



**Department of Veterans Affairs  
Office of Inspector General**

**Office of Healthcare Inspections**

**Report No. 13-00026-352**

**Community Based Outpatient  
Clinic Reviews  
at  
VA Western New York  
Healthcare System  
Buffalo, NY**

**October 25, 2013**

**Washington, DC 20420**

## **Why We Did This Review**

The VA OIG is undertaking a systematic review of the VHA's CBOCs to assess whether CBOCs are operated in a manner that provides veterans with consistent, safe, high-quality health care.

The Veterans' Health Care Eligibility Reform Act of 1996 was enacted to equip VA with ways to provide veterans with medically needed care in a more equitable and cost-effective manner. As a result, VHA expanded the Ambulatory and Primary Care Services to include CBOCs located throughout the United States. CBOCs were established to provide more convenient access to care for currently enrolled users and to improve access opportunities within existing resources for eligible veterans not currently served.

Veterans are required to receive one standard of care at all VHA health care facilities. Care at CBOCs needs to be consistent, safe, and of high quality, regardless of model (VA-staffed or contract). CBOCs are expected to comply with all relevant VA policies and procedures, including those related to quality, patient safety, and performance.

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## Glossary

C&P	credentialing and privileging
CBOC	community based outpatient clinic
EHR	electronic health record
EOC	environment of care
FPPE	Focused Professional Practice Evaluation
FY	fiscal year
HCS	Healthcare System
MH	mental health
NC	noncompliant
NCP	National Center for Health Promotion and Disease Prevention
OIG	Office of Inspector General
PII	personally identifiable information
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network
WH	women's health

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## Executive Summary

**Purpose:** We evaluated select activities to assess whether the CBOCs operated in a manner that provides veterans with consistent, safe, high-quality health care.

We conducted an onsite inspection of the CBOCs during the week of August 12, 2013.

The review covered the following topic areas:

- WH
- Vaccinations
- C&P
- EOC
- Emergency Management

For the WH and vaccinations topics, EHR reviews were performed for patients who were randomly selected from all CBOCs assigned to the parent facility. The C&P, EOC, and emergency management onsite inspections were only conducted at the randomly selected CBOCs (see Table 1).

VISN	Facility	CBOC Name	Location
2	VA Western New York HCS	Lackawanna	Lackawanna, NY
		Niagara Falls	Niagara Falls, NY

**Table 1. Sites Inspected**

**Review Results:** We made recommendations in four review areas.

**Recommendations:** The VISN and HCS Directors, in conjunction with the respective CBOC managers, should take appropriate actions to:

- Ensure that the ordering provider or surrogate is notified of normal cervical cancer screening results within the required timeframe and that notification is documented in the EHR.
- Ensure that patients with normal cervical cancer screening results are notified of results within the required timeframe and that notification is documented in the EHR.
- Ensure that clinicians document all required tetanus and pneumococcal vaccine administration elements and that compliance is monitored.
- Ensure that the Executive Committee of the Medical Staff grants privileges consistent with the services provided at the Lackawanna and Niagara Falls CBOCs.

- Ensure that laboratory specimens are secured during transport from the Lackawanna and Niagara Falls CBOCs to the parent facility to prevent the disclosure of patients' PII.

## Comments

The VISN and Facility Directors agreed with the CBOC review findings and recommendations and provided acceptable improvement plans. (See Appendixes A and B, pages 12–15, for the full text of the Directors' comments.) We will follow up on the planned actions until they are completed.



