

**Guam Memorial Hospital Authority
Inventory Control
Over Controlled Substances**

**Performance Audit
October 1, 2011 through September 30, 2014**

**OPA Report No. 15-07
December 2015**



Guam Memorial Hospital Authority Inventory Control Over Controlled Substances

**Performance Audit
October 1, 2011 through September 30, 2014**

**OPA Report No. 15-07
December 2015**

Distribution:

Governor of Guam
Lt. Governor of Guam
Speaker, 33rd Guam Legislature
Senators, 33rd Guam Legislature
Hospital Administrator, Guam Memorial Hospital Authority
Guam Media via E-Mail



Table of Contents

	Page
Executive Summary	1
Introduction.....	3
Background.....	3
Results of Audit.....	5
Inadequate Controls to Account For and Safeguard Controlled Substances	5
<i>Lost Revenue Due to Usage Discrepancies</i>	<i>5</i>
<i>Discrepancies in End of Day Balances.....</i>	<i>7</i>
<i>Inadequate Accounting for Pharmaceutical Drugs</i>	<i>8</i>
<i>Surprise Count Discrepancy for CS3.....</i>	<i>9</i>
<i>Lack of Independent Verification and Proper Separation of Duties</i>	<i>9</i>
<i>Expired and Destroyed Controlled Substances Could Be Better Accounted For.....</i>	<i>11</i>
<i>Loaned and Borrowed Controlled Substances Outstanding.....</i>	<i>11</i>
<i>Anesthesiologists' Stock Excluded from Inventory List</i>	<i>12</i>
<i>Non-Systematic Filing for Controlled Substance Dispensation</i>	<i>12</i>
Noncompliance with Certain Laws, Requirements, and Internal Policies.....	13
<i>Twelve Physicians without Controlled Substance Registrations for GMHA.....</i>	<i>13</i>
<i>Pharmacy Keys Not Controlled</i>	<i>14</i>
<i>Certain Pharmacy Inventory Control Not Sufficiently Maintained.....</i>	<i>15</i>
Understated Billing Due to Insufficient Fee Schedule Update.....	16
Conclusion and Recommendations	17
Management Response and OPA Reply	18
Appendices	
1: Classification of Monetary Impact	20
2: Objectives, Scope, and Methodology	21
3: Prior Audit Coverage	23
4: Controlled Substances Schedules	26
5: Applicable Laws, Regulations, and Policies.....	27
6: Internal Control Suggestions	31
7: GMHA Management Response	32



EXECUTIVE SUMMARY

Guam Memorial Hospital Authority's Inventory Control Over Controlled Substances OPA Report No. 15-07, December 2015

Our audit found that the Guam Memorial Hospital Authority (GMHA):

- Did not establish adequate controls to account for and safeguard controlled substance inventory. Our findings included the following:
 - An estimated lost revenue of \$10,000 was due to usage discrepancies of 2,906 units versus billings for 12 sampled controlled substances. Of the 2,906 discrepancies, CS5 had the largest discrepancy at 609 units and six other drugs had discrepancies ranging from 244 to 607 units.
 - GMHA's system limitations made it difficult to identify how much of the approximately \$9.6 million (M) spent on pharmaceutical drugs between fiscal year (FY) 2012 and FY 2014 were for controlled substances versus non-controlled substances.
 - Lack of independent verification and proper separation of duties.
 - Expired and destroyed controlled substances did not always reconcile.
 - \$3,164 of loaned and borrowed controlled substances were outstanding.
 - The Anesthesiologists' stock was excluded from the inventory list.
 - Non-systematic filing system of documents for controlled substance dispensation.
- Generally complied with federal and local requirements and controls over controlled substances, but certain requirements and controls were not adhered to. Specifically:
 - 12 physicians did not have the required Controlled Substance Registrations for GMHA with the Department of Public Health and Social Services (DPHSS).
 - The pharmacy keys were accessible to all persons in the Pharmacy instead of controlled by the GMHA Pharmacy Director or his/her designee.
 - Certain pharmacy inventory was not sufficiently maintained.
- Did not accurately and properly bill for controlled substances in accordance with GMHA's prescribed fee schedule. There were \$2,147 in understated billings due to insufficient fee schedule updates for three controlled substances.

Our audit identified a total financial impact of approximately \$15,000, due to lost revenue from understated billings, the need for a fee schedule update, and unpaid loaned controlled substances.

Lost Revenue Due to Usage Discrepancies

We found a net variance of 2,906 units when compared to the total quantities billed for the 12 selected drugs issued to GMHA Nursing Units and anesthesiologists. The discrepancies resulted in understated billings of approximately \$10,000 as GMHA's Billing System is not linked to the Pharmacy's Controlled Substance Inventory Record and the pharmacy encoded charges. If the GMHA systems do not link, it is highly possible that the controlled substances issued by the Pharmacy Department to the nursing units may not be properly accounted for and result in lost revenue.

Lack of Independent Verification and Separation of Duties

For controlled substance deliveries, there is a lack of separation of duties because the pharmacist on duty handles all responsibilities from receipt, storage, recording, issuance, and periodic physical inventories. In addition, there is no independent verification, since the Pharmacy Director, who approves the controlled substance orders, performs the same functions as the Pharmacist on duty. The absence of proper separation of duties over controlled substance processes and independent verification renders weak controls for preventing and detecting loss, misuse, or abuse.

Loaned and Borrowed Controlled Substances Outstanding

For FY 2014, there were 530 controlled substances loaned to or borrowed from other local pharmacies. Of the total quantities, 350 units with a value of \$3,164 remain unpaid. Certain documents supporting the loan or borrowing of 1,615 units, inclusive of substances loaned in prior periods, were not available for examination, because copies were either returned to the borrower or discarded since it is not a DEA requirement.

Noncompliance with Certain Laws, Requirements, and Internal Policies

GMHA generally complied with federal and local laws, requirements, and GMHA internal policies, such as registration with the local DEA office, use of the DEA Form 222 to order Schedule II controlled substances, use of DEA form 41 for destruction of expired controlled substances, and certain required security and storage features. However, certain requirements and internal policies were not adhered to, including 12 physicians without the required Controlled Substance Registration for GMHA with DPHSS and certain inventory controls were not sufficiently maintained.

Insufficient Fee Schedule Update

The latest invoice price plus freight charges for a certain controlled substance were not used as the basis for formulating fee rates charged to patients. For three drugs, we found understatements ranging from \$0.05 to \$9.88 per unit or a total of \$2,147. GMHA's fee rate is formulated based on historical cost, plus markup of 2.756%, for pharmaceuticals. These fee rates are only increased when GMHA decides to increase its fees at a maximum of 5% without public hearing. Fees were recently increased in 2015, five years from the last fee increase in 2010.

Conclusion and Recommendations

To preclude revenue losses due to weak internal control, inventory discrepancies, and inaccurate billings, as well as prevent possible loss, abuse, and misuse, we recommend GMHA (1) designate officials to address the Pharmacy and Billing system linkage issues required to properly account for all controlled substances issued for patient dispensation, ensure accuracy of patient billings, and maintain an accurate automated inventory of controlled substances; (2) establish and implement controls to ensure compliance with laws, requirements, and policies; and (3) ensure that all expired controlled substances be recorded and accounted for in a master record, whether on the Expired Narcotics Log Sheet or another record book. While GMHA was in agreement with OPA's recommendations, the Administrator provided further explanations in response to 11 findings within the report.

Doris Flores Brooks, CPA, CGFM
Public Auditor



Introduction

This report presents the results our audit of the Guam Memorial Hospital Authority's (GMHA) inventory control over controlled substances. The scope of our audit is from October 1, 2011 to September 30, 2014 [fiscal years (FY) 2012 to 2014].

The audit objectives were to determine whether:

1. GMHA established adequate controls to account for and safeguard controlled substances inventory;
2. GMHA complied with federal and local laws, regulations, and policies pertaining to controlled substances; and
3. Controlled substances were accurately and properly billed in accordance with GMHA prescribed rate/fee schedule.

The objectives, scope, methodology, and prior audit coverage are detailed in Appendices 2 and 3.

Background

From FY 2012 to FY 2014, GMHA spent approximately \$9.6 million (M) in pharmaceutical drugs. GMHA was unable to provide the audit team with the breakdown of how much was for controlled substances versus non-controlled substances due to limited capability of the software system.

GMHA, a component unit of the Government of Guam (GovGuam), was created in July 1977 under Public Law No. 14-29 as an autonomous agency. GMHA owns and operates the Guam Memorial Hospital. GMHA also maintains the Skilled Nursing Unit located in Barrigada Heights, Guam, which provides long-term rehabilitation care. The facility has approximately 40 beds and a maximum of 30 residents.

GMHA derives a significant portion of its revenues from third-party payers, including Medicare, GovGuam's Medically Indigent Program, Medicaid, and commercial insurance organizations. GMHA is open 24 hours, 365 days per year, and is one of the healthcare components of GovGuam in which medical services cannot be withheld due to non-payment by the patient.

GMHA has been operating at a loss over the past five years. The average annual operating loss was approximately \$27M from FY 2010 to FY 2014. The independent audit of the FY 2013 and FY 2014 Financial Statements by Deloitte and Touche, LLP emphasized that "GMHA has incurred recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern."

As part of GMHA's health care services, it maintains a Pharmacy that dispenses and administers controlled substances and other pharmaceutical drugs. The GMHA's Pharmacy Department is responsible for ensuring compliance with the regulatory requirements of the U.S. Drug

Enforcement Administration (DEA) and Department of Public Health and Social Services (DPHSS) Controlled Substances Division.

Controlled substances are drugs that are controlled by the DEA in Schedules I to V. These include narcotics, stimulants, depressants, and hallucinogens. Controlled substances are regulated under the Controlled Substance Act [Chapter 21 of the Code of Federal Regulations (CFR)]. Local laws governing controlled substances are codified in Title 9 of the Guam Code Annotated (GCA) Chapter 67, known as the Guam Uniform Controlled Substance Act. DPHSS was given the authority to administer this act locally.

