



IDAHO DEPARTMENT OF
HEALTH & WELFARE

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Dear Vaccine Provider,

During the last legislative session, the Idaho Immunization Reminder Information System (IRIS) statute (Idaho Statute Title 39, Chapter 48, 39-4803) underwent a review, and it was determined that we must make changes to the way we manage data about individuals who have opted-out of participation in IRIS. **This may require some action on your part.**

IRIS is a voluntary, "opt-out" registry, meaning that health care providers can enter protected health information into the system without written patient consent, until they are told not to by the patient or patient's parent/legal guardian. Patient data is entered into IRIS both via electronic data exchange and through manual data entry. Patients 18 years of age or older may request to have their information removed at any time, and legal guardians or parents of minors may request to have information about their children removed.

In order to comply with Idaho Code, a patient (or parent/legal guardian) must opt-out of IRIS through the Idaho Immunization Program. Going forward, patients can request either of the following actions:

1. Removal of all **immunization** related information and retention of non-immunization (demographic) information. This allows IRIS to use the retained demographic information to "block" immunization information for the patient from being inadvertently added back in. The retained information in IRIS is not viewable, but is enough to generate a system message alerting the provider office that the patient has opted out of IRIS.
2. Removal of all **immunization** and **non-immunization** information. Upon receipt of a deletion request of this type, the Idaho Immunization Program deletes **all** information in IRIS related to the individual opting out. IRIS does not retain any information on that individual and therefore the system cannot alert providers that the patient has opted out. It then becomes the responsibility of the patient or patient's parent/legal guardian to inform health care providers if they do not want data entered into IRIS.

While the second option (deletion of immunization and non-immunization data) creates additional responsibilities for both patients and medical providers in Idaho, this option *must* be made available to patients to meet the requirements of Idaho Code 39-4803(4)(a).

Some of your patients might inform you that they have opted out of IRIS and that they do not want your practice to enter their immunizations records into the system. Your office needs to establish a policy for how these requests will be recorded and handled.

Regardless of which option they choose, patients must still opt out through the Idaho Immunization Program. If a patient or parent/legal guardian requests removal of information from IRIS, then please refer them to the Idaho Immunization Program at 208-334-5931 or online at www.immunizeidaho.com.

The enclosed "Q and A" document outlines some questions your office might have regarding how the new process works as well as accounting for vaccine administered to patients who have opted out of IRIS. Please feel free to contact our office by telephone at 208-334-5931 or via email at IIP@dhw.idaho.gov.

Sincerely,

Jennifer Baker, IIS Manager
Idaho Immunization Program

Enclosures:
Q and A Document

Answers to Questions About the New Opt-out Process for IRIS

December 2013

Q. I heard there are now two options for a patient who wants to opt-out of IRIS; what are they?

A. You heard right, there are two opt-out options for having information removed from IRIS. Whichever option they choose, patients must still request to opt-out through the Idaho Immunization Program. The two options are:

Option 1: Patients may opt-out of IRIS and choose to have **only their immunization information removed** from the system; the system keeps enough non-medical information (name, address, phone number, mother's maiden name, date of birth and gender) to allow it to match incoming data attempts. With this option, nothing will change from the way opt-outs has worked in the past. If you try to enter immunization data, or if your EMR attempts to electronically export immunization data for the opted-out patient, IRIS will refuse the data.

Option 2: Patients may opt-out of IRIS and choose to have **all their information removed** from the system. With this option it is the patient's responsibility to inform his/her medical providers that s/he has opted-out of IRIS and to work with you to ensure their information is not re-entered. Since IRIS will contain no information on the people who opt-out under this option, it will not be able to notify you of the opt-out or block data that is input either manually or through electronic data exchange.

Q. Why are there now two options for opting-out of IRIS?

A. Legal counsel has determined that the new opt-out option (Option 2), *must* be offered to IRIS participants in order to meet the requirements of Idaho law 39-4803(4)(a), 39-4804(2)(b) and 39-4804(3)(b).

Q. One of my patients told me her child is opted-out of IRIS, should I confirm this by looking in IRIS?

A. You may. If a parent says that they and/or their child have opted-out of IRIS, you are not required to check in IRIS to see if this is true. However, there are people who *think* they are not in IRIS, but in fact are. The **only** way to opt-out of IRIS is to submit a request to the state (online or in writing) asking to have the record deleted. You may consider trying to look up the child in IRIS, and if you do find him/her in the system you can advise the family on the opt-out procedure.

Q. I administered a dose of state-supplied vaccine to a person who has opted-out of IRIS, how do I account for that vaccine dose?

A. All doses of state-supplied vaccine must be accounted for in IRIS. When a patient receives state-supplied vaccine but does not want to participate in IRIS, the patient is not entered into IRIS; however, the doses administered are entered into IRIS. Instructions for entering an anonymous dose of vaccine into IRIS are attached to this FAQ.