JOHN D. DAIGH, JR., M.D.  
Assistant Inspector General for  
Healthcare Inspections

## Objectives and Scope

### Objectives

- Evaluate whether CBOCs comply with selected VHA requirements regarding the provision of cervical cancer screening, results reporting, and WH liaisons.
- Evaluate whether CBOCs properly provided selected vaccinations to veterans according to Centers for Disease Control and Prevention guidelines and VHA recommendations.
- Determine whether CBOC providers are appropriately credentialed and privileged in accordance with VHA Handbook 1100.19.<sup>1</sup>
- Determine whether CBOCs are in compliance with standards of operations according to VHA policy in the areas of environmental safety and emergency planning.<sup>2</sup>

### Scope and Methodology

#### *Scope*

We reviewed selected clinical and administrative activities to evaluate compliance with requirements related to patient care quality and the EOC. In performing the reviews, we assessed clinical and administrative records as well as completed onsite inspections at randomly selected sites. Additionally, we interviewed managers and employees. The review covered the following five activities:

- WH
- Vaccinations
- C&P
- EOC
- Emergency Management

#### *Methodology*

To evaluate the quality of care provided to veterans at CBOCs, we conducted EHR reviews for the WH and vaccinations topic areas. For WH, the EHR reviews consisted of a random sample of 50 women veterans (23–64 years of age). For vaccinations, the EHR reviews consisted of random samples of 75 veterans (all ages) and 75 additional veterans (65 and older), unless fewer patients were available, for the tetanus and

<sup>1</sup> VHA Handbook 1100.19, *Credentialing and Privileging*, November 14, 2008.

<sup>2</sup> VHA Handbook 1006.1, *Planning and Activating Community-Based Outpatient Clinics*, May 19, 2004.

pneumococcal reviews, respectively. The study populations consisted of patients from all CBOCs assigned to the parent facility.<sup>3</sup>

The C&P, EOC, and emergency management onsite inspections were only conducted at the randomly selected CBOCs. Two CBOCs were randomly selected from the 56 sampled parent facilities, with sampling probabilities proportional to the numbers of CBOCs eligible to be inspected within each of the parent facilities.<sup>4</sup>

In this report, we make recommendations for improvement. Recommendations pertain to issues that are significant enough to be monitored by the OIG until corrective actions are implemented.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

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<sup>3</sup> Includes all CBOCs in operation before October 1, 2011.

<sup>4</sup> Includes 96 CBOCs in operation before October 1, 2011, that had 500 or more unique enrollees.



## CBOC Profiles

To evaluate the quality of care provided to veterans at CBOCs, we designed reviews with an EHR component to capture data for patients enrolled at all of the CBOCs under the parent facility's oversight.<sup>5</sup> The table below provides information relative to each of the CBOCs under the oversight of the respective parent facility.

VISN	Parent Facility	CBOC Name	Locality <sup>6</sup>	Uniques FY 2012 <sup>7</sup>	Visits FY 2012 <sup>7</sup>	CBOC Size <sup>8</sup>
2	Western New York HCS	Dunkirk (Dunkirk, NY)	Rural	1,771	6,986	Mid-Size
		Jamestown (Jamestown, NY)	Rural	1,985	8,751	Mid-Size
		Lackawanna (Lackawanna, NY)	Urban	3,004	11,657	Mid-Size
		Lockport (Lockport, NY)	Rural	1,374	5,674	Small
		Niagara Falls (Niagara Falls, NY)	Urban	1,858	9,283	Mid-Size
		Olean (Olean, NY)	Rural	1,923	9,425	Mid-Size

**Table 2. Profiles**

<sup>5</sup> Includes all CBOCs in operation before October 1, 2011.

<sup>6</sup> <http://vaww.pssg.med.va.gov/>

<sup>7</sup> <http://vssc.med.va.gov>

<sup>8</sup> Based on the number of unique patients seen as defined by VHA Handbook 1160.01, *Uniform Mental Health Services in VA Medical Centers and Clinics*, September 11, 2008, the size of the CBOC facility is categorized as very large (> 10,000), large (5,000-10,000), mid-size (1,500-5,000), or small (< 1,500).

## WH and Vaccination EHR Reviews Results and Recommendations

### WH

Cervical cancer is the second most common cancer in women worldwide.<sup>9</sup> Each year, approximately 12,000 women in the United States are diagnosed with cervical cancer.<sup>10</sup> The first step of care is screening women for cervical cancer with the Papanicolaou test or “Pap” test. With timely screening, diagnosis, notification, and treatment, the cancer is highly preventable and associated with long survival and good quality of life.

