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Governor

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State Surgeon General

INTEROFFICE MEMORANDUM

DATE: March 16, 2010
TO: James D. Boyd, C.P.A., M.B.A., Inspector General
THROUGH: Michael J. Bennett, C.I.A., Director of Auditing
FROM: Mark H. Boehmer, C.P.A., Senior Management Analyst II
SUBJECT: V-0910DOH-017- *Controls over Shipping Pharmaceuticals*

Based on your request, we reviewed 11 Category One Incident Reports (Reports) completed from May 28, 2009 through October 16, 2009 and submitted together to the Office of the Inspector General by Bay County Health Department (CHD). The Reports related to receiving incorrect shipments of pharmaceuticals from wholesale distributors and Department of Health's (DOH) Bureau of Statewide Pharmaceutical Services (BSPS). Category One Reports are considered non-serious in nature and are not required to be submitted to the Office of the Inspector General. However, Bay CHD originated 11 of these Reports over five months and considered there to be sufficient cause for the Office of the Inspector General to be aware of such incidents.

Office of the Inspector General audit staff were requested by the Inspector General to review the Reports and identify possible control deficiencies in the process that may be triggering the high number of similar incidents being reported.

What we observed

Three of the 11 Reports related to incorrect shipments of pharmaceuticals ordered by CHDs and received directly from drug wholesalers. These shipments did not pass through BSPS. Therefore, we did not research these incidents.

One of the 11 Reports related to a shipment of a client-specific prescription filled by BSPS's Central Pharmacy that was to be shipped to Baker CHD, but was erroneously shipped to Bay CHD. We reviewed the shipping document. We consider this to be an isolated incident of human error. Pharmacy staff apparently misread shipping documentation coding "BAK" for "BAY".

The remaining seven Reports helped us identify control deficiencies in BSPS's Warehouse shipping process. We included four recommendations for BSPS management to consider.

We examined documentation of the original orders placed by CHDs, shipping documents, and other supporting documentation. We could not validate Bay CHD's claims of how many items Bay CHD received. Receiving errors on the part of Bay CHD may have contributed to some of these incidents.

1. **Two shipments of pharmaceuticals were made without a supporting order form.**

BSPS implemented a written procedure on August 11, 2009. The procedure for drug product distribution to customers addresses that a shipping list should be prepared upon release of a batch run (order).

Bay CHD ordered three bottles of Prezista 600mg on June 11, 2009. After receiving a call from Bay CHD to inquire of the shipment, the warehouse manager authorized an additional separate shipment of 12 bottles without a supporting order form. The original order of three bottles was subsequently filled. The incident preceded the written procedure. We consider that BSPS subsequently implemented a control to mitigate the incident from reoccurring.

Bay CHD ordered 5 bottles of Lipitor 10mg and 3 bottles of Lipitor 40mg on August 7, 2009. The order was shipped overnight on that date. BSPS management explained Bay CHD called the Warehouse the following Monday to explain Bay CHD had not yet received the needed pharmaceuticals. A duplicate overnight shipment was made on August 13, 2009. This shipment was made without a supporting order form and without the Warehouse determining the shipment status of the first order. The incident preceded the written procedure. We consider that BSPS subsequently implemented a control to mitigate the incident from reoccurring.

No recommendation made.

2. **Pharmaceuticals ordered by CHDs were incorrectly filled because shipments were not verified before leaving the Warehouse.**

- Bay CHD ordered three boxes of Pregnancy Kits on July 8, 2009. Bay CHD claimed the July 15, 2009 shipment included only one box, but BSPS's shipping document showed three boxes were shipped.
- Bay CHD ordered one bottle of Lamotrigine **25mg** (Lamictal) on July 9, 2009. Bay CHD claimed the Warehouse shipped one bottle of Lamotrigine **150mg** (Lamictal), but the shipping document showed one bottle of Lamotrigine **25mg** (Lamictal) was shipped on July 15, 2009. Bay CHD returned the one bottle of Lamotrigine **150mg** (Lamictal) on July 20, 2009.
- Bay CHD ordered one pack (10 doses) of Pneumovax vaccine on July 30, 2009. Bay CHD claimed the Warehouse shipped the order on August 10, 2009 with the vaccine having already passed its expiration date.

BSPS originally implemented a written procedure for drug product distribution to customers on August 11, 2009. The procedure requires that the Warehouse manager will verify on each page of the shipping document, by signature and date, that the order is approved to be released for shipment. The incidents above occurred prior to the written procedure being published.

No recommendation made.

3. Some ordered pharmaceuticals were incorrectly shipped even after shipments were verified before leaving the Warehouse.

BSPS originally implemented a written procedure for drug product distribution to customers on August 11, 2009. The procedure requires that the Warehouse manager will verify on each page of the shipping document, by signature and date, that the order is approved to be released for shipment.

