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TO: Vaccines for Children (VFC) Providers

FROM: John Talarico, D.O., M.P.H., Chief, CDPH, Immunization Branch

SUBJECT: Office of the Inspector General Report Regarding the Program's Vulnerabilities in Vaccine Management

BACKGROUND

In April and May of 2011 the Office of the Inspector General (OIG) of the federal Health and Human Services Agency conducted a routine planned assessment of the Vaccines for Children (VFC) Program aimed at state and provider adherence to federal requirements for vaccine management, including vaccine storage equipment, vaccine management, and VFC program eligibility screening.

The study was conducted with 45 VFC providers from the five largest VFC Grantees nationwide; 9 provider offices from California were included in the study. The report underscores that we must do better at ensuring that vaccines are stored and monitored properly--and that VFC program requirements are being met.

The California VFC program is actively working in partnership with VFC providers to ensure proper vaccine management oversight.

REPORT FINDINGS

The OIG report identifies two types of findings: storage and handling of vaccine and program management issues. Vaccine storage and handling issues include improper temperature and unapproved storage units as well as expired vaccine stored alongside non-expired vaccine. Program management issues include a lack of required documentation, program oversight, and vaccine management at provider sites. The report recommends that CDC continue to work with states to ensure proper storage of vaccines, separation of expired and non-expired vaccines, and adherence to VFC oversight requirements.

Vaccines continue to be safe and offer the best protection against vaccine-preventable diseases. We have attached a document with additional Talking Points for providers and parents.

ACTION STEPS IN RESPONSE TO REPORT FINDINGS

Meeting VFC requirements is a shared responsibility among CDC, state and local health departments, and VFC provider offices. Working together, we will identify and successfully implement solutions.

The CDC has begun working with key partners and stakeholders to identify other steps that need to be taken to address the findings in the report as well as develop longer-term strategies to help providers strengthen their capacity to appropriately store and handle vaccines.

California has developed a number of nationally recognized trainings and educational tools to help provider offices with their storage, handling, and oversight of their vaccines. These include: 5 online training modules, 3 of which are focused on vaccine storage and handling, found at www.eziz.org. An additional module on inventory management is currently in development.

The VFC Program is committed to working with all of our providers to give you the support you need to vaccinate your patients and adhere to the program requirements. Our website, EZIZ, has a vast array of materials on storage and handling (<http://eziz.org/resources/storage-handling-job-aids/>), including our online modules.

WHAT YOU CAN DO

Now is a good time to review your storage and handling practices and ensure you are meeting all program requirements.

- Review the materials located at <http://eziz.org/vaccine-storage/>.
- Ensure all staff have taken the EZIZ lessons on storage and handling. Print and keep the completion certificate as documentation of training.
- Ensure that you have a designated vaccine coordinator and assigned back-up that are familiar and knowledgeable about all program requirements. Information on vaccine coordinator and vaccine management responsibilities can be found at: <http://eziz.org/assets/docs/IMM-968.pdf>.

QUESTIONS?

If you have any questions, please call your VFC Field Representative or the VFC Program at: 877-243-8832 (877-2GET-VFC). You can also visit our website at www.eziz.org.

Encl: Talking points for providers and parents

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OIG VACCINE MANAGEMENT REPORT: TALKING POINTS for Providers

Overarching Key Messages

- The OIG report highlighted that there are some areas where providers can do better in the VFC program.
- The California VFC program is actively working in partnership with VFC providers to ensure proper vaccine management oversight.
- Vaccines continue to be safe and offer the best protection against vaccine-preventable diseases.

OIG Report

- The Office of the Inspector General (OIG) conducted a routine, planned assessment of the Vaccines for Children Program (VFC).
- The OIG study was aimed at assessing if VFC providers are meeting their vaccine management requirements, such as storing vaccine at proper temperature ranges and monitoring expiration dates.
- The report underscores that we must do better at ensuring that vaccines are stored and monitored properly -- and that VFC program requirements are being met.
- The complete report can be accessed on the OIG website:
<http://oig.hhs.gov/oei/reports/oei-04-10-00430.asp>

For Parents/Patients

Vaccines continue to be safe and offer the best protection against vaccine-preventable diseases.

We understand that parents who hear about this report may have questions about their child's vaccinations. We want you to know:

- The main concern with improper storage temperatures is that they can make vaccines less effective rather than less safe.
- In most of the instances, temperatures were only slightly higher or lower than the recommended range and do not lessen the potency of affected vaccines (according to manufacturer data and WHO vaccine stability data). Children do not need to be revaccinated.
- There is every indication that vaccines are doing their job at providing protection against disease.
- The CDC monitors the diseases that vaccines prevent and can see that vaccines are doing their job; we see little vaccine-preventable disease in the U.S.
- Recent outbreaks of measles and pertussis are not linked to less effective or ineffective vaccines

- Cases of measles reported in the United States appear to be associated with unimmunized people and travel, not vaccine storage outside of recommended temperature ranges. Likewise, the primary factor in pertussis outbreaks seen in the U.S. appears to be waning immunity.
- Our provider office will continue to review and ensure proper vaccine management practices to make sure that our vaccines are as effective as possible.
- If parents have any concerns about immunizations, encourage them to talk with their doctor.

Vaccine Safety

- The findings do not raise concerns about the safety of vaccines administered to children.
- The primary focus of the Inspector General's report was on documentation/oversight issues and proper temperature storage for vaccines.
- Without vaccines, children are at risk for getting seriously ill and suffering pain, disability, and even death from diseases like measles and whooping cough.

What Providers are doing

Ensuring the proper storage, handling, and oversight of vaccines is a priority for California VFC providers.

- VFC Providers will continue to work with the California VFC Program and other partners to ensure compliance with proper vaccine management.
- The California VFC Program has developed a number of trainings and educational tools to help provider offices with their storage, handling, and oversight of their vaccines. Providers are encouraged to take advantage of these resources.