VHA policy outlines specific requirements that must be met by facilities that provide services for women veterans.<sup>11</sup> We reviewed EHRs, meeting minutes and other relevant documents, and interviewed key WH program employees. Table 3 shows the areas reviewed for this topic. The review elements marked as NC needed improvement. Details regarding the findings follow the table.

NC	Areas Reviewed
	Cervical cancer screening results were entered into the patient's EHR.
X	The ordering VHA provider or surrogate was notified of results within the defined timeframe.
X	Patients were notified of results within the defined timeframe.
	Each CBOC has an appointed WH Liaison.
	There is evidence that the CBOC has processes in place to ensure that WH care needs are addressed.

**Table 3. WH**

There were 22 patients who received a cervical cancer screening at the VA Western New York HCS's CBOCs.

Provider Notification. VHA requires that normal cervical cancer screening results must be reported to the ordering provider or surrogate within 30 calendar days of the report being issued and the notification is documented in the EHR.<sup>12</sup> We reviewed the EHRs of 21 patients who had normal cervical cancer screening results and did not find documentation in 10 records that the ordering providers or surrogates were notified within 30 calendar days.

<sup>9</sup> World Health Organization, *Comprehensive Cervical Cancer Prevention and Control: A Healthier Future for Girls and Women*, Retrieved (4/25/2013): <http://www.who.int/reproductivehealth/topics/cancers/en/index.html>.

<sup>10</sup> U.S. Cancer Statistics Working Group, United States Cancer Statistics: 1999-2008 Incidence and Mortality Web-based report.

<sup>11</sup> VHA Handbook 1330.01, *Health Care Services for Women Veterans*, May 21, 2010.

<sup>12</sup> VHA Handbook 1330.01.

Patient Notification of Normal Cervical Cancer Screening Results. VHA requires that normal cervical cancer screening results must be communicated to the patient in terms easily understood by a layperson within 14 days from the date of the pathology report becoming available. We reviewed 21 EHRs of patients who had normal cervical cancer screening results and determined that 11 patients were not notified within the required 14 days from the date the pathology reports became available.

## Recommendations

1. We recommended that a process is established to ensure that the ordering provider or surrogate is notified of normal cervical cancer screening results within the required timeframe and that notification is documented in the EHR.
2. We recommended that managers ensure that patients with normal cervical cancer screening results are notified of results within the required timeframe and that notification is documented in the EHR.

## Vaccinations

The VHA NCP was established in 1995. The NCP establishes and monitors the clinical preventive services offered to veterans, which includes the administration of vaccines.<sup>13</sup> The NCP provides best practices guidance on the administration of vaccines for veterans. The Centers for Disease Control and Prevention states that although vaccine-preventable disease levels are at or near record lows, many adults are under-immunized, missing opportunities to protect themselves against tetanus and pneumococcal diseases.

Adults should receive a tetanus vaccine every 10 years. At the age of 65, individuals who have never had a pneumococcal vaccination should receive one. For individuals 65 and older who have received a prior pneumococcal vaccination, one-time revaccination is recommended if they were vaccinated 5 or more years previously and were less than 65 years of age at the time of the first vaccination.

We reviewed documentation of selected vaccine administrations and interviewed key personnel. Table 4 shows the areas reviewed for this topic. The review element marked as NC needed improvement. Details regarding the finding follow the table.

NC	Areas Reviewed
	Staff screened patients for the tetanus vaccination.
	Staff administered the tetanus vaccine when indicated.
	Staff screened patients for the pneumococcal vaccination.
	Staff administered the pneumococcal vaccine when indicated.
X	Staff properly documented vaccine administration.

**Table 4. Vaccinations**

<sup>13</sup> VHA Handbook 1120.05, *Coordination and Development of Clinical Preventive Services*, October 13, 2009.