The DEA is the primary federal agency responsible for enforcing the Controlled Substance Act. It developed regulatory requirements governing the prescribing, administering, and dispensing of controlled substances, which are outlined in the Pharmacist Manual. The DEA has strict requirements for record keeping and documentation, dispensing, special handling, and inventory controls over controlled substances. See Appendix 5 for excerpts from the Pharmacist Manual.

Controlled substances are divided among five “schedules” depending upon their medical use and potential for abuse that could lead to physical or psychological dependency. See Appendix 4 for the details of the controlled substance schedules.

The Pharmacy inventory is defined as the quantity of medications, goods, or materials on hand that is purchased and brought into the Pharmacy’s storage spaces and controlled until it is dispensed to a patient or a user Department.

GMHA has formulated its internal policies and procedures pertaining to controlled substances. Excerpts may be found in Appendix 5.

Results of Audit

Our audit found that the Guam Memorial Hospital Authority (GMHA):

- Did not establish adequate controls to account for and safeguard controlled substance inventory. Our findings included the following:
 - An estimated lost revenue of \$10,000 was due to usage discrepancies of 2,906 units versus billings for 12 sampled controlled substances. Of the 2,906 discrepancies, CS5 had the largest discrepancy at 609 units and six other drugs had discrepancies ranging from 244 to 607 units.
 - GMHA could not ascertain how much of the approximately \$9.6M spent on pharmaceutical drugs between fiscal year (FY) 2012 and FY 2014 were for controlled substances versus non-controlled substances.
 - Lack of independent verification and proper separation of duties.
 - Expired and destroyed controlled substances did not always reconcile.
 - \$3,164 of loaned and borrowed controlled substances were outstanding.
 - The Anesthesiologists' stock was excluded from the inventory list.
 - Non-systematic filing system of documents for controlled substance dispensation.
- Generally complied with federal and local requirements and controls over controlled substances, but certain requirements and controls were not adhered to. Specifically:
 - 12 physicians did not have the required Controlled Substance Registrations for GMHA with the DPHSS.
 - The pharmacy keys were accessible to all persons in the Pharmacy instead of being controlled by the GMHA Pharmacy Director or his/her designee.
 - Certain Pharmacy inventory was not sufficiently maintained.
- Did not accurately and properly bill for controlled substances in accordance with GMHA's prescribed fee schedule. There were \$2,147 in understated billings due to insufficient fee schedule updates for three controlled substances.

Our audit identified a total financial impact of approximately \$15,000, due to lost revenue from understated billings, fee schedule updates, and unpaid loaned controlled substances.

Inadequate Controls to Account For and Safeguard Controlled Substances

During our audit, we found several instances in which GMHA's controls could be improved to account for, safeguard, and prevent the loss, abuse, or misuse of controlled substances.

Lost Revenue Due to Usage Discrepancies

The pharmacists manually record the controlled substances processes into the Controlled Substances Inventory Record (CSIR) binders. The processes to be recorded include the receipts of controlled substances; returns from the different hospital departments or Nursing Units due to low usage or nearing expiration; returns from external third-party borrowings; issuances to different Nursing Units for patient dispensation, anesthesiologists, or loans to external third parties; and the removal of expired drugs from stock. The CSIR also reflects the end-of-day balances of controlled substances.

In our analysis of the data recorded in the CSIR for FY 2014, we found a net understatement of 2,906 units of controlled substances between the CSIR and what was billed.

The DEA Pharmacist Manual Section I (Preface) states that all legitimate handlers of controlled substances must maintain a strict accounting of all controlled substances transactions.

We selected 12 controlled substances and compared the controlled substance issuance data within the manually updated CSIR binders against the drug quantities billed to the patients provided by the Billing system-generated Fees Usage Report from GMHA’s Optimum System. The Fees Usage Report reflected the total quantities and amounts billed per controlled substance based on the applicable charge code rate.

Based on the initial data provided, we found a discrepancy of 12,413 units or \$76,000 compared with the CSIR. However, it was later discovered that the initial Fee Usage Report was incorrect, with GMHA citing that the quantities in the initial data they provided were the number of patients instead of the number of controlled substance units billed. A new data set was provided after the exit meeting held in December 2015, which the audit team spent additional time to validate and analyze.

Based on the second data set provided, we found that the total controlled substance quantities reported in the CSIR, as issued out to the different GMHA Nursing Units and anesthesiologists for patient dispensation, was over by 3,014 units for ten substances and short by 108 units for two substances when compared to the Fees Usage Report. The discrepancies resulted in a net understated billing of 2,906 units and a net lost revenue of approximately \$10,000. For the 12 selected controlled substances, five controlled substances had variances between 14 and 94 units, and seven controlled substances had variances of 244 units to 609 units. Per the CSIR, the top three heavily used controlled substances were CS1 with 17,320 tablets and a discrepancy of -334 units, CS4 with 8,142 vials and a discrepancy of -607 units, and CS2 with 7,263 vials and a discrepancy of -428 units.

See Table 1 below for details of discrepancies.

Table 1: Summary of Drug Usage Discrepancies

Name	Price Per Unit	GMHA Optimum System		CSIR		Discrepancy	
		Qty	Amount	Qty	Amount	Qty	Amount
CS5	\$ 3.61	2,679	\$ 9,671.19	3,288	\$ 11,869.68	-609	\$ (2,198.49)
CS4	\$ 4.53	7,535	\$ 34,133.55	8,142	\$ 36,883.26	-607	\$ (2,749.71)
CS2	\$ 4.53	6,835	\$ 30,962.55	7,263	\$ 32,901.39	-428	\$ (1,938.84)
CS7	\$ 4.53	702	\$ 3,180.06	1,097	\$ 4,969.41	-395	\$ (1,789.35)
CS1	\$ 0.91	16,986	\$ 15,457.26	17,320	\$ 15,761.20	-334	\$ (303.94)
CS8	\$ 5.00	546	\$ 2,730.00	799	\$ 3,995.00	-253	\$ (1,265.00)
CS6	\$ 9.04	1,871	\$ 16,913.84	2,115	\$ 19,119.60	-244	\$ (2,205.76)
CS9	\$ 3.14	50	\$ 157.00	113	\$ 354.82	-63	\$ (197.82)
CS12	\$ 0.91	122	\$ 111.02	161	\$ 146.51	-39	\$ (35.49)

Name	Price Per Unit	GMHA Optimum System		CSIR		Discrepancy	
		Qty	Amount	Qty	Amount	Qty	Amount
CS10	\$ 5.08	149	\$ 756.92	191	\$ 970.28	-42	\$ (213.36)
CS11	\$ 0.91	29	\$ 26.39	15	\$ 13.65	14	\$ 12.74
CS3	\$ 30.95	3,090	\$ 95,604.55	2,996	\$ 92,726.20	94	\$ 2,878.35
	TOTAL	40,594	\$ 209,704.33	43,500¹	\$ 219,711.00	-2,906	\$ (10,006.67)

The Chief Hospital Pharmacist could not explain the reason for the variances between the Pharmacy's CSIR and GMHA's billing system. He indicated that the Billing System is not linked to either the CSIR or pharmacy encoded charges within the Pharmacy System, which he believes are more accurate. He noted that the new Optimum System, which was launched in August 2015, will not solve the problem. He believes it will cost GMHA several million dollars to implement another system to fix the issues.

Discrepancies in End of Day Balances

GMHA Policy # 602 (Pharmacy Inventory Control) states that the pharmacy inventory shall be maintained accurately by the Pharmacy Department. In addition, the Pharmacy Department shall develop a monitoring and recording system, whether manual or computerized that will ensure that all movement of inventory in the Pharmacy Department is recorded timely and correctly.

During our review of the end-of-day balances of controlled substances within the CSIR for the 12 selected controlled substances, we observed the following:

- Corrections to several mathematical errors were made between several days to over four months later;
- The corrections were usually made when physical counts were conducted, which are not set regularly for all controlled substances;
- Of the 12 selected controlled substances, five substances (CS1, CS3, CS4, CS5, and CS7) had mathematical errors, which either overstated or understated the end-of-day balances of the controlled substances recorded within the CSIR;
- There were six discrepancies for CS4 between April and July 2014, which were discovered and corrected in August 2014; and
- Numerical corrections were manually entered into the CSIR (binder) without an initial by the person making the corrections and supervisory approval.

See Table 2 for details.

¹ The amounts do not take into account any outstanding stock as of September 30, 2014 as these were not examined. The outstanding anesthesiologist stock was subsequently identified as of June 30, 2015. See discussions under "Anesthesiologists' Stock Excluded from Inventory List."

Table 2: Errors on Controlled Substance Inventory Logbook

Name	Date of Discrepancy	EOD Balance per CSIR	OPA Calculated EOD Balance	Discrepancy Amount (CSIR Under)	Date Corrected/ Physical Inventory	Remarks
CS6	4/26/2014	2,624	3,624	(1,000)	05/16/14	Understatement of EOD balance. Corrected after almost a month during physical inventory.
CS7	5/26/2014	1,110	1,100	10	08/16/14	Overstatement of EOD balance. Corrected after almost three months, during physical inventory.
CS5	9/2/2014	1,580	1,580	0	09/02/14	EOD balance of 1580, was changed to 1581 without explanation during physical inventory on 09/02/14
CS3	4/27/2014	1,222	1,522	(300)	08/17/14	Understatement of EOD balance. Corrected after almost 4 months, during physical inventory.
CS4	4/11/2014	5,245	5,235	10	04/24/14	Overstatement of EOD balance. Corrected within the month during physical inventory.
CS4	6/12/2014	3,435	3,535	(100)	08/10/14	Understatement of EOD balance. Corrected after two months.
CS4	6/25/2014	3,040	3,145	(105)	08/11/14	Understatement EOD balance. Corrected after two months.
CS4	6/30/2014	2,830	2,925	(95)	08/10/14	Understatement of EOD balance. Corrected after almost two months.
CS4	7/8/2014	2,505	2,500	5	08/11/14	Overstatement of EOD balance. Corrected after over one month.
CS4	7/31/2014	1,780	1,675	105	08/10/14	Overstatement of EOD balance. Corrected several days later.
CS1	8/5/2014	1,410	1,417	(7)	08/17/14	Understatement of EOD balance. Corrected after several days.

