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.