

Testimony
North Dakota Administrative Code
Legislative Management's Administrative Rules Committee
Wednesday, March 14, 2012
North Dakota Department of Health

Chapter 33-06-04
33-06-04-11 Vaccines

1. These rule changes did result from statutory changes related to Senate Bill 2276, which required the Department of Health to supply federal and state purchased vaccines to local public health units for administration to all children, including those with insurance.
2. These rule changes did not result from any federal statute or regulation.
3. A hearing notice was published in 52 daily or weekly newspapers in the state from August 30 through September 5, 2011. A public hearing was held October 6, 2011. Oral and written comments were received through October 19, 2011. The State Health Council adopted the proposed changes on November 15, 2011.
4. The Department of Health did not receive any comments from the public regarding the rule changes.
5. Approximate costs for public notice:

Newspaper publication of hearing notice: \$ 1,484.24

6. The intent of the proposed rule change is to make changes to the vaccine administration fee cap for state-supplied vaccines.

On May 20, 2011, Senate Bill 2276 was signed into law and filed with the Secretary of State with an effective date of July 1, 2011. This bill required the North Dakota Department of Health to provide local public health units with federally and, if needed, state-supplied vaccines for insured children. Prior to that, local public health units were using privately purchased vaccines and billing insurance for the cost of the vaccine and the higher, private administration fee.

Starting October 1, 2011, local public health units began vaccinating insured children with state-supplied vaccine. North Dakota Century Code 23-01-04.2 requires the state health department to adopt rules defining appropriate administration fees for vaccine provided to health-care providers from the state. Administrative Rules 33-06-04-11 limited the vaccine administration fee for federally- and state-supplied vaccines to \$13.90, the federal regional fee cap. North Dakota local public health units needed to be able to have their actual vaccine administration costs covered and the previous North Dakota Administrative Rules limited the amount that could be charged to less than what their actual costs are. The Department of Health did not want local public health units to receive a lower reimbursement rate for administering vaccines to insured children than they were receiving when using privately purchased vaccine for insured children.

The federal entitlement program, Vaccines For Children (VFC), provides vaccines for children who are either Medicaid-eligible, American Indian, uninsured or underinsured. The Health Care Financing Administration (HCFA), now the Centers for Medicare and Medicaid Services (CMS), published a notice of the federal regional administration fee caps in the Federal Register on October 3, 1994 (59 FR 50235). This limits the vaccine administration fee for vaccines administered through the VFC program to \$13.90. The vaccine administration fee cap will continue to be in place for VFC vaccine even with the administrative rule change. The VFC program does not have any authority over administration fees charged to state vaccine-eligible children or privately insured children.

Health-care providers and local public health units cannot refuse to vaccinate a child with state-supplied vaccine if the parent is unable to pay the administration fee.

The following is a summary of the changes:

The rules were changed to reflect that the North Dakota vaccine administration fee cap only applies to vaccines obtained through the Vaccines For Children program.

7. A regulatory analysis was not issued or required.
8. A regulatory analysis and economic impact statement of impact on small businesses was prepared and is attached.

9. These rules have no fiscal effect on state revenues and expenditures.
10. A constitutional takings assessment was not prepared.
11. These rules were adopted as emergency rules based on the grounds that “a delay in the effective date of the rule is likely to cause a loss of funds appropriated to support a duty imposed by law upon the agency.” The local public health units would have experienced significant financial losses due to administering state-supplied vaccines and being restricted to a lesser administration fee than they received prior to SB 2276 being implemented. The Department of Health requested approval for emergency rulemaking from the Governor. The Governor’s approval letter is attached.

The proposed rule changes were discussed with local public health units and distributed to Senate Bill 2276 sponsors, as required by Century Code 28-32-10. Senator Judy Lee did provide comments regarding the proposed changes, but did not suggest any changes to the proposed rules and was supportive of the change in vaccine administration fees for local public health units. The Department of Health responded to her comments.

Small Entity Regulatory Analysis for Proposed Changes to Administrative Code 33-06-04-11
State-supplied Vaccine Administration Fee Cap.

1. Was establishment of less stringent compliance or reporting requirements for small entities considered?

Not applicable. No reporting requirements are required for small entities regarding the proposed changes to the administrative code.