Without an automated process for recording the movement of controlled substances inventory, it is difficult to detect mathematical errors. We also observed that the manual recordings could be easily altered. Making changes, corrections, or alterations of inventory should not be allowed without supervisory approval. We suggest automating the recording of controlled substance inventory for better control and to prevent possible manipulation of data, as well as ensuring that inventory alternations are only made with supervisory approval.

Inadequate Accounting for Pharmaceutical Drugs

Between FY 2012 and FY 2014, GMHA spent a total of approximately \$9.6M in pharmaceutical drugs based on the Materials Management System Purchase Order report provided by the Pharmacy Buyer II. However, the amounts could not be ascertained by GMHA. Based on the data provided, GMHA could not readily identify how much of the \$9.6M was for controlled substances versus non-controlled substance due to the limited capability of the system software. The Chief Hospital Pharmacist confirmed that GMHA's system could not easily extract data pertaining to only the controlled substances. See Table 3 for pharmaceutical purchases per fiscal year.

Table 3: Pharmaceutical Drug Purchases

Fiscal Year	Total Purchases
2014	\$ 3,376,884
2013	2,885,696
2012	3,311,846
Total	\$ 9,574,426

Surprise Count Discrepancy for CS3

The audit team judgmentally selected five controlled substances and visited GMHA Pharmacy on June 12, 2015. We observed the Chief Hospital Pharmacist conduct a physical count of the selected drugs and identified a discrepancy of 2,245 units of CS3, while the other four selected drugs matched with the CSIR.

During the surprise physical count, the audit team observed that the controlled substances were crammed inside locked cabinets in the Narcotics Storage Room.

The Chief Hospital Pharmacist explained that the camera inside the Narcotics Storage Room was being repaired at the time of our visit, thus the controlled substances were all stuffed inside the cabinets in order to maintain compliance with the DEA, which required that the drugs be kept in cabinets.

On June 16, 2015, during a second unannounced physical count of an additional five judgmentally selected controlled substances and a recount of CS3, we noted that all six drugs were accounted for. We also noted that the controlled substances were neatly organized in the locked cabinets within the Narcotics Storage Room compared to our initial walk through on June 3, 2015. We requested to take pictures of the condition of the Narcotics Storage Room, but the Chief Hospital Pharmacist denied our request citing security reasons.

During our walkthrough at two nursing units (Emergency Room and Intensive Care Unit), we requested to count three and two judgmentally selected controlled substances, respectively, all of which did not have any discrepancies compared to their Narcotic Count Worksheets.

During our walkthrough at the Skilled Nursing Unit, we also requested to count ten judgmentally selected controlled substances, all of which did not have any discrepancies compared to the Narcotic Count Worksheet.

Lack of Independent Verification and Proper Separation of Duties

Separation of duties calls for assigning different employees the responsibility for authorizing transactions, recording transactions, and maintaining custody of assets. Separation of duties helps to limit the possibility that one person could perpetrate and conceal errors or irregularities in the normal course of performing his or her duties. For controlled substances, the duties of ordering, storing, recording of receipts and issuances, and inventorying through regular physical counts should be separated.

At the Pharmacy, the Chief Hospital Pharmacist initiates the orders for controlled substances and signs DEA Form 222 for ordering Schedule II controlled substances. The Pharmacy Buyer II faxes

the orders to the suppliers. Typically, and upon delivery to GMHA, all orders for the Pharmacy Department are forwarded directly to the pharmacy warehouse, where a pharmacy technician opens the box(es), verifies the contents received with the invoices and other supporting documents, records the delivery in the Material Management System, and stores them in the warehouse.

When a pharmacy technician determines that the items received are controlled substances, they are forwarded to the Narcotics Storage Room within the Pharmacy to be received by the Chief Hospital Pharmacist or the pharmacist on duty. The receiving pharmacist then manually logs the controlled substances received in the Controlled Substance Inventory Record (binders) and stores the substances in the Narcotics Storage Room. The same day that controlled substances are delivered, the same pharmacist on duty is also responsible for issuing controlled substances to the various departments within GMHA.

Therefore, on the delivery days for controlled substances, there is a potential lack of separation of duties wherein the pharmacist on duty handles all responsibilities from receipt, storage, recording, and issuance of controlled substances. The pharmacists also performs the monthly physical inventories of the controlled substance assigned to them.

When a pharmacist receives the delivered controlled substances, there should be a second person within the Pharmacy Department to verify and witness the storing of these controlled substances within the Narcotics Storage Room. Likewise, the logging in of the received controlled substances within the inventory binders should be performed by a second person.

When a pharmacist enters the Narcotics Storage Room to retrieve the controlled substances on order, that same pharmacist should not also be responsible for logging out those controlled substances. In effect, this will ensure that there is an independent verification that the controlled substances retrieved matches the physician order and the quantity recorded.

The Chief Hospital Pharmacist indicated that GMHA has mitigating controls such as the triplicate DEA Form 222 for ordering Schedule II controlled substances, which are reviewed by the DEA. In addition, The Chief Hospital Pharmacist is the only person authorized to order Schedule II controlled substances. However, we are concerned that there is a potential that the Chief Hospital Pharmacist is able to perform all the controlled substance processes that should be separated and there is no independent review of this Pharmacist's work.

According to the Chief Hospital Pharmacist, the Pharmacy Department with 10 full-time pharmacists is short compared to the national level. He explained that GMHA is servicing approximately 200 bed patients, plus the 42 beds at the Skilled Nursing Unit. Per the American Society of Health-System Pharmacists' 2013 Pharmacy Staffing Survey Results, there should be 11.7 full-time pharmacists per 100 occupied beds.²

The absence of independent verification and proper separation of duties over the handling and inventory of controlled substances render the controls weak and could potentially result in loss, abuse, or misuse.

² <http://www.ashp.org/DocLibrary/MemberCenter/SPPM/2013-ASHP-Staffing-Survey.pdf>.

Expired and Destroyed Controlled Substances Could Be Better Accounted For

GMHA Policy # 909 states that all expired, deteriorated, or non-reusable controlled substances shall be listed and all information about each drug is completed.

DEA Form 41 contains an inventory of controlled substances that are surrendered to DEA for destruction. GMHA also maintains an Expired Narcotics Log Sheet (ENLS), which lists the controlled substances that are returned from the various nursing units and slated to be destroyed and witnessed by the DEA. Any expired controlled substances on stock in the Narcotics Storage Room are deducted directly from the CSIR. To obtain the true count of expired controlled substances to be destroyed, one must consider the quantities of each controlled substance listed within the ENLS and those deducted from the CSIR.

On February 14, 2014, 69 units of CS5 were removed from the stock, since the controlled substance expired on February 1, 2014, per the CSIR. In addition, eight units were recorded on the ENLS between May and December 2014. However, only three units were recorded on DEA Form 41. There was no documentation in any of the files on what happened to the remaining 74 units.

According to the Chief Hospital Pharmacist, they do not record all expired controlled substances in the ENLS, since this is not a DEA required form. GMHA neither maintained a master record of all expired controlled substances slated for destruction nor compared this data against the controlled substances counted and recorded on DEA Form 41 prior to destruction.

For consistency, better control, and although the ENLS is not a DEA required form, we recommend that all expired controlled substances be recorded and accounted for in a master record, whether on the ENLS or another record book.

During our surprise physical count, we observed that the expired controlled substances were left on an open tray located inside the Narcotics Storage Room instead of in a locked safe or double-locked cabinet. The Chief Pharmacist explained during the exit meeting in December 2015 that the mitigating control was that the expired controlled substances were waiting to be processed for destruction, but were still located within the Narcotics Storage Room instead of the main pharmacy area and was not easily accessible. For better controls, the expired controlled substances should be stored in a secure holding area while awaiting to be processed for destruction.

Loaned and Borrowed Controlled Substances Outstanding

Tile 9 GCA §67.307 (Order Forms) and DEA Pharmacist's Manual Section IV (Transfer or Disposal of Controlled Substances) require the use of DEA Form 222 for GMHA to distribute controlled substances to another pharmacy. In addition, GMHA Policy # 605 (Loan and Borrow of Pharmaceuticals) allows the Pharmacy Director to authorize the loaning and borrowing of drugs to other pharmacies. A Loan and Borrow Form is required to be completed, and the receiving Pharmacy is responsible for records maintenance. The Loan and Borrow Form shall carry consecutive numbers for tracking purposes. Per GMHA Policy # 605, loaned or borrowed drugs shall be returned in a timely manner.

Our review of the CSIR indicated that there were several instances in which certain controlled substances were loaned to private pharmacies and clinics. However, GMHA has not provided

evidence of monitoring the timely return of loaned controlled substances or the maintenance of a complete file of the Loan and Borrow Forms within its records. In addition, the Loan and Borrow Forms were not pre-numbered for tracking purposes.

Based on FY 2014 CSIR data, GMHA loaned 530 units of seven controlled substances to five pharmacies and hospitals. Of the quantities loaned, 180 were returned, while 350 units with a value of \$3,164 remained uncollected as of the report date.

During FY 2014, GMHA borrowed 180 units of two controlled substances (CS2 and CS8) from another pharmacy. The CSIR had no record whether GMHA already returned the 180 units.

The 75 units of CS5 borrowed by an outside pharmacy in April and May 2014 had no DEA Form 222 on file to be executed by the third party. According to the Chief Hospital Pharmacist, GMHA copies of the DEA form were given back to the pharmacy when the drugs were returned in August 2014.

