent of the authorized representatives for each Party. However, the Parties acknowledge that changes and updates to the Appendices may occur during the term of the DUA; the Parties agree that such changes and updates are incorporated upon issuance.
3. This DUA may otherwise be terminated with ninety (90) days' advance written notice by either party.
4. Any notice required under this DUA must be in writing and sent by electronic mail (iisinfo@cdc.gov) with written acknowledgement of receipt to the email address for each Party provided below.
5. Each Party represents that the individual signing below on behalf of the party has the authorization to bind the party indicated to this DUA. This DUA may be signed in counterparts and signatures provided electronically will be deemed originals.

CENTERS FOR DISEASE CONTROL AND PREVENTION AND JURISDICTION

By: Shannon Stokley -S Digitally signed by Shannon Stokley -S
Date: 2020.12.07 07:53:59 -05'00'

Name: Shannon Stokley

Title: Associate Director for Science

Date: December 7, 2020

Email: zma2@cdc.gov

By: _____

Name: _____

Title: _____

Date: _____

Email: _____

NEW MEXICO DEPARTMENT OF HEALTH

By: 

Name: Billy J. Jimenez

Title: Acting Secretary of Health

Date: 12/5/2020

Email: billy.jimenez@state.nm.us