Q. A parent asked me to opt their child out of IRIS without submitting a request to the state program, is this possible?

A. No. Only state staff can delete an immunization record completely from IRIS. Until the state program receives a formal request, either through the online form or in writing, the patient's information will remain in IRIS.

Q. My practice's EHR/EMR does not have the option of excluding one patient's record when I electronically export data to IRIS. How do I stop that patient's information from being re-entered into IRIS from my electronic export for a patient who has chosen to have *all* information removed from IRIS?

A. This is a difficult problem for which there is no easy answer. Some options, none of them ideal, are:

1. Do not enter that patient's immunizations into the regular immunization section your EHR/EMR, but keep them in a notes field that does not export to IRIS;
2. Advise the patient that s/he must seek immunizations elsewhere. If this extreme option is chosen, you may consider advising patients that you can continue to provide immunization services if they chose opt-out option #1 where their demographic, non-medical information is retained in IRIS so IRIS can block their medical information from re-entering the system during electronic export;
3. Stop electronic exports from your EHR/EMR to IRIS, and return to manual data entry into IRIS for state-supplied vaccines;
4. Contact your EHR/EMR vendor to see if they have an upgrade option that will allow your system to block data exchange on a patient by patient basis.

Q. One of my patients opted-out of IRIS using Option 1 where they allow demographic, non-medical information to be retained in the system. What impact does this opt-out have on my practice?

A. None. If you manually enter vaccine information into IRIS, you will see an alert notifying you that this patient has opted-out of IRIS and you need to enter that dose as anonymous. If you electronically export data from your EMR to IRIS, IRIS will automatically reject incoming vaccine information for anyone who has opted-out using Option 1.

Q. One of my patients informed me that he had opted-out of IRIS and that I should not re-enter his information, should I document this in the patient's chart?

A. This is a decision that must be made by your practice, but it's recommended that you document the patient's request. This documentation may serve as liability protection to your practice, a reminder to staff, and as an indication to new staff after a staff change-over.

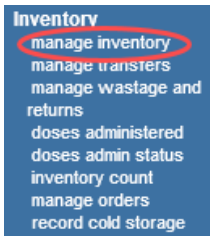
Accounting for a Dose of Vaccine Administered to a Patient Who Has Opted-out of IRIS

Providers are responsible to account for all doses of vaccine supplied by the Idaho Immunization Program (IIP). Accountability is completed in Idaho's Immunization Reminder Information System (IRIS). In addition, each dose of IIP-supplied vaccine must be entered into IRIS within 28 days of administration (see the [Provider Agreement](#)); however, not all patients choose to participate in IRIS.

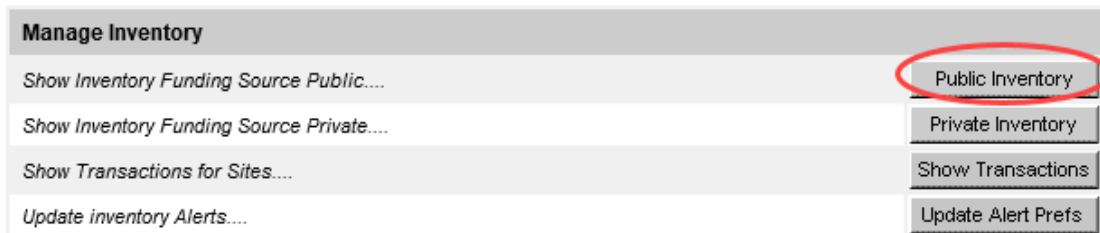
IRIS is a voluntary opt-out registry, meaning healthcare providers can enter protected health information into the registry without written consent, until the patient or the patient's parent or legal guardian would like to opt-out of IRIS. If the patient or patient's parent or legal guardian would like to opt-out of IRIS, then the patient or the patient's parent or legal guardian must contact the IIP at (208) 334-5931 or iip@dhw.idaho.gov.

If a patient who has opted-out of IRIS receives a dose of IIP-supplied vaccine, then the "anonymous" dose administered still needs to be accounted for in IRIS. The process for entering an anonymous dose of administered vaccine is outlined below.

1) Log into IRIS. On the left-hand side in the **Inventory** section, click *manage inventory*.



2) The **Manage Inventory** screen will display. Click the *Public Inventory* button.



3) The **Manage Inventory – Funding Source Public** screen will display. Select the vaccine administered to the patient by clicking the box in front of the Trade Name and corresponding lot number physically administered to the patient.

Accounting for a Dose of Vaccine Administered to a Patient Who Has Opted-out of IRIS

Manage Inventory - Funding Source Public

Providers are not able to manually modify quantities with a Funding Source Public. If manual changes need to be made to your organization's public vaccine inventory, then please contact the Idaho Immunization Program at (208) 334-5931 or IP@dhw.idaho.gov to work with vaccine management staff.