The 1,615 units of Schedule III to V controlled substances that were either returned, paid, or borrowed by GMHA or other pharmacies between November 2013 and August 2014, did not have a Loan and Borrow Form on file. This 1,615 is inclusive of controlled substances loaned in prior periods. According to the Pharmacy Buyer II, the forms were discarded once the controlled substances were paid, since there was no DEA requirement to maintain the forms.

Anesthesiologists' Stock Excluded from Inventory List

During our review of the balances of controlled substances per CSIR as of June 3, 2015, we noted two of the twelve sampled controlled substances totaling 168 units that were unused in the anesthesiologists' stock binder maintained in the Pharmacy. These controlled substances were already manually deducted from the inventory balance and excluded from the inventory report. There were 105 unused CS2 units and 63 unused CS4 units in the anesthesiologist stock.

Controlled substances dispensed by the anesthesiologists are recorded in the stock binder and documented in the Controlled Substances Dispensing, Administration and Wastage Record for Anesthesiologists.

The quantity of unused controlled substances in the anesthesiologist stock should be included in the inventory report even though these are subjected to the periodic physical count by the Pharmacists for effective monitoring.

Non-Systematic Filing for Controlled Substance Dispensation

The Controlled Drug Administration Record documents the controlled substances issued by the Pharmacy Department to the Nursing Units. These records contain the controlled substances being issued and returned, the dates of issuance and return, the issuing and receiving persons, the names and signatures of physicians dispensing the controlled substances, and the record of waste and spoilage. While the controlled substances records were placed in boxes, which were labeled and stacked neatly, it took the audit team an inordinate amount of time to locate the records selected for review as they are not systematically filed. For example, records are not filed sequentially by number, date of issuance, or date of return. The same is true for filing the Controlled substance

Dispensing, Administration and Wastage Record of Anesthesiologist, which documents controlled substances dispensed by the anesthesiologists.

According to the Chief Hospital Pharmacist, a systematic filing system cannot be achieved due to lack of personnel.

We recommend the GMHA Administrator designate officials to address the Pharmacy and Billing system linkage issues required to properly account for all controlled substances issued for patient dispensation and ensure accuracy of patient billings.

Noncompliance with Certain Laws, Requirements, and Internal Policies

GMHA generally complied with DEA requirements, such as registration with the local DEA office, use of the DEA Form 222 when ordering Schedule II controlled substances, use of DEA form 41 for destruction of expired controlled substances, physical inventory, and certain required security and storage features. However, the Controlled Substance Registration requirement and internal policies were not adhered to, resulting in several areas for improvement. For example:

- Twelve physicians did not have Controlled Substance Registrations for GMHA with DPHSS;
- The pharmacy keys were accessible to all persons in the Pharmacy instead of controlled by the GMHA Pharmacy Director or his/her designee; and
- Certain Pharmacy inventory was not sufficiently maintained.

Twelve Physicians without Controlled Substance Registrations for GMHA

Title 21 CFR Part 1301 (Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances) § 1301.12 (Separate registrations for separate locations) states that a separate registration is required for each principal place of business or professional practice where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.

Title 9 GCA §§ 67.302(a), 67.302(e), and 67.303(a) state the following:

- A person who dispenses a controlled substance within Guam or who proposes to dispense a controlled substance within Guam, shall obtain annually a registration issued by DPHSS;
- A practitioner must be registered with DPHSS before dispensing a controlled substance included in Schedules I³ to V; and
- A separate registration is required for each principal place of business or professional practice where the applicant manufactures, distributes, and dispenses controlled substances.

GMHA Policy # 902 (Registration for Controlled Substances) requires physicians to register with the DEA and DPHSS in order to see patients and dispense medications at the hospital.

Inquiries with DPHSS confirmed that 12 of the 25 randomly selected GMHA physicians who dispensed controlled substances at GMHA in FY 2014 did not have the required Controlled

³ Schedule I controlled substances were not included as part of our audit.

Substances Registrations for GMHA with DPHSS. They only had the registrations for their private practices or for their clinics. See Table 4 below for details.

Table 4: Physicians Without DPHSS Registrations for GMHA

Name	Title	Date of Issuance	DPHSS Remarks
Physician 1	Anesthesiologist	8/8/2014	CSR for GMH Expired 06/30/12
Physician 2	Not a GMHA Staff	9/10/2014	No CSR for GMHA
Physician 3	Not a GMHA Staff	9/9/2014	No CSR for GMHA
Physician 4	Not a GMHA Staff	8/24/2014 9/9/2014	No CSR for GMHA
Physician 5	Not a GMHA Staff	9/9/2014	No CSR for GMHA
Physician 6	Hospitalist - General Surgery	9/9/2014	No CSR for GMHA
Physician 7	Not a GMHA Staff	9/4/2014	No CSR for GMHA
Physician 8	Physician - Pediatrics	8/19/2014	No CSR for GMHA
Physician 9	Hospitalist - Internal Medicine	8/19/2014 8/24/2014	No CSR for GMHA
Physician 10	Not a GMHA Staff	9/14/2014	No CSR for GMHA
Physician 11	Not a GMHA Staff	9/14/2014	No CSR for GMHA
Physician 12	Physician – Radiology	8/19/14	No CSR for GMHA

During the exit meeting in December 2015, the Chief Hospital Pharmacist indicated that the physicians are working with DPHSS on the matter.

Pharmacy Keys Not Controlled

GMHA Policy # 306 (Pharmacy Key Control) requires the Pharmacy Director to control the keys for every locked room, controlled substance storage, cabinets, closets, and refrigerators that are installed inside of the pharmacy.

The Chief Hospital Pharmacist explained that only pharmacists have access to the Narcotics Storage Room, in which the Pharmacist must have an electronic badge, as well as the keys to the Narcotics Storage Room.

During the initial walkthrough, the audit team observed that the electronic badge access was not working and the keys for locked areas within the Pharmacy Department are hung on a pillar inside the Pharmacy. Therefore, all persons inside the Pharmacy Department potentially have access to the following locked areas: the Narcotics Storage Room, controlled substance storage cabinets, closets, and refrigerators.

In contrast, the charge nurse at the Skilled Nursing Unit has custody of the keys for the locked room and cabinet where the controlled substances are stored. The controlled substances are counted every shift by the incoming and outgoing nurses and will not be cleared until the balance of the drugs in the Narcotic Count Worksheet match with the physical count.

The Chief Pharmacist indicated that the electronic badge access was inoperable during our initial walkthrough, but it was undergoing repairs. After our exit meeting in December 2015, the audit team observed that the electronic badge access was operating as intended.

For better control and in compliance with the policy, access to the Narcotics Storage Room and cabinet should be restricted to the designated person only. In addition, in the event that the electronic badge access to the Narcotics Storage Room become inoperable, it is important that the keys be maintained by assigned persons by shift or stored in an area that is not potentially accessible to all persons who enter the Pharmacy Department.

Certain Pharmacy Inventory Control Not Sufficiently Maintained

GMHA Policy # 602 (Pharmacy Inventory Control) states that pharmacy inventory shall be maintained accurately by the Pharmacy Department. The policy also states that perpetual inventory records should at all times reflect the total inventory quantity on-hand. In addition, the policy requires Monthly Drug Usage reports to be generated by the Computer Center and delivered to the Director of Pharmacy, who shall review the report monthly and choose a minimum of three drug items to be spot checked for accuracy of reconciliation to the physical inventory.

The Chief Hospital Pharmacist stated that GMHA maintains a Controlled Substance Inventory Record (binder) that reflects the perpetual inventory per controlled substance. However, the Pharmacy does not maintain an automated perpetual inventory record that reflects the total inventory quantity of all controlled substances on hand. Instead, the audit team found that the Pharmacy maintains a manual inventory system by which the activities associated with each controlled substance (additions, transfers out/in, expirations, etc.) are updated in the binders that are located outside the Narcotics Storage Room.

We found that the Monthly Drug Usage Report was not generated for review by the Chief Hospital Pharmacist. Although, pharmacists are assigned certain controlled substances to inventory, there did not appear to be set frequencies for conducting inventories. For example, the inventory of CS4 was performed four months apart, whereas CS1 was inventoried monthly.

Independent physical count is performed once a year by the external auditors, in which the external auditors observe the count done by the agency representative. The external auditors identified discrepancies between the general ledger balance and physical count balance in pharmacy inventory (inclusive of controlled substances) of \$116,540 in FY 2012, \$150,266 in FY 2013, and \$29,031 in FY 2014.

We recommend the GMHA Administrator to establish and implement internal controls to ensure compliance with various federal and local laws, requirements, and internal policies. See Appendix 6 for some suggestions to be considered. Where there is a conflict between, GMHA should revisit how it could align its internal policies with existing federal and local laws.

Understated Billing Due to Insufficient Fee Schedule Update

Our test of the 12 selected controlled substances revealed that the fee rates for three of the selected controlled substances (CS10, CS7, and CS12) were below the cost to procure these drugs by \$0.05 to \$9.88. For example, CS10 was purchased at a unit cost of \$14.96 (inclusive of estimated freight), but customers were billed \$5.08 per unit, or a variance of \$9.88 per unit. Based on the FY 2014 usage of the three drugs, the total amount under-billed was \$2,147. See Table 5 below for details.