Documentation of Vaccinations. Federal Law requires that documentation for administered vaccines include specific elements, such as the vaccine manufacturer and lot number of the vaccine used.<sup>14</sup> We reviewed the EHRs of 15 patients who received a tetanus vaccine administration at the parent facility or its associated CBOCs and did not find documentation of all the required information related to tetanus vaccine administration in 3 of the EHRs. We reviewed the EHRs of 26 patients who received a pneumococcal vaccine administration at the parent facility or its associated CBOCs and did not find documentation of all the required information related to pneumococcal vaccine administration in 8 of the EHRs.

### **Recommendation**

**3.** We recommended that managers ensure that clinicians document all required tetanus and pneumococcal vaccine administration elements and that compliance is monitored.

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<sup>14</sup> Childhood Vaccine Injury Act of 1986 (PL 99 660) sub part C, November 16, 2010.

## Onsite Reviews Results and Recommendations

### CBOC Characteristics

We formulated a list of CBOC characteristics that includes identifiers and descriptive information for the randomly selected CBOCs (see Table 5).

	<b>Lackawanna</b>	<b>Niagara Falls</b>
<b>VISN</b>	2	2
<b>Parent Facility</b>	Western New York HCS	Western New York HCS
<b>Types of Providers</b>	Licensed Clinical Social Worker Nurse Practitioner Physician Assistant Primary Care Physician	Licensed Clinical Social Worker Nurse Practitioner Primary Care Physician
<b>Number of MH Uniques, FY 2012</b>	462	303
<b>Number of MH Visits, FY 2012</b>	2,786	2,022
<b>MH Services Onsite</b>	Yes	Yes
<b>Specialty Care Services Onsite</b>	No	No
<b>Ancillary Services Provided Onsite</b>	No	No
<b>Tele-Health Services</b>	MH Retinal Imaging	Audiology Dermatology MH MOVE <sup>15</sup> Retinal Imaging Wound Care
<b>Table 5. Characteristics</b>		

<sup>15</sup> VHA Handbook 1120.01, *MOVE! Weight Management Program for Veterans*, March 31, 2011.

## C&P

We reviewed C&P folders, scopes of practice, meeting minutes, and VetPro information and interviewed senior managers to determine whether facilities had consistent processes to ensure that providers complied with applicable requirements as defined by VHA policy.<sup>16</sup> Table 6 shows the areas reviewed for this topic. The CBOCs identified as NC needed improvement. Details regarding the findings follow the table.

NC	Areas Reviewed
	Each provider's license was unrestricted.
<b>New Provider</b>	
	Efforts were made to obtain verification of clinical privileges currently or most recently held at other institutions.
	FPPE was initiated.
	Timeframe for the FPPE was clearly documented.
	The FPPE outlined the criteria monitored.
	The FPPE was implemented on first clinical start day.
	The FPPE results were reported to the medical staff's Executive Committee.
<b>Additional New Privilege</b>	
	Prior to the start of a new privilege, criteria for the FPPE were developed.
	There was evidence that the provider was educated about FPPE prior to its initiation.
	FPPE results were reported to the medical staff's Executive Committee.
<b>FPPE for Performance</b>	
	The FPPE included criteria developed for evaluation of the practitioners when issues affecting the provision of safe, high-quality care were identified.
	A timeframe for the FPPE was clearly documented.
	There was evidence that the provider was educated about FPPE prior to its initiation.
	FPPE results were reported to the medical staff's Executive Committee.
<b>Privileges and Scopes of Practice</b>	
	The Service Chief, Credentialing Board, and/or medical staff's Executive Committee list documents reviewed and the rationale for conclusions reached for granting licensed independent practitioner privileges.
Lackawanna Niagara Falls	Privileges granted to providers were setting, service, and provider specific.

<sup>16</sup> VHA Handbook 1100.19.

NC	Areas Reviewed (continued)
	The determination to continue current privileges was based in part on results of Ongoing Professional Practice Evaluation activities.
<b>Table 6. C&amp;P</b>	

**Clinical Privileges.** The Executive Committee of the Medical Staff granted clinical privileges for procedures that were not performed at the Lackawanna and Niagara Falls CBOCs for two of five providers. The providers were granted privileges that included arterial punctures and insertion of nasogastric tubes.

