

**AGREEMENT TO PARTICIPATE
Immunization State-Supplied Vaccine (SSV) Program,
Rhode Island Child and Adult Immunization Registry (RICAIR), and
KIDSNET**

Terms and Conditions

To participate in the Rhode Island Department of Health's (RIDOH) Immunization State-Supplied Vaccine (SSV) Program, in order to receive state-supplied vaccine at no cost for insured and uninsured Rhode Island residents, I hereby enter into this agreement (Agreement) on the following conditions and on behalf of myself and all the practitioners, nurses, and associated individuals (or parties) within the medical office, group practice, managed care organization, community/migrant/rural clinic, or health delivery facility of which I am the Medical Director/Lead Physician or designee. The Rhode Island Child and Adult Immunization Registry (RICAIR) is the Rhode Island immunization registry for all ages. KIDSNET refers to the integrated childhood information system. My practice/facility and staff agree to:

General requirements for all practice types:

1. Enroll in the SSV Program annually. Enrollment is for a period of up to 12 months (July 1-June 30) and must be completed for each state fiscal year before vaccine orders may be placed.
2. Administer all state-supplied vaccines to patients in eligible age cohorts as recommended by the Advisory Committee on Immunization Practices (ACIP) and in accordance with RIDOH vaccine policies. Comply with the appropriate and most current immunization schedules, dosages and contraindications that have been established by the ACIP-recommended immunization schedule, unless in my medical judgment, and in accordance with accepted medical practice, I deem such compliance to be medically inappropriate.
3. Keep a current copy of each of the following documents at the practice/facility for use, distribution and/or reference: "It's Federal Law!", the most current Vaccine Information Statements (VIS) for distribution to patients, CDC Vaccine Storage & Handling Toolkit, notice of the Vaccine Adverse Event Reporting Form (VAERS) and notice of the Vaccine Injury Compensation Program (VICP).
4. Maintain an Immunization Record of each vaccine given to include the date administered, administration site, lot number, manufacturer, the publication date on the VIS, the date the VIS was given, practice name, address, and the signature or initials of the person administering the vaccine. For electronic reporting of immunizations to RIDOH, practices must maintain any data required by the current Rhode Island standards for HL7 reporting.
5. Not use vaccines ordered for adults on individuals less than 19 years of age, or use vaccines ordered for children on individuals 19 years of age and older.
6. Comply with RIDOH requirements for vaccine ordering, vaccine accountability (including any vaccine reporting that is required to the immunization information system), and vaccine management. Agree to operate within the SSV Program in a manner intended to avoid fraud and abuse. The Immunization SSV Program's Fraud & Abuse Policy can be found on the Immunization Resource Manual webpage: <http://www.health.ri.gov/immunization/for/providers/#>.