Table 5: Summary of Insufficient Fee Rate

Name	GMH A Fee Rate	Unit price per Latest Invoice	Estimated Pro-Rated Freight/Unit	Total Cost per Unit	Variance	FY 2014 Usage	Total Variance
CS10	\$ 5.08	12.96	\$ 2.00	\$ 14.96	\$ (9.88)	191	\$ (1,866.32)
CS7	\$ 4.53	3.93	\$ 0.83	\$ 4.76	\$ (0.23)	1097	\$ (252.31)
CS12	\$ 0.91	0.06	\$ 0.90	\$ 0.96	\$ (0.05)	161	\$ (8.05)
Total							\$ (2,146.68)

In addition, according to the GMHA Charge Master, rate increases occurred in 2010 and 2015. Based on our analysis, the rate increases were not adequate to cover the cost of these controlled substances. GMHA's fee rate is formulated based on original cost plus mark up of 2.756% for pharmaceuticals. These fee rates are only increased when GMHA's Board decides to increase its fees at a maximum of 5% without public hearing. The last two increases of 5% were effective April 2010 (for selected items only) and April 2015 (for all items).

During the exit meeting in December 2015, the GMHA Administrator and CFO indicated that GMHA has to undergo a lengthy and bureaucratic process in order to get an updated fee schedule approved, which includes going to the Legislature and setting up a hearing. GMHA's statutorily allowed 5% increase may not necessarily cover the costs of certain pharmaceuticals, including controlled substances.

GMHA should regularly review and update its fee schedule to ensure that the amounts charged are not insufficient to cover the cost of the pharmaceuticals. The Administrator and CFO both requested that GMHA be allowed the flexibility to at least recover the hospital's costs.

Conclusion and Recommendations

Our audit found that GMHA generally complied with federal and local requirements for registrations and controls, but certain requirements and controls are needed to deter possible loss, waste, and abuse of controlled substances. In addition, there was a lack of independent verification and proper separation of pharmacist duties pertaining to controlled substance processes, and controlled substances were not accurately and properly accounted for. We also found the following:

- GMHA was unable to identify how much of the \$9.6M spent on pharmaceutical drugs were for controlled substances versus non-controlled substances due to GMHA's system limitations;
- Twelve physicians did not have Controlled Substance Registrations for GMHA with the DPHSS;
- Weak controls over controlled substances pertaining to borrowings and loans, expired and destroyed controlled substances, and manual recording and correction of errors on inventory data; and
- System linkage deficiencies between the Pharmacy and Billing systems resulted in approximately \$10,000 in estimated lost revenue for 2,906 units that were unaccounted for in the billing system.

Our testing also noted additional data discrepancies, such as the insufficient fee schedule updates resulted in an under-billing of \$2,147 for three controlled substances and 350 unpaid loaned drugs with a value of \$3,164.

Our audit identified a total financial impact of approximately \$15,000.

The lack of separated duties could interfere with the timely detection of intentional or unintentional errors. In addition, inadequate security and internal controls over controlled substances make them vulnerable to theft and mismanagement.

To preclude further revenue losses due to weak internal control, inventory discrepancies, and inaccurate billings, as well as prevent possible loss, abuse, and misuse of controlled substances, we recommend the GMHA Administrator:

1. Designate officials to address the Pharmacy and Billing system linkage issues required to properly account for all controlled substances issued for patient dispensation and ensure accuracy of patient billings.
2. Establish and implement internal controls to ensure compliance with various federal and local laws, requirements, and internal policies. See Appendix 6 for some suggestions to be considered.
3. Ensure that all expired substances are recorded and accounted for in a master record, whether on the Expired Narcotics Log Sheet or another record book.

Management Response and OPA Reply

We transmitted a draft report to the GMHA Administrator and CFO in November 2015 for their official response. We met with the GMHA management in December 2015, wherein the Administrator was in agreement with OPA's three recommendations and provided further detailed responses to 11 areas. See Appendix 7 for GMHA's official response. Our reply to the comments are summarized below.

1. ***Pharmacy Keys Not Controlled.*** The Administrator stated that they have a six-layered security system. We suggest that in the event that the electronic badge access to the Narcotics Storage Room becomes inoperable, it is important that the keys be maintained by assigned persons by shift or stored in an area that is not potentially accessible to all persons who enter the Pharmacy. Therefore, the finding remains.
2. ***Certain Pharmacy Inventory Control Not Sufficiently Monitored.*** The Administrator stated that the independent auditor "certifies" GMHA's controlled substance inventory annually. Our review of the annual financial audits identified discrepancies between the general ledger balance and physical count balance in the pharmacy inventory (inclusive of controlled substances) of \$116,540 in FY 2012, \$150,226 in FY 2013, and \$29,031 in FY 2014. Therefore, the finding remains.
3. ***Lack of Independent Verification and Proper Separation of Duties.*** The Administrator provided examples of separation of duties already in place within the Pharmacy. However, the audit team is concerned that when a pharmacist enters the Narcotics Storage Room to retrieve the controlled substances on order, that same pharmacist should not also be responsible for logging out those controlled substances. In addition, there is a potential that the Chief Hospital Pharmacist is able to perform all the controlled substance processes that should be separated and there is no independent review of this Pharmacist's work. Therefore, the finding remains.
4. ***Lost Revenue Due to Usage Discrepancies.*** The Administrator acknowledged that efforts must be made to capture 100% of all controlled substance charges. While the initial discrepancy identified was reduced from \$76,000 to \$10,000 based on the updated data on controlled substances, this finding remains.
5. ***Discrepancies in End of Day Balances.*** The Administrator responded that it is standard practice to allow the pharmacist on duty to reconcile any controlled substance discrepancies and to adjust inventories upon discovery. Without an automated process for recording the movement of controlled substances inventory and requiring supervisory approvals prior to making changes, it is difficult to detect mathematical errors and the manual recordings could easily be altered. Therefore, this finding remains.
6. ***\$2K Understated Billing Due to Insufficient Fee Schedule Update.*** The Administrator stated that GMHA is required to go through a five-step process to update medication prices and has requested that it be allowed the liberty to update medication prices due to market fluctuations. We agree that GMHA should be allowed the flexibility to update its fee schedule to at least cover costs. Therefore, the finding remains.

7. **2,245 Initial Surprise Count Discrepancy for CS3 Injection.** While the Administrator expanded on the explanation already included in the report, this finding remains.
8. **Unreconciled Differences for Expired and Destroyed Controlled Substances.** OPA disagrees with GMHA's response that the report should be updated to reflect 158 units of CS5 on the DEA Form 41, where our report stated only three vials of injectable CS5 100 MCG/2ML were on DEA Form 41. GMHA arrived at the 158 units of CS5 by adding up the three vials of injectable CS5 100 MCG/2ML and the 155 vials of 50 MCG/ML. Therefore, the finding remains.
9. **Loaned and Borrowed Drugs Outstanding.** The Administrator stated that loaned medications are fully monitored and that there are instances where GMHA will not accept a medication for return based on the current expiration dates and inventory on hand. As stated in our report, our review of the CSIR indicated that there were several instances in which certain controlled substances were loaned to private pharmacies and clinics and these remained outstanding as of September 2014. Therefore, the finding remains.
10. **Anesthesiologist's Stock Excluded from Inventory List.** This finding remains as GMHA accepted OPA's recommendation.
11. **Non-Systematic Filing System for Controlled Substance Dispensation.** The Administrator acknowledged that GMHA has 11 full time Pharmacists and that the allied health professionals are in short supply on Guam. In addition, GMHA Pharmacy is constantly recruiting via the student internship program. Therefore, this finding remains.

We also provided a draft report to the GMHA Oversight Chairperson of the 33rd Guam Legislature and met with him in December 2015.

The legislation creating the Office of Public Accountability requires agencies to prepare a corrective action plan to implement audit recommendations, to document the progress in implementing the recommendations, and to endeavor to have implementation completed no later than the beginning of the next fiscal year. Accordingly, we will be contacting the GMHA Administrator to provide target dates for the implementation of the recommendation.

We appreciate the cooperation and assistance of all GMHA departments during the course of this audit.

OFFICE OF PUBLIC ACCOUNTABILITY



Doris Flores Brooks, CPA, CGFM
Public Auditor

Appendix 1:
Classification of Monetary Impact

Finding No.	Finding Description	*Other Financial Impact
1	Inadequate Controls to Account For and Safeguard Controlled Substances Lost Revenue Due to Usage Discrepancies Discrepancies in End of Day Balances Inadequate Accounting for Pharmaceutical Drugs Surprise Count Discrepancy for CS3 Lack of Independent Verification and Proper Separation of Duties Expired and Destroyed Substances Could Be Better Accounted For Loaned and Borrowed Drugs Outstanding Anesthesiologists' Stock Excluded from Inventory List Non-Systematic Filing System for Controlled Substance Dispensation	\$ - \$ 10,007 \$ - \$ - \$ - \$ - \$ - \$ 3,164 \$ - \$ -
2	Noncompliance with Certain Laws, Requirements, and Internal Policies	\$ -
3	Understated Billing Due to Insufficient Fee Schedule Update	\$ 2,147
Totals		\$ 15,318

This report presents the results of our audit of the GMHA Inventory Control over Controlled Substances for the period October 1, 2011 to September 30, 2014 and other periods deemed necessary. The audit objectives were to:

- Determine whether GMHA established adequate controls to account for and safeguard controlled substances inventory;
- Determine whether GMHA complied with federal and local laws and regulations pertaining to controlled substances;
- Determine whether controlled substances were accurately and properly billed in accordance with GMHA prescribed rate/ fee schedule.

Scope Limitations:

- Test samples were limited to FY 2014 because GMHA's controlled substance inventory is still in a manual system. An inordinate amount of time and effort would have been required for the audit team to recreate the data and perform analyses.
- GMHA could not ascertain the accuracy of the amount of pharmaceuticals purchased between FY 2012 and FY 2014, due to GMHA's system limitations.
- The anesthesiologists logbook for controlled substance received from stock and dispensed to patients as of September 30, 2014 were not examined.

