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Missouri State Auditor

HEALTH AND SENIOR SERVICES

Influenza Vaccine Compliance Requirements

October 2008
Report No. 2008-70



auditor.mo.gov



Better Implementation of New Law Relating to Influenza Vaccines Needed

The Department of Health and Senior Services (DHSS) provides education and information to the public and health care providers about appropriate administration, storage and handling of vaccines for children, adolescents and adults. The DHSS also ensures the influenza (flu) vaccine is available to as many Missourians as possible. Our audit objective was to evaluate compliance with state law restricting the amount of mercury in vaccines administered to children under 3 and knowingly pregnant women.

Some providers not notified of new state law

DHSS received complaints related to the new mercury-free state law from approximately 100 providers during the 2007-08 flu season, according to a DHSS official. This official said these providers inquired as to when DHSS became aware of the legislation and why the providers were not notified of the legislation. DHSS officials said DHSS communicated the new state law requirements to certain providers. However, DHSS did not notify some providers, professional organizations, or the public through any announcements or system wide notifications before the law became effective. In addition, many providers had already ordered flu vaccines before the notifications were sent. DHSS officials said the state law did not require DHSS to notify the public or providers of the new law; however, one of these officials said the public views DHSS as the resource to communicate new health alerts.

Some children received the flu vaccine containing mercury

Some children under 3 were, and some pregnant women may have been, inappropriately administered the flu vaccine containing mercury because the provider did not become aware of the law until after the flu season began (about six months after the law became effective in April 2007). In addition, a DHSS official stated DHSS received approximately 10 calls from providers who said they had already purchased the flu vaccine containing mercury before they became aware of the law. These 10 providers said they planned to continue to administer the vaccine to children under 3 and/or knowingly pregnant women, even though it violated state law.

Shortage of flu vaccine not defined

State law allows the Director of DHSS, with the approval of the Governor, to exempt the use of a mercury-free vaccine if a potential public health emergency exists, such as a shortage of vaccine. During the September 2007 Advisory Committee on Childhood Immunization (ACCI) meeting, the committee developed a recommendation to assist the Director in determining the circumstances under which an exemption to mercury-free flu vaccines should be enacted. The ACCI documentation stated the purpose of the recommendation is to ensure young children, who are at greatest risk for complications and hospitalizations from influenza, are appropriately immunized if there is a substantial delay or shortage in the supply of mercury-free vaccine. However, DHSS has not approved the committee's recommendation as of June 2008, a nine month delay.

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Abbreviations

ACCI	Advisory Committee on Childhood Immunization
CDC	Center for Disease Control and Prevention
DHSS	Department of Health and Senior Services
MSMA	Missouri State Medical Association
RSMo	Missouri Revised Statutes



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Honorable Matt Blunt, Governor
and
Jane Drummond, Director
Department of Health and Senior Services
Jefferson City, MO

The Department of Health and Senior Services (DHSS), Division of Community and Public Health, Section for Disease Control and Environmental Epidemiology, Bureau of Immunization Assessment and Assurance Unit provides education and information to the public and health care providers about appropriate administration, storage and handling of vaccines for children, adolescents and adults. The unit also ensures the influenza (flu) vaccine is available to as many Missourians as possible. Our audit objective was to evaluate compliance with state law restricting the amount of mercury in vaccines administered to children under 3 and knowingly pregnant women.

Improvements are needed to ensure children under 3 and knowingly pregnant women are not administered vaccines containing mercury because the Department of Health and Senior Services (DHSS) did not adequately notify providers of the new state law requirements. In addition, DHSS did not maintain documentation of provider complaints received, and did not adopt an advisory committee recommendation to define a flu vaccine shortage.

We conducted our audit in accordance with the standards applicable to performance audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States. Those standards require that we plan and perform our audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides such a basis. Key contributors to this report included John Luetkemeyer and Amanda Locke.

A handwritten signature in cursive script that reads "Susan Montee".