- Bay CHD ordered six boxes (days) of **100mg** Fluconazole on July 22, 2009. The Warehouse shipped two boxes (days) of **150mg** Fluconazole on July 29, 2009. This incident preceded the written procedure. However, there apparently was no comparison of the shipment to the order form.
- Bay CHD ordered 45 boxes of Low-Ogestral on August 5, 2009. The Warehouse recorded shipping 45 boxes of Low-Ogestral on August 11, 2009. DOHP 395-1-08, *Policies and Procedures for County Health Departments*, explains CHD personnel receiving shipments will certify the receipt of pharmaceuticals. Bay CHD certified it received 48 boxes of Low-Ogestral. There was no documentation at the Warehouse to support the over-shipment. This incident preceded the written procedure. However, there apparently was no comparison of the shipment to the order form.
- Bay CHD ordered two vials of **250mg** Ceftriaxone on September 17, 2009. The Warehouse shipped two vials of **1 gram** Ceftriaxone on September 17, 2009.

<p><u>We recommend</u> BSPS management enforce its written procedure and ensure all orders are verified for accuracy before shipment.</p>

4. Some orders were filled for one CHD, but shipped to a different CHD.

- Pasco CHD ordered one vial of Ceftriaxone 250mg on September 17, 2009. The Warehouse filled the order to go to Pasco CHD, but shipped the order to Bay CHD on September 17, 2009.
- Pasco CHD ordered 20 dose injections of Medroxyprogesterone (Depo) and two boxes of Pregnancy Test Kits on September 17, 2009. The Warehouse filled the order to go to Pasco CHD, but shipped the order to Bay CHD on September 17, 2009. This order was shipped separately from the above Ceftriaxone order.

BSPS implemented a written procedure for drug product distribution to customers on August 11, 2009. The procedure requires that Warehouse workers seal each box containing the order and affix the appropriate mailing label.

We recommend BSPS implement a control to ensure the accuracy of the shipping process at the point from sealing each box of an order to the point of affixing the shipping label.

5. The Warehouse did not have a control in place regarding returned pharmaceuticals. Pharmaceuticals could not be accounted for.

Bay CHD ordered one bottle of Lamotrigine **25mg** (Lamictal) on July 9, 2009. According to Bay CHD, the Warehouse shipped one bottle of Lamotrigine **150mg** (Lamictal), even though the shipping document indicated the correct order was shipped on July 15, 2009. Bay CHD shipped the Lamotrigine **150mg** (Lamictal) back to the Warehouse on July 20, 2009 using FedEx Tracking Number 869851017297. The Warehouse had no documentation to support receiving or re-stocking to inventory the return shipment. FedEx delivered to a "S. Mainer" at the address of the Warehouse. There was no S. Mainer employed by BSPS. The Warehouse was not aware that these pharmaceuticals were unaccounted for until our request for documentation.

BSPS management explained it is currently the responsibility of the CHD to send returned shipments back to the Warehouse. Any one of the BSPS staff may receive and accept a call or e-mail notification from a CHD of an incorrect shipment. These notifications may be forwarded to an assigned employee that may follow-up to have the shipment returned. However, there was no control to ensure a uniform process.

We recommend a change in current policy (DOHP 395-1-08, *Policies and Procedures for County Health Departments*). BSPS should implement a control that assumes immediate control of items to be returned to BSPS upon notification from the customer. The process should ensure control over shipping the item(s) back to BSPS, verify that the item(s) have been returned and re-stocked to inventory, quarantined, or other necessary outcome. A CHD as customer has little incentive upon shipping inventory back to the Warehouse, to ensure returned pharmaceuticals are received by the Warehouse and appropriately handled. Placing such responsibility on BSPS adds continuity to the process and adds more certainty as to the final outcome that returned pharmaceuticals are appropriately handled.

6. Written procedures did not adequately address management's intent that both the person filling an order and a separate person verifying the order document their action.

BSPS implemented a written procedure for drug product distribution to customers on August 11, 2009. The procedure requires that the Warehouse manager verify on each page of the shipping document, by signature and date, that the order is approved to be released for shipment. There is no written requirement that the person filling the bulk order initial or otherwise sign-off on the shipping document. Management explained their intent during our review that both the person filling the order and a second person that verifies the order should initial and date the shipping document.

The written procedure that preceded the August 11, 2009 document required only that the Order Form be initialed and dated on each sheet. There was no written requirement prior to August 11, 2009 that the person filling the bulk order initial or otherwise sign-off on the shipping document. There was also no written requirement that a second person verify the order.

We reviewed 14 shipping documents that related to the seven Incident Reports:

	Filler Initialed or Signed Shipping Document	Verifier Initialed or Signed Shipping Document
1	Yes	Yes
2	No	Yes
3	No	No
4	Yes	No
5	Yes	Yes
6	No	No
7	Yes	Yes
8	No	No
9	Yes	No
10	Yes	No
11	Yes	Yes
12	Yes	No
13	Yes	Yes
14	Yes	Yes

Of the 14 shipping documents we examined, there was no initialing or signature to document the employee who filled the order in four instances (28%). There was no initialing or signature to document that an order was verified as correct in seven instances (50%).

We recommend BPS implement a written policy that requires the person that fills an order to initial or otherwise signify on the shipping document some identifier of that person's identification. A second (different) qualified employee should review and document approval of each shipment for correctness before shipping. To assist staff in documenting who filled an order and who reviewed the order prior to shipment, BPS could consider altering the shipping document to include specific spaces on the document for the two reviews to be noted with an initial line and a date line for both the person filling the order and the person verifying the shipment. Providing specific spaces on the shipping document may help prompt those who perform these functions, thus increasing the frequency of sign-offs.

MHB

cc: Shairi R. Turner, M.D., M.P.H.

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