



AIRA
AMERICAN IMMUNIZATION
REGISTRY ASSOCIATION

INFORMATION REQUEST

Topic: Reporting Requirements, Enforcement, and Penalties

Request Date: March 6, 2018

Information Requested:

1. Is reporting required in your jurisdiction?
2. Does your IIS apply penalties, whether in statute, regulation, or other mechanism, for failure to report?
3. What types of penalties are applied (e.g. monetary)?
4. What parameters are in place for reporting in a timely manner (e.g. within 7 days, 30 days)?
5. What enforcement activities are required (e.g. additional IIS staff, partnerships with licensing boards, etc.)?
6. What are the challenges of applying penalties?

Requesting Member: Amanda Harris (NV)

Responding Member(s): Hilda Dupwe (AK), Donna Isaacs (Clinch River Health Services), Sheila Lovett (GA), Teri Nicholson (IL), Tricia Charles (MA), Patricia Swartz (MD), Miriam Muscoplat (MN), Alicia McGirl (MO), Jeffrey McIntyre (MS), Michelle Hood (NE), Erica Martinez (NM), Monica Sull (NYC), Michael Flynn (NYS), Stephen White (SC), Tim Neely (WV), Jude Alden (WY)

Results:

AK:

1. Yes – mandatory for children less than 22 years of age. Voluntary by physicians on adult immunizations.
2. Yes, in statute and rule/regulation
3. Monetary
4. Within 2 weeks
5. None
6. No penalties have been charged. No mechanism for accepting penalty payment or guidance on how to expense the funding once collected.

Note: Arkansas statute and rule/regulation states that a monetary penalty will be charged for providers who do not report vaccinations administered. There is however no



enforcement authority infrastructure for collecting the penalty. In addition, there is hesitancy to fine providers who are in the process of meaningful use onboarding and aren't reporting until the testing is completing.

CR Health:

1. No
2. Not yet
3. N/A
4. No charge for interface with IIS in Virginia
5. With the interface there is no need for additional staff as it goes straight to IIS.
6. N/A

GA:

1. Yes, reporting via our IIS is required under the Georgia Registry Law.
2. A penalty is included in the statute, but we do not have an enforcement mechanism in place at this time.
3. The penalty is monetary.
4. We have a 30-day reporting period.
5. All of the above would be useful in enforcing compliance.
6. Identifying the appropriate entity and mechanism for enforcing the penalty.

IL: Illinois does not have mandatory reporting except if they participate in the VFC program. Then they are required to report to the IIS. If they do not, then they cannot participate in the program and privileges will be revoked.

MA:

1. Yes
2. Because we are still on-boarding throughout the state, we are not implementing any penalties at this time. However, we do anticipate doing so in the future.
3. We are not sure at this time, but some ideas were not allowing state supplied vaccine ordering, or revoking medical license, denial of Medicare billing
4. We have regulations that stipulate a 7-day mandatory reporting time frame.
5. We have partnerships with MCAAP who have offered support in onboarding pediatric providers.
6. N/A at this time



MD:

1. Maryland has no statewide mandate, but we implemented a VFC mandate (last year) for VFC providers to report.
2. See #3
3. If the VFC providers fail to report, their VFC status gets suspended (which means they cannot order vaccines) until they start reporting.
4. We recommend they report within 7 business days.
5. Partnering with state VFC program/staff, attending required webinar training once a year, and complying with VFC program requirements.
6. Suspension from VFC program is difficult because we cannot let them go too long without the ability to order vaccines to provide to Medicaid children.

MN:

1. Reporting to the IIS is required for pharmacists only in Minnesota.
2. The pharmacy mandate is part of the pharmacy statutes, so the health department/IIS has no authority. As far as I know, there are not any penalties.
3. No penalties.
4. As part of the [MIIC Data Use Agreement](#) that organizations sign every three years, we request data within 7 days.
5. There is no enforcement of this standard.

MO:

1. Not at this time.
2. No

MS:

1. Yes
2. No
3. N/A
4. 10 days after administration. No penalties are assessed
5. None
6. None

VFC providers are required to report for inventory purposes and ordering. Challenges include non-Provider Hospitals that are non MU or VFC.



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NE:

1. No
2. N/A
3. N/A
4. Since we do not require reporting – we don't have any parameters in place, however we do create weekly and monthly reports to monitor timeliness and continuation of reporting
5. N/A
6. N/A

NM:

1. Yes, per state statute, all vaccinating providers are required to report all immunizations (birth to death)
2. We're currently working on regulations to implement penalties (We're hopeful to have these regulations in place by the end of the FY)
3. Proposed penalties, include:

7.5.5.... **SANCTIONS AND NONCOMPLIANCE**

- A. A reporter is in noncompliance if they fail to follow any of the above regulations.
- B. If noncompliance is substantiated, the department will issue the reporter a plan of correction.
 - (1) The reporter must correct any deficiencies identified in the plan of correction within a fixed period of time to be determined by the department and included in the plan of correction.
- C. Upon expiration of the correction date as stated in the plan of correction, a separate civil monetary penalty of \$100 may be imposed for each repeated instance of noncompliance, including, but not limited to each invalid or improper entry. The monetary penalty shall not exceed \$5,000 per report.