7. Comply with RIDOH's requirements for proper vaccine storage and handling, which include, but are not limited to, SSV Program-approved 24/7 temperature monitoring equipment for proper refrigeration, and to document twice daily temperature checks and records of actions taken for temperatures outside the recommended range of 36 F - 46 F (Fridge) and <5 F (Freezer).
 - Effective January 1, 2018, all SSV Program participating providers are required to have a calibrated data logger, and a back-up data logger for use when recalibration, repair, or replacement is warranted.
 - RIDOH will maintain a backup supply for those who have received and maintain the SSV Program provided cloud-based data loggers for use during the recalibration process.
 - The practice is responsible for loggers necessary to transfer or relocate vaccines and may not remove the storage unit logger unless all vaccines are being removed from the unit.
 - Each data logger must come with a current, valid certificate of calibration issued by an ILAC MRA-accredited lab or a certificate of calibration statement indicating it meets ISO 17025 standards.
 - The practice will be responsible for the repair of any damages to the data logger or replacement of damaged data logger. If the data logger unit is misplaced and cannot be found, the practice is responsible to replace the data logger. The replacement data logger must be comparable, as determined by the SSV Program, to the one that was lost. It is the practice's responsibility to contact the vendor to purchase the replacement data logger.
8. Not impose a charge to eligible patients for the cost of any state-supplied vaccine. SSV Program eligibility is available to all individuals under the age of 19 and for those 19 and older who are either a RI resident (some ordering restrictions apply) or receive health benefits through a RI employer. Vaccines administered to ineligible patients are not allowed and failure to report vaccine administered to ineligible patients would be considered fraud & abuse.
9. Effective each enrollment year, have a designated "Vaccine Contact" and "Back Up Vaccine Contact" complete the current You Call the Shots, Vaccine Storage and Handling training module at:
<https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp> and keep the training certificate of completion on file to be viewed at the request of RIDOH.
10. Ensure a Vaccine Storage Emergency Preparedness Plan is completed, posted, and read by current and new staff, and updated as needed. Have a valid and current copy of the plan available for review during scheduled or unscheduled quality assurance visits by RIDOH.
11. Comply with RIDOH's Vaccine Replacement Policy for wasted and/or spoiled vaccine due to negligence, including but not limited to, failure to properly order, store, and handle state-supplied vaccines. RIDOH's Vaccine Replacement Policy can be found on the Immunization Resource Manual webpage at
<http://www.health.ri.gov/immunization/for/providers/#>.
12. Acknowledge that any future program enrollments will be denied until all outstanding reporting or financial obligations from the previous year(s) are met.
13. Accommodate any state request for a scheduled or unscheduled on-site inspection of patient vaccine records, vaccine inventory, data logger(s), and/or storage facilities.

14. Attend/complete trainings (informational/technical assistance) sessions as required by RIDOH.
15. Make any changes to the practice/facility name, lead physician, address, phone or fax number, office manager, vaccine contact, or delivery information via the SSV Program website prior to ordering.
16. Submit any transfer of vaccines between two currently enrolled SSV Program practices through RIDOH's on-line ordering system, OSMOSSIS. Proper packaging (responsibility of the practice requesting the transfer) is required for all approved transfers. Transfer of vaccines to a practice that is not enrolled in the SSV Program is strictly forbidden and may constitute a claim of fraud and abuse and would be subject to local and federal penalties.
17. All vaccines currently in inventory supplied through the SSV Program must be transferred to another enrolled practice prior to the practice closing or decision to discontinue participation in the SSV Program. All vaccines shipped through the SSV Program remain the property of RIDOH and may be removed or transferred from the facility if RIDOH deems necessary.
18. No software, programs, or electronic devices other than those approved by RIDOH can interface with state supplied datalogger temperature monitoring devices and the Cloud system. Any integration or coordination failure can materially affect the practice's ability to manage its vaccine inventory. Also, no third party vendors should monitor a site's vaccine temperatures. Vaccine management is the responsibility of the practice and designated staff.
19. Practices utilizing SSV Program vaccine for individuals less than 19 years of age must have a current agreement to participate in the Federal Vaccines for Children (VFC) program and understand that all requirements of that agreement are also applicable to state-supplied vaccines.
20. All practices receiving SSV Program vaccines must participate in RICAIR.

RICAIR and KIDSNET Requirements:

21. Participate in efforts to establish an electronic interface for submission of immunizations to RICAIR.
22. Report patient specific immunizations to RICAIR for all individuals less than 19. Also report patient specific immunizations to RICAIR for individuals 19 years of age and older after an electronic interface is approved for that purpose.
23. Submit demographic and historical immunization data for new patients to RICAIR within a week of first encounter and provide the parents with RICAIR and KIDSNET information provided by RIDOH.
24. Submit accurate and complete data on all immunizations administered to RICAIR, within one week of new/current vaccine administration.
25. Update demographic data including promptly updating RICAIR or KIDSNET when individuals have left the practice.
26. Submit to RICAIR immunizations administered by other Providers for individuals within one week of receiving the information. In addition, electronic submissions shall include both administered and historical vaccines when first added to the electronic health record.
27. Inform all staff who use RICAIR and KIDSNET, including Query/Response services, of their legal responsibilities under the State's Confidentiality of Health Care Information Act (RI Gen. Laws Chapter 5-37.3), the Health Insurance Portability and Accountability Act, as amended and including all rules and regulations promulgated

thereunder (HIPAA), and all other applicable federal and state laws relating to confidentiality of this information.