Susan Montee, CPA
State Auditor

Better Implementation of New Law Relating to Influenza Vaccines Needed

Improvements are needed to ensure children under 3 and knowingly pregnant women are not administered vaccines containing mercury because the Department of Health and Senior Services (DHSS) did not adequately notify some providers of the new state law requirements. In addition, DHSS did not maintain documentation of provider complaints received, and did not adopt an advisory committee recommendation to define a vaccine shortage.

Background

The DHSS, Division of Community and Public Health, Section for Disease Control and Environmental Epidemiology, Bureau of Immunization Assessment and Assurance Unit provides education and information to the public and health care providers about appropriate administration, storage and handling of vaccines for children, adolescents and adults. The unit also ensures the flu vaccine is available to as many Missourians as possible. Missouri's Advisory Committee on Childhood Immunization (ACCI) is required by state law¹ to develop plans to increase the childhood immunization rate in the state.

In 1999 and 2000, the United States Public Health Service, including the Food and Drug Administration, the National Institutes of Health, Center for Disease Control and Prevention (CDC), the Health Resources and Services Administration, and the American Academy of Pediatrics issued statements recommending vaccine manufacturers reduce or eliminate thimerosal² in vaccines as a precautionary measure. In 2001, the Institute of Medicine Immunization Safety Review Committee³ recommended "full consideration be given to removing thimerosal from any biological product to which infants, children, and pregnant woman are exposed."⁴ In 2005, the Missouri General Assembly established a state law⁵ requiring children under 3 and knowingly pregnant women be administered vaccines with no more than one microgram of mercury per five tenths milliliter dose (mercury-free). This law became effective April 1, 2007. Other states, including California, Illinois, Iowa and Delaware, have also established similar legislation.

¹ Section 192.630, RSMo

² Thimerosal is a mercury-containing organic compound.

³ The Immunization Safety Review Committee was a project within the Institute of Medicine that addressed current and emerging vaccine-safety concerns. The committee provided independent, non-biased advice to vaccine policy-makers, as well as practitioners and the public.

⁴ "Thimerosal in Vaccines," *United States Food and Drug Administration*, <<http://www.fda.gov/cber/vaccine/thimerosal.htm>> , accessed June 3, 2008.

⁵ Section 191.235, RSMo

Currently all routinely recommended pediatric vaccines contain no thimerosal, or only trace amounts, with the exception of the influenza (flu) vaccine. The flu vaccine is currently available in both a thimerosal-preservative containing formulation and in formulations containing no thimerosal, or only trace amounts. According to the CDC website,⁶ the CDC recommends children ages 6 to 59 months and pregnant women be administered with either reduced or standard mercury containing flu vaccine annually. However, the CDC also states there is no convincing evidence of harm from vaccines containing low doses of mercury, except for minor reactions at the injection site, and the risk of not vaccinating outweighs any theoretical mercury risk.

Scope and Methodology

To evaluate compliance with state law, we reviewed applicable state laws, interviewed officials and/or staff at DHSS, the ACCI, the American Academy of Pediatrics, the Missouri State Medical Association (MSMA) and a private practice. We also reviewed ACCI minutes, searched Internet sites and reviewed other applicable information to obtain additional background information.

Some Providers Not Notified of New Law

DHSS received complaints related to the new mercury-free state law from approximately 100 providers during the 2007-08 flu season, according to a DHSS official. This official said these providers inquired as to when DHSS became aware of the legislation and why the providers were not notified of the legislation. An MSMA official told us the organization also received complaints at the beginning of the flu season from approximately nine physicians that were not informed of the state law before they purchased the incorrect flu vaccine. This MSMA official also said the MSMA had not been informed of the state law and inquired with DHSS as to why better communication had not occurred.

DHSS officials said DHSS communicated the requirements of the new state law to providers that attended voluntary Vaccines for Children Program⁷ training courses in 2006. However, DHSS did not notify providers who did not attend the training courses, professional organizations, or the public through any announcements or system wide notifications before the law became effective in April 2007. In addition, DHSS initiated the following communications about the new state law: (1) information was sent to all

⁶ "Thimerosal in Seasonal Influenza Vaccine," Center for Disease Control and Prevention, <<http://cdc.gov/flu/about/qa/THIMEROSAL.HTM>>, accessed May 28, 2008.