Audit Methodology

Our audit methodology included a review of federal and local laws, internal policies, and other information pertinent to inventory control over controlled substances. We also performed the following:

- Performed a walkthrough and interviewed with GMHA personnel involved with the different controlled substance processes.
- Performed physical counts of judgmentally selected controlled substances in the Pharmacy Narcotics storage room and selected Nursing Units.
- Performed an accounting of inventory end balances as of September 30, 2014 of 12 selected drugs and an analysis of the recorded data.
- Judgmentally selected and tested 12 controlled substances or 21% of the 57 controlled substances with balance per the CSIR as of June 3, 2015.
- Examined and verified the DEA registrations, DPHSS registrations, required DEA forms, purchase orders and invoices, and other documents relevant to the testing of controlled substance processes.
- To test billings, compared drug issuances (usage in quantities) to the different Nursing Units per CSIR and compared billings generated from the billing system.
- Reviewed controls and documentation on controlled substances borrowings and destruction of expired controlled substances.
- Interviewed GMHA's procedure of formulating fee charge for pharmaceuticals, reviewed existing Fee Rates, and compared with latest purchase cost per Invoices.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. Except for the scope limitations noted, we believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our objectives.

Financial Audit Reports –FY 2012 to FY 2014

Audit findings and comments pertained to lack of a perpetual inventory system due to system deficiencies, pharmaceutical inventory discrepancies, possible inventory misstatement, and potential for misappropriations.

- GMHA does not maintain perpetual pharmacy inventory records.
- Only year-end physical count is performed and the General Ledger is adjusted to reflect the results of the count without investigation of the differences. See Table 1 below for the annual inventory discrepancies.

Pharmaceutical, Drug, and Medicine Inventory Discrepancies –FY 2012-2014

Fiscal Year	General Ledger (GL) Balance	Balance per Count	Difference
2012	Unknown ⁴	\$ 569,268	\$ 116,540
2013	941,425	1,091,691	(150,226)
2014	3,569,225	3,540,193	29,031

- The pharmacy inventory may potentially be misstated.
- The potential for misappropriation of accounts exist such that it could not be prevented or detected in a timely manner.

GMHA replied to a pharmacy related finding for FY 2012, indicating that the software from GMHA’s current vendor, NTT Data, does not have the functionality pertaining to a perpetual inventory system. GMHA will not be able to comply with the recommendation pending acquisition of the new institutional software system that includes a pharmacy management component.

Eide Bailly- March 2010 GMHA Operational Assessment

Eide Bailly, LLP conducted an operational assessment of GMHA in March 2010 in order to identify opportunities for improving long-term financial performance. The report outlined the following key findings and opportunities involving pharmaceuticals and billings.

- **Pharmacy Department**

Key Findings

- If the pharmaceutical vendor is on hold, then the pharmacy staff have to go outside the normal channel and borrow from neighboring facilities at higher costs.
- Orders cancelled due to a vendor hold have to be re-ordered often at a higher price.
- Returns and expired pharmaceuticals are not actively being managed for refunds or credits.
- Updates to the charge master are not timely and charges are often missed.

⁴ The FY 2012 financial audit did not disclose the GL balance.

- No recent updates to the charge master for pharmaceuticals.

Opportunities

- Improve communication with the business office to build an understanding with pharmacy staff regarding the updating of the charge master for new pharmaceuticals.
 - Create a policy and procedure for the management of expired pharmaceuticals, and establish responsibility and accountability for managing the process in a timely manner.
 - Establish a procurement process for new pharmaceuticals that includes increased communication regarding charge master updates, pricing updates, and delivery status.
- **Hospital Information Management (HIM) Key Findings**
 - The HIM department is affected by a significant breakdown in processes in the Revenue Cycle.
 - Errors are occurring in the coding and billing processes, because the software system is not set up to automatically transfer HIM coding to claims.
 - Additional efforts are being expended to follow up with third-party payers due to the breakdown in the Revenue cycle.
 - **Other Hospital Departments - Nursing, Labor and Delivery, Operating Room and Recovery, Laboratory, Rehabilitation, Respiratory Therapy, and Radiology**

Key Findings

- All department managers do not have a thorough understanding of how supplies are charged, what is included in the standard room rate, how they should be budgeted, and the charge master process.
- Significant concerns exist regarding charges, including keeping the charges current on the charge master and who sets the charges.
- Materials Management does not have a system in place for setting surgical charges and keeping them up-to-date.
- There is a considerable amount of lost charges.
- The laboratory does not receive any communication from the billing office regarding which tests are being denied, thus, there are tests that are not being charged.
- Special tests were charged to the patient before the bill is received from the reference lab, eliminating the ability to charge for additional testing.
- New tests that are not in the charge master are not updated in a timely manner.
- Need to provide training for technicians for entering charges, and establish accountability within the process for accuracy and timeliness.
- The department auditing process indicates that many charges are not occurring.

Recommendations

- Training to occur with the department manager regarding how the charges are set, who sets the charges, and how to manage the charge master on an ongoing basis.

- Providing education to the department manager about the entire billing and charging system.
- Reviewing the current process, then brainstorming ideas that would improve the capture of supply charges.

GMHA Report No. HI-EV-OIA-0001-2014-Office of Inspector General-US Department of the Interior

The report is the Office of the Inspector General's evaluation of GMHA's ability to meet the medical care needs of the citizens of Guam. Generally, the report states that GMHA's cash flow is negative and its reimbursement rates and fee schedules are out of date. GMHA's financial situation may jeopardize the future medical needs of the citizens of Guam. A specific finding related to GMHA billings states that GMHA does not have a regular schedule for reviewing its fee schedule and has not adjusted its fees since the early 1990s. Current fees are not sufficient to cover operating costs. The Office of the Inspector General recommended that GMHA: (1) fully implement the new hospital fee schedule when it is approved; and (2) review the fee schedule on a regularly scheduled basis, and where necessary, make adjustments to ensure costs are covered.

GMHA Report to the Media dated January 28, 2013

- GMHA discovered and corrected a computer software problem that resulted in unbilled pharmacy charges totaling almost \$2M.
- There were more than \$1.9M in pharmaceutical charges that were not captured or billed from May 2012 to January 2013. The internal report indicates that the problem is now fixed.
- NTT Data confirmed that a flawed software upgrade caused the billing error.
- The insurance companies will be billed back charges in the next ten business days.
- Processes are now in place to ensure that all hospital charges are matched to appropriate billing charges.
- Over 120,000 line items of Pharmacy Department charges did not "cross" from the clinical system to the billing system because of the software processing issue. Estimated unbilled charges ranged from \$800,000 to \$1.8M.
- The head of the Pharmacy Department said that "pharmacy and nursing have been doing everything appropriately at this time."

Appendix 4:**Controlled Substances Schedules**

- **Schedule I⁵** – (1) the substance has a high potential for abuse; (2) has no currently accepted medical use in treatment in the U.S.; and (3) lacks accepted safety use under medical supervision.
- **Schedule II**- (1) the substance has a high potential for abuse; (2) the substance currently has accepted medical use in treatment in the U.S., or currently accepted medical use with severe restrictions; and (3) the abuse of the substance may lead to severe psychological or physical dependence. Schedule II substances have the highest potential for abuse among controlled substances with accepted medical use.
- **Schedule III**- (1) the substance has potential for abuse less than the substance included in Schedules I and II; (2) the substance currently has accepted medical use in treatment in the U.S.; and (3) abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.
- **Schedule IV**- (1) the substance has a low potential for abuse relative to substances included in Schedule III; (2) the substance currently has accepted medical use in treatment in the U.S.; and (3) abuse of the substance may lead to limited physical dependence or psychological dependence relative to substances included in Schedule III.
- **Schedule V**- (1) the substance has a low potential for abuse relative to substances included in Schedule IV; (2) the substance currently has accepted medical use in treatment in the U.S.; and (3) abuse of the substance may lead to physical dependence or psychological dependence relative to the substances included in Schedule IV.

⁵ Schedule I substances were not part of our audit.

Title 21 United States Code (USC) Controlled Substances Act Part C Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances § 822. Persons Required to Register

- Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.
- Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event, however, shall such registrations be issued for less than one year nor for more than three years.

Title 9 GCA Chapter 67 Guam Uniform Control Substance Act

- **§ 67.302. Registration Requirements.** (a) A person who manufactures, distributes or dispenses a controlled substance within Guam shall obtain annually a registration issued by DPHSS in accordance with rules adopted by DPHSS.

(e) A separate registration is required for each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances.
- **§ 67.303. Registration.** (c) A practitioner must be registered with DPHSS before dispensing a controlled substance included in Schedules II through V.
- **§ 67.306. Records of Registrants.** A person registered to manufacture, distribute or dispense controlled substances shall keep records and maintain inventories in compliance with Federal law, and rules adopted by DPHSS.
- **§ 67.307. Order Forms.** A registrant may distribute a substance included in Schedule I or II to another registrant only by means of an order form.

US Pharmacist Manual

The Pharmacist manual is intended to summarize and explain the basic requirements for prescribing, administering and dispensing controlled substances under the Controlled Substances Act (CSA), Title 21, United States Code (21 U.S.C.) 801-971 and the DEA Regulations, Title 21 Code of Federal Regulations (21 C.F.R.), Parts 1300 to End. Excerpts of some sections are as follows:

- **Section V- Security Requirements.** The breakage or spillage of controlled substances does not constitute a "loss" of controlled substances. When there is breakage, damage, or spillage or some other form of destruction, any recoverable controlled substances must be disposed of according to DEA requirements. Damaged Goods may be disposed of through shipment to a reverse distributor or by a DEA approved process.

- **Section VI-Recordkeeping Requirements**
 - 1) Every pharmacy must maintain complete and accurate record on a current basis on controlled substances purchased, received, stored, distributed, dispensed, or otherwise disposed of.
 - 2) Records and Inventories of Schedule II controlled substances must be maintained separately from all other records of the registrant.
 - 3) All records and inventories of Schedules III, IV, and V controlled substances must be maintained either separately from all other records or in such a form that the information required is readily retrievable from the ordinary business records.
 - 4) Records Required are not limited to the following:
 - Executed and unexecuted official order form (DEA Form 222)
 - Power of Attorney authorization to sign order form
 - All inventory records of controlled substances including the initial and biennial inventories date as of beginning or close of business
 - Record of controlled substances distributed (sales to other registrants, return to vendors, distributions to reverse distributors)
 - Record of controlled substances dispensed
 - DEA registration certificate
 - 5) Prescription Records
 - A file for Schedule II controlled substances dispensed
 - A file for Schedule III, IV, and V controlled substances dispensed
 - A file for all non-controlled drugs dispensed.