Record Anonymous Doses (vaccine administered to a patient who has opted-out of IRIS)...
(select lots from the table below) Modify Quantity

Go to the Manage Wastage and Returns screen... Manage Wastage and Returns

Show Transactions for Sites... Show Transactions

Return to the Manage Inventory Screen... Cancel

Site: 003 - WESTERN RUSSET FAMILY CARE CLINIC Show Active Inactive Non-Expired Expired

Select	Trade Name	NDC	Description	Lot Number	Quantity On Hand	Active	Funding Source	Exp Date
<input checked="" type="checkbox"/>	Adacel	49281-0400-10	ADACEL; SDV; 10-PACK	C3941AA	7	Y	Public	01/18/2019
<input type="checkbox"/>	Gardasil 9	00006-4119-03	HPV9 Gardasil 9; SDV; 10-PACK	G97531	8	Y	Public	12/01/2018
<input type="checkbox"/>	Infanrix	58160-0810-11	INFANRIX; SDV; 10-PACK	INF153489	10	Y	Public	09/01/2018

4) Click the *Modify Quantity* button.

Manage Inventory - Funding Source Public

Providers are not able to manually modify quantities with a Funding Source Public. If manual changes need to be made to your organization's public vaccine inventory, then please contact the Idaho Immunization Program at (208) 334-5931 or IP@dhw.idaho.gov to work with vaccine management staff.

Record Anonymous Doses (vaccine administered to a patient who has opted-out of IRIS)... **Modify Quantity**
(select lots from the table below)

Go to the Manage Wastage and Returns screen... Manage Wastage and Returns

Show Transactions for Sites... Show Transactions

Return to the Manage Inventory Screen... Cancel

Site: 003 - WESTERN RUSSET FAMILY CARE CLINIC Show Active Inactive Non-Expired Expired

Select	Trade Name	NDC	Description	Lot Number	Quantity On Hand	Active	Funding Source	Exp Date
<input checked="" type="checkbox"/>	Adacel	49281-0400-10	ADACEL; SDV; 10-PACK	C3941AA	7	Y	Public	01/18/2019
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<input type="checkbox"/>	Infanrix	58160-0810-11	INFANRIX; SDV; 10-PACK	INF153489	10	Y	Public	09/01/2018

5) The **Manage Inventory-Modify Quantity Funding Source Public** screen will display.

1. Enter the number of doses administered, to a patient who has opted-out of IRIS participation, in the Number of Doses field.
2. Enter the date, or use the calendar tool to select the date, the dose was administered in the Transaction Date field.
3. Click the *Save* button.

Accounting for a Dose of Vaccine Administered to a Patient Who Has Opted-out of IRIS

Manage Inventory - Modify Quantity Funding Source Public

Save Changes to Quantity On Hand for Selected Sites... **3** Save

Return to the Previous Screen... Cancel

Modify Quantity On Hand for Selected Site(s)						
Trade Name	NDC	Description	Lot Number	Quantity On Hand	Reason	Detail
Adacel	49281-0400-10	ADACEL; SDV; 10-PACK	C3941AA	7	Anonymous Dose	
Action	Number of Doses	Transaction Date	Explanation			
Subtract	1 1	08/10/2017 08/10/2017	Dose of vaccine administered to a patient who has opted out of IRIS through the Idaho Immunization Program.			

The dose of IIP-supplied vaccine administered to a patient who chose to not participate in IRIS (opted-out) has now been accounted for in your organization's Public inventory. When a Show Transactions or Doses Administered report is run, the dose will appear as OptOut or Anonymous, as shown in the examples below.

From the Show Transactions report (.pdf format):

Organization Name	Transaction	Lot \ Trade Name	Type	Qty	Patient Name	DOB
003 - WESTERN	08/10/2017	C3941AA \ Adacel	OptOut	-1.0		

From the Doses Administered report:

Group Name	Trade Name	Funding Type	Doses												Doses Given to Anonymous Patients	Total	
			<1 yr	1 yr	2 yrs	3-5 yrs	6 yrs	7-10 yrs	11-12 yrs	13-18 yrs	19-24 yrs	25-44 yrs	45-64 yrs	65+ yrs			
Pertussis (Tdap)-	Adacel	PUB	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	1.0

Note: All providers who administer IIP-supplied vaccines are required by Idaho Code, Title 39 Chapter 48 Section 04 (<http://legislature.idaho.gov/idstat/Title39/T39CH48SECT39-4804.htm>), to notify patients or a patient's parent or legal guardian that participation in IRIS is voluntary and dose administered information will be entered into IRIS unless the patient has opted out of participation through the Idaho Immunization Program.