### Recommendation

4. We recommended that the Executive Committee of the Medical Staff grants privileges consistent with the services provided at the Lackawanna and Niagara Falls CBOCs.

## EOC and Emergency Management

### EOC

To evaluate the EOC, we inspected patient care areas for cleanliness, safety, infection control, and general maintenance. We reviewed relevant documents and interviewed key employees and managers. Table 7 shows the areas reviewed for this topic. The CBOCs identified as NC needed improvement. Details regarding the findings follow the table.

NC	Areas Reviewed
	The CBOC was Americans with Disabilities Act compliant, including: parking, ramps, door widths, door hardware, restrooms, counters.
	The CBOC was well maintained (e.g., ceiling tiles clean and in good repair, walls without holes, etc.).
	The CBOC was clean (walls, floors, and equipment are clean).
	Material safety data sheets were readily available to staff.
	The patient care area was safe.
	Access to fire alarms and fire extinguishers was unobstructed.
	Fire extinguishers were visually inspected monthly.
	Exit signs were visible from any direction.
	There was evidence of fire drills occurring at least annually.
	Fire extinguishers were easily identifiable.
	There was evidence of an annual fire and safety inspection.
	There was an alarm system or panic button installed in high-risk areas as identified by the vulnerability risk assessment.
	The CBOC had a process to identify expired medications.
	Medications were secured from unauthorized access.
	Privacy was maintained

NC	Areas Reviewed (continued)
	Patients' personally identifiable information was secured and protected.
Lackawanna Niagara Falls	Laboratory specimens were transported securely to prevent unauthorized access.
	Staff used two patient identifiers for blood drawing procedures.
	Information Technology security rules were adhered to.
	There was alcohol hand wash or a soap dispenser and sink available in each examination room.
	Sharps containers were less than 3/4 full.
	Safety needle devices were available for staff use (e.g., lancets, injection needles, phlebotomy needles).
	The CBOC was included in facility-wide EOC activities.
<b>Table 7. EOC</b>	

PII. We found that the transportation of laboratory specimens from the Lackawanna and Niagara Falls CBOCs to the parent facility did not ensure the security of patients' PII. CBOC staff placed the specimens in an unlocked plastic box, and the facility van driver transported the box in an unlocked zipper bag to the parent facility for processing. The specimen labels disclosed patients' names and social security numbers. The specimen containers were not locked; therefore, staff could not ensure the security of patients' PII.

### Recommendation

5. We recommended that laboratory specimens are secured during transport from the Lackawanna and Niagara Falls CBOCs to the parent facility to prevent the disclosure of patients' PII.

### Emergency Management

VHA policy requires each CBOC to have a local policy or standard operating procedure defining how medical and MH emergencies are handled.<sup>17</sup> Table 8 shows the areas reviewed for this topic.

NC	Areas Reviewed
	There was a local medical emergency management plan for this CBOC.
	The staff articulated the procedural steps of the medical emergency plan.
	The CBOC had an automated external defibrillator onsite for cardiac emergencies.
	There was a local MH emergency management plan for this CBOC.

<sup>17</sup> VHA Handbook 1006.1.



<b>NC</b>	<b>Areas Reviewed (continued)</b>
	The staff articulated the procedural steps of the MH emergency plan.
<b>Table 8. Emergency Management</b>	

All CBOCs were compliant with the review areas; therefore, we made no recommendations.

## VISN 2 Director Comments

**Department of  
Veterans Affairs**

**Memorandum**

**Date:** September 20, 2013  
**From:** Interim Network Director, VISN 2 (10N2)  
**Subject:** **CBOC Reviews at VA Western New York HCS**  
**To:** Director, Bedford Regional Office of Healthcare Inspections  
(54BN)  
Acting Director, Management Review Service (VHA 10AR  
MRS OIG CAP CBOC)

1. I concur with the conclusions and recommendations presented by the Office of Healthcare Inspection, and present to you a plan of action to correct those areas with findings and recommendations.
2. If you have any questions, please contact Kathryn Varkonda, RN, MSN, Performance Manager, VA Western New York Healthcare System at 716-862-6380.