- **Section VII- Inventory Requirements**
 - 1) An "inventory" is a complete and accurate list of all stocks and forms of controlled substances in the possession of the registrant as determined by an actual physical count for schedule II substances on hand and an estimated count or measure of the contents of a schedule III, IV or V controlled substance (unless the container holds more than 1,000 tablets or capsules in which case an exact count of contents must be made).
 - 2) The Controlled Substance Act (CSA) requires that all inventory records of Schedule II controlled substances must be kept separate from all other controlled substances.
 - 3) The registrant is required to take a biennial inventory (every two years) which requires the same information as the initial inventory of controlled substances.

▪ **Section VIII- Ordering Controlled Substances**

- 1) Only schedules I and II controlled substances are ordered with the official form (DEA Form 222) or the electronic equivalent.
- 2) Each DEA Form 222 must be signed and dated by a person authorized to sign a registration application or a person granted a power of attorney.
- 3) When the items are received, the pharmacist must document on the purchaser's copy (copy three) the actual number of packages received and the date received.
- 4) The executed DEA Form 222 must be maintained separately from the pharmacy's other business records.
- 5) Any registrant (pharmacy) may authorize one or more individuals, whether or not they are located at the registered location, to obtain and execute DEA Forms 222 by granting a power of attorney to each such individual.
- 6) The power of attorney must be signed by the same person who signed the most recent application for registration or renewal registration, as well as the Individual being authorized to obtain and execute the DEA Forms 222.

Selected GMHA Policies on Controlled Substances

▪ **Policy No. 901- Controlled Substances General Policy**

1. GMHA will register with DEA and DPHSS Controlled Substances Division for the dispensing and administration of controlled drugs.
2. Pharmacy maintains a record book showing the signatures and DEA numbers of Practitioners.
3. A perpetual inventory of controlled drugs has to be maintained.
4. The pharmacy shall record all dispensing of controlled drugs and all floor stock issuing to the nursing station.
5. Wastage of any unused portion of tablets, liquid, injection, and spilled, contaminated, and refused doses must be properly documented.
6. Destructions and returns must be documented.

▪ **Policy No. 902- Registration for Controlled Substances**

1. The Hospital Administrator will register for the entire hospital with DEA and local Public Health Controlled Substance Division. Hospital registration covers both inpatient and outpatient dispensing and administration.
2. The hospital is the registrant for DEA registration.
3. All physicians that are either hired or not hired by GMHA, must be registered with the DEA and local DPHSS Controlled Substances Division in order to see patients in the hospital.
4. The Pharmacy Department is required to register with the local DPHSS annually.

- **Policy No. 907- Controlled Substances Acquisition Process**
 1. Director of Pharmacy and Senior are authorized to sign DEA Form 222 having the authorized power of attorney of the GMHA Administrator.
 2. The First and Second copy of DEA Form 222 goes to the vendor and the third copy in the acquisition record file in the main controlled substance safe.
 3. Voided DEA forms are recorded and maintained in the acquisition record file.

- **Policy No. 908-Controlled Substances, Storage and Security-Pharmacy**
 1. Controlled substances are stored in a locked substantially constructed safe or double locked cabinet.
 2. Combinations for Mosler safe are disclosed only to the pharmacist. Only the designated pharmacists or Pharmacy Director have access to the safe.
 3. Expired substances shall be stored in a locked safe or cabinet and away from the regular storage area.

- **Policy No. 306- Pharmacy Key Control**
 1. The Director of the Pharmacy controls the keys for every locked room, controlled substance storage, cabinets, closets and refrigerators installed inside the pharmacy.
 2. The combination to the Main Stock Controlled Substance safe is only given to the Pharmacist who is responsible for the stock of controlled substances. The combination to controlled substance work safes shall only be given to the pharmacists.

- **Policy No. 605 – Loan and Borrow of Pharmaceuticals**
 1. The Director of the Pharmacy authorizes the loaning and borrowing of drugs.
 2. The loan and borrow form shall be used for each transaction. The loan and borrow form shall carry consecutive numbers for tracking purposes. Once the transaction is completed, the medication that is loaned/borrowed will be credited/debited from Pharmacy inventory.
 3. The Pharmacy Buyer is responsible for the maintenance of the loan and borrow records, as well as the return of any borrowed drugs and the request for loaned drugs to be returned.

Appendix 6:**Internal Control Suggestions**

We made several internal control suggestions for consideration, as follows.

1. Making changes, corrections, or alterations of inventory should not be allowed without supervisory approval. We suggest automating the recording of controlled substance inventory for better control and prevent possible manipulation of data.
2. The duties of ordering, storing, recording of receipts and issuances, and inventorying through regular physical counts should be separated.
3. When a pharmacist receives the delivered controlled substances, there should be a second person within the Pharmacy Department to verify and witness the storing of these controlled substances within the Narcotics Storage Room.
4. The logging in of the received controlled substances within the inventory binders should be performed by a second person.
5. When a pharmacist enters the Narcotics Storage Room to retrieve the controlled substances on order, that same pharmacist should not also be responsible for logging out those controlled substances. In effect, this will ensure that there is an independent verification that the controlled substances retrieved matches the physician order and the quantity recorded.
6. Expired controlled substances should be stored in a secured holding area while awaiting to be processed.
7. The quantity of unused controlled substances in the anesthesiologist stock should be included in the inventory report even though these are subjected to the periodic physical count by the Pharmacists for effective monitoring.
8. Access to the Narcotics Storage Room and locked cabinets should be restricted to the designated person only.
9. In addition, in the event that the electronic badge access to the Narcotics Storage Room become inoperable, it is important that the keys be maintained by assigned persons by shift or stored in an area that is not potentially accessible to all persons who enter the Pharmacy.
10. Where there is a conflict between federal and local laws, requirements, and internal policies, GMHA should revisit how it could align its internal policies with existing federal and local laws and requirements.
11. GMHA should regularly review and update its fee schedule to ensure that the amounts charged are not insufficient to cover the cost of the pharmaceuticals.

Appendix 7:
GMHA Management Response



Guam Memorial Hospital Authority
Aturidåt Espetåt Mimuriåt Guåhan



850 GOV. CARLOS CAMACHO ROAD
OKA, TAMUNING, GUAM 96913
TEL: 647-2444 or 647-2330
FAX: (671) 649-0145

DATE: 09 December 2015
TO: Mrs. Doris Flores Brooks, CPA, CGFM, Public Auditor
FR: Mr. Theodore Lewis, MBA, GMHA CEO *TL*
RE: **Response to OPA Audit of GMHA Inventory Controls Over Controlled Substances**

Hafa Adai,

For the last few months, the Guam Office of Public Accountability (OPA) has been auditing the Guam Memorial Hospital (GMH) Department of Pharmacy's inventory controls over controlled substances (CS). All information has been provided in a timely manner, and the auditors have had unrestricted access to all documents within the boundaries of the Health Insurance Portability and Accountability Act (HIPAA).

Overall, GMH is in agreement with the OPA's recommendations. GMH fully strives to be exceedingly compliant with all applicable laws and regulatory standards. The audit process has proven to be a valuable tool to improving our accountability over CS. We recognize the opportunities for improvement with our billing system, internal controls, and documentation of expired CS.

Please allow us to highlight some areas of exceptional performance. The GMH pharmacy takes pride on our U.S. Drug Enforcement Agency (DEA) compliance, and meets or greatly exceeds all compliance standards assessed by the OPA. Also, based on the OPA's sampled data, the CS inventory record keeping has an accuracy rate of 99.998%, and the CS charge capture rate is 93.46%. Lastly, GMH's CS are safely stored and backed by our 6-layered security system. Ultimately, GMH's control over CS is above standard.

A detailed response to each audit finding is attached to this cover letter. We truly appreciate the OPA's efforts to help us improve and remain fully accountable.

Happy Holidays,

TL *TL*

CC:
Mrs. Benita Manglona, CPA, CGMA, GMHA CFO
GMHA Board of Trustees
Senator Dennis Rodriguez, GMHA Oversight Chairperson

RECEIVED
OFFICE OF PUBLIC ACCOUNTABILITY
BY: *Andriana Quitagua*
DATE: *December 09, 2015*
TIME: *4:23* AM PM

Findings and Responses:

Audit Finding #1: Pharmacy Keys Not Controlled

Official Response: Please include in the report that access to the narcotics room requires an electronic security access, such access is controlled by the chief pharmacist, and only pharmacists are granted access. The electronic security badge access is a key. The manual key-lock mechanism is an extra measure implemented for security, and to exceed DEA compliance. The manual key is stored at the pharmacist's desk and a pharmacist is on duty 24/7. The manual key alone will not open the narcotics room door. Of note, during one of the many unannounced OPA visits, the CC camera system was being installed. The wiring/ power supply to the electronic badge access was momentarily shut down, to extend the power supply to the CC camera system. All CS were secured during the camera installation, and remain fully accounted for. This was the only incident of the electronic badge access being inoperable, it was momentary, and the electronic badge access was operational during all other unannounced OPA visits. Ultimately, the key access to the narcotics room is tightly secured. The report should detail GMH's 6-layered security system for our CS. The 6-layered system includes: 1. all CS are stored in a dedicated and securely locked room, 2. electronic badge security is required to access the narcotics room, 3. a manual key-lock system is also required to access the narcotics room, 4. a manual key-lock system is required to access each of the 3 secured C-II narcotics steel and fire proof cabinets, 5. the steel cabinets are securely bolted into the wall, and 6. the narcotics room is monitored by a CC camera system. This arrangement truly exceeds the DEA minimum requirements.