⁷ The Vaccines for Children program is part of the federal immunization grant (CFDA No. 93.268) that allows DHSS to distribute vaccines to local health agencies and other providers who then distribute these vaccines to eligible children. Not all providers in the state are participants in the Vaccines for Children program.

Local Public Health Agencies in Missouri via email notifications through DHSS' "Friday Facts" electronic bulletins on June 15, 2007 and July 13, 2007, (2) an informational mailing was distributed to all Vaccines for Children providers on September 26, 2007, (3) information was distributed to Vaccine for Children participants along with the Vaccine for Children flu order form on October 3, 2007, (4) a survey was distributed to Vaccine for Children providers along with additional information regarding the legislation on October 18, 2007, and (5) the provisions of the new legislation were discussed at Influenza Workshops (not specifically for Vaccine for Children providers) on August 8, August 21, September 13 and September 18, 2007. However, the mailing and distribution of information did not occur until after the law had become effective and many providers had already ordered flu vaccines.

DHSS officials said the state law did not require DHSS to notify the public or providers of the new law; however, one of these officials said the public views DHSS as the resource to communicate new health alerts. This official said providers were also not notified by other professional organizations who support these providers.

Some children received the flu vaccine containing mercury

Some children under 3 were, and some pregnant women may have been, inappropriately administered the flu vaccine containing mercury. One provider told us her practice inappropriately administered the flu vaccine containing mercury to children under 3 before the provider became aware of the new state law. This provider did not become aware of the law until after the flu season began, about six months after the law became effective in April 2007. A DHSS official also said it is possible other children under 3 or pregnant women may have been administered the inappropriate vaccine based on the complaints DHSS received from providers. This official stated DHSS received approximately 10 calls from providers who said they had already purchased the flu vaccine containing mercury before they became aware of the law. These 10 providers said they planned to continue to administer the vaccine to children under 3 and/or knowingly pregnant women, even though it violated state law. According to a DHSS official, state law does not require DHSS to determine the extent that children under 3 or knowingly pregnant women had been administered vaccines containing mercury and DHSS does not have the funding or infrastructure to collect this information.

Providers may have incurred loss

Providers may have incurred a loss for ordering the incorrect flu vaccine. A DHSS official said it is possible providers incurred a loss if the inappropriate vaccine could not be administered to other patients. DHSS officials said they do not know the estimated loss incurred by the providers and one of these officials said DHSS has not performed any reviews to

identify the estimated loss. This DHSS official further said DHSS is not required by state law nor does DHSS have the funding or infrastructure to collect this information.

DHSS has not approved ACCI recommendation to ensure health alerts and updates are adequately communicated

During the April 2008 ACCI meeting, the committee addressed the inadequate communication of the flu vaccine requirements. The committee recommended DHSS work with the Board of Healing Arts and other practitioners to develop and establish a better way to communicate health alerts and updates. However, a DHSS official said the recommendation has not been approved nor implemented by DHSS as of June 2008.

Documentation of complaints not maintained

DHSS did not maintain documentation of complaints received nor who made the complaints regarding DHSS' failure to notify providers of the new law. A DHSS official said no documentation was maintained of the conversations nor the specific complaints because DHSS was not directed to maintain this documentation. As a result, DHSS is unable to ensure appropriate action was taken to resolve complaints.

Shortage of Flu Vaccine Not Defined

State law allows the Director of DHSS, with the approval of the Governor, to exempt the use of a mercury-free vaccine if a potential public health emergency exists, such as a shortage of vaccine. During the September 2007 ACCI meeting, the committee developed a recommendation to assist the Director in determining the circumstances under which an exemption to mercury-free flu vaccines should be enacted. The ACCI documentation stated the purpose of the recommendation is to ensure young children, who are at greatest risk for complications and hospitalizations from influenza, are appropriately immunized if there is a substantial delay or shortage in the supply of mercury-free vaccine. However, DHSS has not approved the committee's recommendation as of June 2008, a nine month delay. A DHSS official said the recommendation has not been approved by DHSS due to staff turnover in an upper management position.