7.5.5.... **ADMINISTRATIVE REVIEW**

If the Division issues a civil monetary penalty, the reporter will have 10 days from issuance of that civil monetary penalty to request an administrative review.

- (1) An administrative review will be conducted by the Division Bureau Chief or designee within 30 days of the request for review.



- (2) At the administrative review, the reporter will have the opportunity to appear in person to present documents and evidence to refute the results of the investigation. The reporter may choose to send in records for review and not appear in person.
 - (3) The Bureau Chief or designee will complete their review and either overturn, modify, or uphold the civil monetary penalty within 10 days of the completion of the administrative review.
4. 10 days of administration
 5. At present time the only enforcement activities available are ordering suspension/hold for providers who participate in the VFC program.
 6. Unknown at this time.

NYC:

1. Yes, for immunizations administered to any individual 0 through 18 years of age
2. Providers can be fined for not reporting under NYC's Health Code, but we have never fined anyone.
3. N/A
4. Within 14 days of administration
5. NYC's approach has been to try to create incentives for providers to participate so that they will want to report. NYC's reporting mandate only got our IIS so far – not far enough. The game changer was linking VFC vaccine distribution to CIR reporting, which resulted in much more complete reporting. A big reason for that was because NYC has such a high proportion (~72%) of children and adolescents eligible for VFC/other publicly purchased vaccines, so most pediatric providers (>80%) participate in VFC. The other game changer has been Meaningful Use (MU)/interoperability. Enabling providers to report directly from EHRs (with no extra work) eliminated reporting burden, and MU policy provided financial incentives for reporting to an IIS.

NYS:

1. NYS public health law 2168 requires those who immunization individuals under the age of 19 to report them within 14 days. Immunizations administered in NYC get reported to CIR and in NYS outside NYC to DOH.
2. Since it's in the law books, not reporting is technically a violation of PHL and can be fined is but never applied. HOWEVER, more effectively is not allowing providers to order new VFC vaccine if they haven't been reporting. This is strictly a decision by Immunization Bureau.



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3. If we ever applied the fine for violating PHL, I think it's \$5000 per violation. We interpret that to be \$5000 for each administered and not reported to NYS.
4. PHL 2168 requires reporting within 14 days of administration.
5. Same as three and again we really use VFC accountability more than PHL violation.
6. To fine someone would involve DOH legal and the decision would move up the chain. Withholding VFC ordering is a decision strictly left to the Bureau.

SC:

1. Yes, we have a regulation 61-120 which requires all immunization providers to report all doses of administered vaccines into the registry within 10 business days of administration.
2. We have the ability to do so, however we have not exercised this ability.
3. We could issue a Public Health Order which would be a monetary fine up to \$1k per incident, each day until it is corrected. However, we typically give them a certain amount of time to comply (which they do) before we go that route. To date, we have fortunately not had to go down this route.
4. 10 business days from the date of administration. However, there are exceptions allowed within the regulation if a hardship is found and approved by the Immunization Division.
5. A LOT more IIS staff would be needed to enforce this regulation to the fullest in order to ensure compliance to the regulation. We typically don't find out about providers failing to report to the registry until annual VFC enrollment time. This is one thing that we check before we approve a VFC application. However, one thing that we do not have is a mechanism for ensuring that non VFC providers are submitting information to the registry for their private doses. If someone has a mechanism for this, I'd love to hear about their process. This makes it difficult to assess penalties due to consistency.
6. See #5 above

WV:

1. Reporting in WV is required by rule (same as law) for persons through 18 years of age. The Pharmacy board voted to make all of their own administered vaccines reportable to the IIS also.
2. There is a monetary penalty but it has never been used.
3. Monetary at \$500.00 per incident.
4. The rule requires reporting with 2 weeks of immunization administration.



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5. There have been no enforcement activities and I doubt there ever would be any enforcement. We do talk about the rule with physicians and the fact that there is a fine.
6. While we have talked about using the fine, we ultimately feel that it would do more harm than good.

WY:

1. Yes
2. As this is a recent requirement (Feb. 7, 2018), we have not yet had to; however, will likely address this in the future as not reporting is a violation of law.
3. Nothing has been formally outlined, but after all other corrective action has taken place, the penalty for violating law includes fines.
4. None, the rules that require reporting are in effect. Time frame for becoming compliant will depend on WY IMM ability to facilitate connections, etc.
5. None have been defined.
6. TBD