Audit Finding #2: Certain Pharmacy Inventory Control Not Sufficiently Maintained

Official Response: GMH maintains a manual perpetual inventory for all CS medications and the CSIR is updated with each transaction. The only DEA requirement for narcotic inventory is a Bi-Annual CSIR inventory which has been completed this year alone on 9/26/15, 8/17/15, 6/3/15, and 5/15/15. Thus, GMH truly exceeds the DEA requirements and is exceptionally compliant. In addition, the chief pharmacist spot checks 5 C-II inventory counts on a monthly basis. An independent auditor, Deloitte and Touche, certifies our CS inventory yearly. The OPA notes that error corrections may take 3-4 months. This duration is reasonable, as CS are stored in many areas (ER, operating room, labor room, ICU, surgical, SNU, med-tele, radiology, etc.) and it takes this length of time for the CS administration records to be returned to the pharmacy. All CS administration records must be completely logged by the nursing units, and certified by the nursing unit supervisor, before they can be returned to the pharmacy. Lastly, the OPA identified 1 unjustified correction in the CSIR out of 43,591 CS units dispensed to the nursing units, which is an inventory accuracy rate of 99.998%. Otherwise, we can improve by increasing the frequency of CS inventory reconciliation.

Audit Finding #3: Lack of Independent Verification and Proper Separation of Duties

Official Response: The independent auditor, Deloitte and Touche, certifies GMH's CS inventory on an annual basis. The DEA requires the Chief Pharmacist to document and verify the CS inventory twice a year, and this year alone the GMH Chief Pharmacist has completed this task on 4 occasions. Also, the OPA report should mention for all C-IIs, the Chief Pharmacist must complete the DEA 222 forms upon product arrival. When a pharmacist places an C-II into inventory, the Chief Pharmacist must verify the National-Drug-Code # of the arrived C-II, the quantity received, and the date received. All the information is recorded onto the DEA 222 form, and serves as a double check/ independent verification against the pharmacist whom accepts, and adjusts, the CS inventory. This completed information must match the DEA 222 copy provided by the supplier/ vendor, as well as the DEA 222 copy submitted to the DEA. Thus, an independent verification for C-II medications does exist. Also, no other pharmacist has been issued a POA to order C-II medications, which is a very substantial and executive separation of duty. Please note, GMH is truly compliant for the verification process of C-II procurement and documentation.

Audit Finding #4: Lost Revenue Due to Usage Discrepancies

Official Response: Of special note, the updated data on the 12 sampled controlled substances identifies 40,594 charges captured out of 43,434 units dispensed to the nursing units, which is a charge capture rate of 93.46%. The charge capture rate is truly exceptional given GMH currently operates on a manual system. The OPA's data values the sampled medications at \$219,857.81. The \$10,153.48 variance is from a total amount of \$219,857.81, which is a differential of 4.897%. Although, GMH has performed exceptionally well given the limitations of a manual system, we acknowledged efforts must be made to capture 100% of all CS charges.

Audit Finding #5: Discrepancies in End of Day Balances

Official Response: The audit correctly states that all but one of the mathematical errors in the CSIR has been justified, from the 12 controlled substances sampled. This lone unjustified correction is out of 43,591 CS units dispensed to the nursing units. This indicates an accuracy rate of 99.998% and strongly credits GMH's exceptional CS inventory record keeping. Additionally, the OPA states that changes to the CSIR should not be allowed without supervisory approval. It is within the pharmacists' scope of practice for the GMH pharmacists to adjust CS inventories. The GMH pharmacy is an extremely high volume operation, and any CS inventory discrepancies need to be reconciled upon discovery. The chief pharmacist may not be on site when the discrepancies are identified, and the pharmacists on duty are 'supervisors'. It is standard practice within a hospital pharmacy to allow the pharmacist on duty to reconcile any CS inventory discrepancies. Again, GMH has exceeded the DEA requirements of Bi-Annual inventory verification, maintains a perpetual CS inventory, and the CS inventory is certified annually by the independent auditor Deloitte and Touche.

Audit Finding #6: \$2K Understated Billing Due to Insufficient Fee Schedule Update

Official Response: For each of the last 3 years, the pharmacy has forwarded pricing updates to the charge master for review. GMH does not have a fast-track mechanism to update medication prices. A 5-step process is required to update a medication price: 1. Departmental recognition and approval, 2. GMH CFO approval, 3. GMH Board of Trustees approval, 4. Public hearing, and 5. Legislative approval. Medication prices are highly volatile and difficult to update in real time. GMH should have the liberty to update medication prices due to market fluctuations.

Audit Finding #7: 2,309 Initial Surprise Count Discrepancy for CS3 Injection

Official Response: During one of the unannounced OPA audits, a contractor was installing a CC camera system into the narcotics room. The contractor also arrived unannounced, and the identified CS3 injections which are stored in the open area of the narcotics room, were locked into 2 different narcotics cabinets for security purposes while the contractor was working. At this moment, it was not known to the chief pharmacist that the CS3 inventory was split for temporary storage/ security, which is the root cause for the initial discrepancy.

Audit Finding #8: Unreconciled Differences for Expired and Destroyed Controlled Substances

Official Response:

- A. GMH fully strives to maintain DEA compliance. The chief pharmacist personally invites the DEA to the GMH pharmacy to monitor the management of expired narcotics (6/24/15, 2/11/15, 1/2014, etc.). As the OPA correctly states, there is no requirement for the additional expired narcotics log sheet. The intent for the expired narcotics log sheet is to take additional measures to monitor the expiration of CS returned from the nursing units, as identified on the log sheet by the administration record control number. The expired medications from the nursing units have already been deducted from the CSIR. The OPA specifically cites GMH for not including an expired C-IV in the CSIR inventory. But, the CSIR inventory is specific to active, non-expired, medications. The OPA is comparing data that cannot be aligned. The expired narcotics log sheet is intended to document expired narcotics from the nursing units, and the DEA form 41 is a comprehensive listing of all expired narcotics (nursing units and pharmacy stock). Although all the information recorded on the DEA form 41 is certified by a representative of the DEA, we acknowledge the OPA's recommendation to establish an intermediate step for documenting expired CS.
- B. The OPA report states that GMH has underreported the amount of an injectable C-II on the DEA form 41. The OPA states that GMH had a documented shortfall of 61 expired an injectable C-II, and only reported a quantity of 3 units on DEA form 41. The DEA form 41 (package 10, line 2, line 5, & line 6) identifies a quantity of 158 units. Please update the report to reflect the true amount of 158 units, versus the reported 3 units. Again, this information has been certified by the DEA.

Audit Finding #9: Loaned and Borrowed Drugs Outstanding

Official Response: The loaned medications are fully monitored by the chief pharmacist and pharmacy buyer. There are cases where GMH will not accept a medication for return based on current expiration dates and current inventory on hand. The value of the outstanding borrowed medications may be considered immaterial.

Audit Finding #10: Anesthesiologist's Stock Excluded from Inventory List

Official Response: The anesthesiologist's narcotics are inventoried monthly and fully accounted for. GMH accepts the OPA's recommendation to include this inventory in the DEA Bi-Annual reporting requirements.

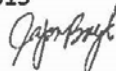
Audit Finding #11: Non-Systematic Filing System for Controlled Substance Dispensation

Official Response:

- A. The CS administration records are organized by Month/ Year/ Medication, and available for review back to January 2009. The anesthesiologists' administration records are separated by Year/ Individual anesthesiologist. The DEA only requires us to keep these records for a period of only 2 years, and GMH truly exceeds this requirement. The records are stored in stacked boxes that take some time to retrieve. The intent for stating the need for additional manpower, was to identify how GMH could further sub-organize the CS records and minimize any delays in record keeping. There is constant movement of the CS administration records between the nursing units and pharmacy as nursing documentation is required on these forms. The maintenance of these forms is high volume work (~ 80,000 doses documented/ year). Although the OPA was able to locate all targeted records, we aim to keep all CS inventory records readily retrievable.

- B. The OPA correctly identifies the GMH pharmacy as understaffed, especially with pharmacists. The OPA cites a 2013 study with the average number of hospital pharmacists as 11.6 FTEs/ 100 beds. GMH has approximately 220 beds, serves 30 beds at SNU, and also provides medications to the approximately 830 clientele at the Department of Corrections. The GMH pharmacy operates with only 11 FTE pharmacists. The upper management at GMH has fully supported the pharmacy in hiring personnel, but allied health professionals are in short supply on Guam. The GMH Department of Pharmacy is constantly recruiting via our student internship program.

Prep By: Jason Boyd, PharmD., GMH Director of Pharmacy
December 9, 2015





**Guam Memorial Hospital Authority
Inventory Control Over Controlled Substances
Report No. 15-07, December 2015**

ACKNOWLEDGEMENTS

Key contributions to this report were made by:

Andriana Quitugua, Audit Staff
Maria Thyrsa Bagana, Auditor-in-Charge
Rodalyn Gerardo, CIA, CGFM, CPA, CGAP, CGMA, Audit Supervisor
Doris Flores Brooks, CPA, CGFM, Public Auditor

MISSION STATEMENT

**To ensure the public trust and assure good governance,
we conduct audits and administer procurement appeals,
independently, impartially, and with integrity.**

VISION

The Government of Guam is the model for good governance in the Pacific.

CORE VALUES

Objectivity: To have an independent and impartial mind.

Professionalism: To adhere to ethical and professional standards.

Accountability: To be responsible and transparent in our actions.

REPORTING FRAUD, WASTE, AND ABUSE

- **Call our HOTLINE at 47AUDIT (472-8348)**
- **Visit our website at www.opaguam.org**
- **Call our office at 475-0390**
- **Fax our office at 472-7951**
- **Or visit us at Suite 401, DNA Building in Hagåtña**

All information will be held in strict confidence.