*(original signed by:)*

James Cody, FACHE

**VA Western New York HCS Director Comments****Department of  
Veterans Affairs****Memorandum**

**Date:** September 20, 2013  
**From:** Director, VA Western New York HCS (528/00)  
**Subject:** **CBOC Reviews at VA Western New York HCS**  
**To:** Interim Network Director, VISN 2 (10N2)

1. Thank you for the opportunity to review and respond to the subject report.
2. I concur with the conclusions and recommendations presented by the Office of Healthcare Inspection, and present to you a plan of action designed to correct those areas with findings and recommendations.
3. If you have any questions or need further information, please contact Kathryn Varkonda, RN, MSN, Veterans Affairs Western New York Healthcare System Performance Manager at (716) 862-6380.

*(original signed by:)*

**BRIAN G. STILLER**  
Medical Center Director

## Comments to OIG's Report

The following Director's comments are submitted in response to the recommendations in the OIG report:

### **OIG Recommendations**

1. We recommended that a process is established to ensure that the ordering provider or surrogate is notified of normal cervical cancer screening results within the required timeframe and that notification is documented in the EHR.

Concur

Target date for completion: January 17, 2014

Facility Response: WH program manager will be receiving a list of the Cervical Cancer screenings performed throughout the facility from the lab, and will ensure that provider or surrogate are notified of the results. An audit will be conducted monthly to ensure that this is happening in a timely manner, and emails educating providers and other staff has been sent out to remind them of the process for notification of results.

2. We recommended that managers ensure that patients with normal cervical cancer screening results are notified of results within the required timeframe and that notification is documented in the EHR.

Concur

Target date for completion: January 17, 2014

Facility Response: WH program manager will be receiving a list of the Cervical Cancer screenings performed throughout the facility from the lab, and will ensure that patients are notified of results within the required timeframe and that notification is documented in the EHR. Emails educating providers and other staff have been sent out to remind them of the process for patient notification of results and documentation.

An audit will be conducted monthly to ensure that patient notification is completed within the required timeframe with documentation in the EHR. Thirty charts per month will be audited. If the number is < 30, 100% of charts will be audited.

Education of staff completed in September. Monthly audits will commence in October 2013.

In progress.

**3.** We recommended that managers ensure that clinicians document all required tetanus and pneumococcal vaccine administration elements and that compliance is monitored.

Concur

Target date for completion: October 17, 2013

Facility Response: Staff have been educated on all required tetanus and pneumococcal vaccine administration documentation elements in EHR.

An audit will be conducted monthly to ensure compliance with documentation of all required elements for tetanus and pneumococcal vaccine administration. Thirty charts per month will be audited. If the number is < 30, 100% of charts will be audited.

Education of staff completed in September. Monthly audits will commence in October 2013.

In progress.

**4.** We recommended that the Executive Committee of the Medical Staff grants privileges consistent with the services provided at the Lackawanna and Niagara Falls CBOCs.

Concur

Target date for completion: January 17, 2014

Facility Response: Privileging process will be reviewed and, moving forward, a system will be in place that ensures privileges granted consistent with services at the specific site.

**5.** We recommended that laboratory specimens are secured during transport from the Lackawanna and Niagara Falls CBOCs to the parent facility to prevent the disclosure of patients' PII.

Concur

Target date for completion: October 17, 2014

Facility Response: We have acquired plastic locks that will be used in the green duffle bag that is used for carrying laboratory specimens from the CBOCs to the Lab in Buffalo. Lab personnel at the CBOC will secure the duffle bag with plastic lock, which will be opened in the medical center lab by the VA staff member receiving the laboratory specimens.

## OIG Contact and Staff Acknowledgments

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