A DHSS official said DHSS conducted surveys with local public health agencies and private providers as of October 2007 to determine whether there was an adequate supply of the mercury-free flu vaccine. DHSS' survey identified the following based on provider inventory estimates:

- Of the 87 local public health agencies that responded to DHSS' survey, 56 (64 percent) and 52 (60 percent) did not have enough mercury-free vaccine for children under 3 and knowingly pregnant women, respectively.
- Approximately 25,300 additional doses of mercury-free vaccine were needed for the 220 private providers within the Vaccines for Children program who responded to the survey.

A DHSS official said because providers were unaware of the new legal requirements and ordered the wrong vaccine, DHSS initially perceived a shortage of the mercury-free flu vaccine may have existed for the 2007-08 flu season. An ACCI member said informal discussions about declaring a state shortage occurred with the Director of DHSS; however, a shortage was not declared. A DHSS official said although DHSS became aware that supplies of mercury-free flu vaccine were still available, DHSS did not formally notify providers. The DHSS informally communicated with providers participating in the Vaccines for Children Program.

Some may not have been vaccinated

A DHSS official said some providers may not have had the inventory to administer the mercury-free flu vaccine and some children under 3 or knowingly pregnant women may not have received the flu vaccine because of the incorrect orders of this vaccine. Not immunizing individuals against the flu vaccine could have led these individuals to have flu complications or hospitalization.

Conclusions

DHSS did not adequately notify providers and the public of a new state law requiring children under 3 and knowingly pregnant women to be administered mercury-free vaccines. As a result, and contrary to the new law, some providers administered the flu vaccine containing mercury to children under 3 and possibly pregnant women. In addition, DHSS has not approved an advisory committee recommendation to ensure future health alerts and updates are distributed to health care providers, and did not maintain documentation of complaints received regarding DHSS' failure to adequately notify providers of the new law.

DHSS also has not taken action to address an advisory committee recommendation to assist the Director in determining the circumstances under which an exemption to mercury-free flu vaccines should be enacted.

Recommendations

We recommend the Director of the Department of Health and Senior Services:

- 2.1 Approve and implement the ACCI recommendation to work with the Board of Healing Arts and other practitioners to ensure health alerts and updates are effectively communicated to the providers and to the public.
- 2.2 Maintain documentation of complaints received and actions taken to resolve complaints.

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- 2.3 Address the ACCI recommendation to determine the circumstances under which an exemption to mercury-free vaccines should be enacted.

Agency Comments

- 2.1 *DHSS concurs with this recommendation. DHSS is currently working to improve its collaborative efforts with professional organizations. The Bureau of Immunization Assessment and Assurance (BIAA) has revised its website to be more user-friendly and a better source of information for providers as well as citizens. The bureau will continue to update the website to ensure the most current information is available. The bureau will also continue to explore other avenues such as working with the Board of Healing Arts regarding future communications.*

As the top public health agency in Missouri, DHSS works hard to ensure citizens are properly immunized against diseases. The department accomplishes this through a variety of efforts, most notably the federally-funded VFC program. But while DHSS is acutely interested in immunization-related issues, it is important to understand that the DHSS-BIAA has neither the statutory authority nor the statutory responsibility for assuring health care providers meet influenza vaccine compliance requirements. Rather, health care providers bear the responsibility for assuring they are practicing medicine in compliance with applicable statutes and regulations.

- 2.2 *DHSS concurs with this recommendation. DHSS is developing procedures to document formal complaints. This will include documentation of actions taken to resolve complaints.*

- 2.3 *DHSS concurs with this recommendation. The ACCI chair, in collaboration with the State Epidemiologist, has drafted a policy regarding this issue. Once BIAA has completed its review of the policy, it will be sent to DHSS Director for approval.*

It should be noted that the DHSS Director did not declare a state shortage of preservative free vaccine during the 2007-2008 flu season because no such shortage occurred. In fact, VFC providers returned 4,073 doses of expired preservative free vaccine, which is considered wastage.