2. Was establishment of less stringent schedules or deadlines for compliance or reporting requirements considered for small entities?

Not applicable. No reporting requirements are required for small entities regarding the proposed changes to the administrative code.

3. Was consolidation or simplification of compliance or reporting requirements for small entities considered?

Not applicable. No reporting requirements are required for small entities regarding the proposed changes to the administrative code.

4. Were performance standards established for small entities for replacement design or operational standards required in the proposed rule?

Not applicable. No performance standards are required regarding the proposed changes to the administrative code.

5. Was exemption of small entities from all or any part of the requirements in the proposed rule considered?

Not applicable. No requirements are included in the proposed changes to the administrative code.

Small Entity Economic Impact Statement for Changes to Administrative Code 33-06-04-11
State-supplied Vaccine Administration Fee Cap.

1. Which small entities are subject to the proposed rule?

Healthcare providers that administer non-VFC (Vaccines For Children) state-supplied vaccines are subject to the proposed rule. (VFC-eligible children include those who are either American Indian, Medicaid-eligible, uninsured, or underinsured) At this time, the rule change mostly applies to North Dakota local public health units that use state-supplied vaccines to vaccinate insured children. Senate Bill 2276 was signed into law and filed with the Secretary of State with an effective date of July 1, 2011. This bill requires the North Dakota Department of Health to provide local public health units with federally and, if needed, state-supplied vaccines for insured children.

2. What are the administrative and other costs required for compliance with the proposed rule?

There is no expected increase in the administrative costs required to comply with the proposed rule. Healthcare providers will now be able to bill insurance for a higher administration fee for non-VFC state-supplied vaccines than previously allowed.

Non-VFC state-supplied vaccines are currently mostly used at local public health units to vaccinate insured children. Prior to October 1, 2011, local public health units purchased private vaccine and billed insurance for the cost of the vaccine and their usual and customary administration fee. Without the proposed rule change, local public health units would have received a lower reimbursement rate for administering vaccines to insured children than they were receiving prior to October 1, 2011.

This change allows providers to charge their usual and customary fees for non-VFC state-supplied vaccine administration. If a patient is unable to pay the administration fee, a provider may not refuse to vaccinate the patient. Providers are still limited as to how much they can charge for the vaccine administration fee for VFC-eligible children at \$13.90, which is the federal fee cap.

3. What is the probable cost and benefit to private persons and consumers who are affected by the proposed rule?

The proposed rule does not change the costs or benefits to private persons and consumers.

Non-VFC state supplied vaccines are mostly supplied to local public health units for administration to insured children. The local public health units will bill insurance for their usual and customary vaccine administration fees. Prior to October 1, 2011,

health units used privately purchased vaccine for insured children and billed their usual and customary vaccine administration fee to insurance, so there is no change in the cost to the consumer or to health insurance companies. If an individual is unable to afford the administration fee (if insurance does not fully cover the cost), then the provider must still administer the state-supplied vaccine and waive the administration fee.

4. What is the probable effect of the proposed rule on state revenues?

There would be no effect on state revenues.

5. Is there any less intrusive or less costly alternative methods of achieving the purpose of the proposed rule?

Not applicable. The purpose of the proposed rule is to allow healthcare providers to charge their usual and customary fee for non-VFC state-supplied vaccine administration, instead of being limited to \$13.90. Prior to October 1, 2011, local public health units purchased private vaccine and billed insurance for the cost of the vaccine and their usual and customary administration fee. Without the proposed rule change, local public health units would have received a lower reimbursement rate for administering vaccines to insured children than they were receiving prior to October 1, 2011.



— State of —
North Dakota
Office of the Governor

Jack Dalrymple
Governor

August 22, 2011

Terry Dwelle
State Health Officer
Department of Health
600 East Boulevard Avenue
Bismarck, ND 58505-0200

Dear Dr. Dwelle,

On August 18, 2011, I received your request for approval of emergency rulemaking to amend North Dakota Administrative Rule 33-06-04-11 regarding coverage of vaccine administration costs to health care providers.

I have reviewed the request pursuant to N.D.C.C. § 28-32-03 and I find that an emergency rulemaking is reasonably necessary and I therefore approve adoption of your proposed rules as interim final rules.

Sincerely,

Jack Dalrymple
Jack Dalrymple
Governor