28. Provide to the custodial parents, legal guardian(s), and those legally authorized to care for a child (*i.e.*, foster parents), and adult patients access to the information contained in RICAIR and KIDSNET, including printed copies at no cost to the family upon request.
29. Utilize RICAIR and KIDSNET, including Query/Response services, only for obtaining information needed for treating or coordinating care for their patients. Any use of this information by either the Provider or staff for purposes other than those specifically stated in this document may be a violation of the provisions of RI Gen. Laws Chapter 5-37.3 and/or HIPAA, and subject to the penalties contained therein.
30. Maintain a signed RICAIR or KIDSNET confidentiality statement or equivalent confidentiality agreement for each user authorized to use RICAIR or KIDSNET under their Provider ID. Provide RICAIR or KIDSNET staff with access to the signed confidentiality statements in the Provider's office for audit purposes.
31. The practice shall maintain applicable business associate or trading partner agreements with any entities sending or querying data to or from RICAIR for their practice. Authorized queries are limited to those done on behalf of the practice identified in this Agreement.
32. Authorize RIDOH to work with the practice's electronic health record vendor or data host to configure, test, and establish on-going electronic submission of immunization data and Query and Response functionality with RICAIR. This may include direct access to patient medical data.
33. Access RICAIR and KIDSNET only at computers that do not have general public access and ensure that user IDs and passwords are not shared.
34. Prohibit downloading data from RICAIR and KIDSNET to portable devices (such as laptops, tablets, or flash drives) unless the device is appropriately secured and encrypted. These data are subject to the same terms and conditions as KIDSNET use.
35. Authorize RIDOH to share RICAIR and KIDSNET data with Managed Care Organizations, provided data are not publicly released and the Provider is not identified without the Provider's consent. Further authorize the release of RICAIR and KIDSNET data as permitted by law.
36. Take prudent precautions to ensure that all RICAIR and KIDSNET users are aware of and abide by the terms of this Agreement.
37. Report to RIDOH by telephone call or email any use or disclosure including any data breach of RICAIR and KIDSNET data not provided for by this Agreement, as well as any attempt to use or disclose as soon as possible, and in no case, later than five calendar days after becoming aware of the use or disclosure.
38. The Vaccine Contact will be the RICAIR/KIDSNET Group Administrator, unless another person is designated, with the following responsibilities:
 - Create RICAIR/KIDSNET web users as authorized by the Medical Director for the purpose of treating or coordinating care for patients
 - Provide user support for forgotten User IDs and passwords.
 - Notify RICAIR/KIDSNET promptly if there is a change in Medical Director/Lead Physician or if a change in RICAIR/KIDSNET Group Administrator is requested
 - Promptly terminate RICAIR/KIDSNET access for any user who leaves the practice or whose duties no longer require access.

39. Assure that all SSV Program, RICAIR, and KIDSNET users are aware of and abide by the terms of this Agreement.

Special requirements for Seasonal Influenza Participation:

40. Participation in the Seasonal Influenza Vaccine portion of the SSV Program will require the submission of weekly reports through the electronic reporting mechanism identified by RIDOH.
41. Use of state supplied influenza vaccines for patients who are ineligible is strictly forbidden and may be subject to claim of fraud and abuse, with all appropriate penalties and fees.
42. Failure to report accurate doses administered information will impact the availability of vaccine supply for the following influenza seasonal campaign. It is the responsibility of the practice to reconcile all dose reporting prior to enrollment for the next state fiscal year.

This Agreement is binding on the parties hereto and will remain in effect until: (1) RIDOH terminates this Agreement, at any time or there is a failure to comply with the SSV Program requirements; (2) the practice terminates this Agreement for reasons determined by the Medical Director (Lead Physician) of the practice; or (3) there is a change of the Medical Director (Lead Physician) and/or entity name, or failure to renew annual enrollment.

By agreeing to these terms and conditions, each practice, together with its providers and staff, is communicating its willingness to participate in, and abide by, the requirements of the SSV Program, RICAIR, and KIDSNET.