



U.S. Department of Justice

Office of the Deputy Attorney General

Associate Deputy Attorney General

Washington, D.C. 20530

November 7, 2011

The Honorable Carolyn N. Lerner
Special Counsel
Office of Special Counsel
1730 M Street, N.W., Suite 218
Washington, D.C. 20036-4505

Re: OSC File Nos. DI-11-2109 and DI-11-2110

Dear Ms. Lerner:

This responds to your July 1, 2011 correspondence wherein you refer for investigation allegations raised by employees of the United States Department of Justice, Federal Bureau of Prisons, based on your conclusion that there is a substantial likelihood that the information provided by the employees discloses a violation of law, rule, or regulation. Specifically, your letter reports that Medical Officers Pradip M. Patel, M.D., and Nicoletta A. Turner-Foster, M.D., employees at the Federal Correctional Institution Fort Dix, NJ (FCI Fort Dix), alleged that FCI Fort Dix employees did not timely collect samples for medically ordered laboratory diagnostic tests, including blood, stool, and urine samples, which in turn caused delays in receiving results that were needed for medical diagnoses.

You requested an investigation and report on the allegations. Enclosed herein is the Department's Report of Investigation submitted in accordance with 5 U.S.C. § 1213(d). The Attorney General has delegated to me authority to review and sign the report. That delegation is likewise enclosed. Please feel free to contact me at your convenience regarding this matter.

Sincerely,

A handwritten signature in blue ink, appearing to read "Scott N. Schools".

Scott N. Schools
Associate Deputy Attorney General

Enclosures

**Department of Justice
Report of Investigation**

OSC Case Nos. DI-11-2109 and DI-11-2110

I. The Predicate for the Investigation

This investigation was initiated based upon the disclosure of Medical Officers Pradip M. Patel, M.D., and Nicoletta A. Turner-Foster, M.D., (the whistleblowers), that Bureau of Prisons (BOP) employees at the Federal Correctional Institution, Fort Dix, NJ (FCI Fort Dix), did not timely collect samples for medically ordered laboratory diagnostic tests, including blood, stool, and urine samples, which in turn caused delays in receiving results that were needed for medical diagnoses.

The whistleblowers alleged that physicians and other medical professionals often receive laboratory reports several months or more after they have placed orders for medical tests, resulting in substandard care for patients. They alleged that, although they order medical tests that require the collection of blood, urine, or other samples from inmates, Carolyn Johnson, the only Laboratory Technician¹ at the facility who is responsible for collecting and shipping the samples for testing, is unable to collect the samples in a timely manner because of a backlog of such orders. The delay in the collection of samples also delays the results. According to the whistleblowers, without timely test results, they are unable to provide complete and accurate patient assessments and treatment. Patients with serious medical conditions, such as human immunodeficiency virus (HIV), diabetes, poor liver function, kidney disease, and hepatitis C, may experience complications and/or harm if they are untreated or receive inadequate medication while awaiting laboratory results. In addition, the whistleblowers emphasized that medications must be monitored through laboratory testing to establish their safety and effectiveness. They alleged that delays in the collection of laboratory samples and receipt of diagnostic test results create a substantial and specific danger to patient health and safety.

The whistleblowers assert they have raised these issues to management officials, including Donna Zickefoose, Warden; Abigail Lopez de LaSalle, M.D., Clinical Director (CD); and Michelle Baker, Health Services Administrator (HSA). However, they allege the managers have not addressed the delays in receiving medical testing results, a chronic problem ongoing for more than one year. The whistleblowers stressed that several months is an unacceptably long time to wait for laboratory testing and results for patients requiring medical evaluations.

II. The Investigation

This investigation commenced in July 2011, upon receipt of the Office of Special Counsel (OSC) letter referring the above-described whistleblower allegations to the Attorney General for investigation pursuant to 5 U.S.C. § 1213, and concludes with this report. The investigation

¹ The terms "Laboratory Technician" and "Phlebotomist" are used interchangeably in this report.

included on-site visits by the BOP Office of Internal Affairs (OIA), during the week of August 1, 2011, and the week of September 12, 2011. During the course of its investigation, the OIA conducted twelve interviews of BOP employees (including the whistleblowers); collected and examined various memoranda, email, and other records pertaining to the related events; and researched applicable agency rules and regulations.

III. Summary of Evidence Obtained from the Investigation

FCI Fort Dix was opened in September of 1992, and is located in Burlington County, NJ, on a United States Army Post. The institution occupies 333 acres which were formally utilized as Basic Training brigades.

FCI Fort Dix is made up of 64 buildings with two adjacent, separately fenced, areas known as the east and west compounds.

FCI Fort Dix is a low-security facility that houses approximately 4,850 inmates. In addition, a satellite camp was opened in January 2000 and holds approximately 450 inmates. Each compound has its own perimeter security, inmate visiting room, and outside administrative buildings. A compound consists of six housing units, Health Services, a chapel, a gymnasium, an education building, dining halls, and administrative offices to include Safety and Psychology.

The Health Services department at FCI Fort Dix is comprised of 46 staff members, and includes a CD, HSA, two Assistant HSAs, four medical doctors, ten Mid-Level Practitioners (MLPs), and nine nursing and Emergency Medical Technician (EMT) staff members. FCI Fort Dix contracted with one phlebotomist until recently. The contractor provided an additional phlebotomist on September 7, 2011, September 26, 2011, and October 4, 2011. The physicians are responsible for Chronic Care Clinics (CCC), and their caseloads range from 435 to 530 in number.

The investigation revealed that a large number of laboratory tests had been ordered but had not been conducted at FCI Fort Dix, as reported by the whistleblowers. A print-out drawn from the Bureau Electronic Medical Records (BEMR) and supplied to the OSC by the whistleblowers identified 1,199 lab tests that had not been conducted for the time period of January 2009 to April 15, 2011. A print-out requesting the same information, but run by Dr. Jeffrey Allen, Chief Physician, BOP, Central Office, for the time period of January 2008 to July 28, 2011 revealed a total of 1,141 delinquencies. It was determined that the problem with the delinquent lab tests was systemic and multi-faceted. Several factors contributed to the delinquency of ordered lab work at FCI Fort Dix:

- For more than one year, FCI Fort Dix utilized only one contract phlebotomist. The administration consistently attempted to locate another phlebotomist, but was unsuccessful for a variety of reasons. Most often the applicants could not qualify for the positions because of credit or citizenship issues.
- The one phlebotomist at FCI Fort Dix, Carolyn Johnson, receives notice from the

Health Information Technicians (HITs) of laboratory testing needing to be completed. Because of the tremendous workload and number of ordered tests at FCI Fort Dix, the tests eventually fell behind. In addition, inmates who reported for tests but were not prepared (e.g. reporting for fasting tests after eating a meal) were required to be rescheduled.

- When the HITs scheduled the requested laboratory tests they looked at a range of 30 days in the past and 30 days in the future to schedule the tests. This would allow some tests to "fall below the radar." Staff at FCI Fort Dix indicated the 30-day ranges were designed to handle all "sick leave" patients and to ensure that laboratory results were drawn from Chronic Care inmates.
- Several inmates on the list generated from BEMR were transferred to FCI Fort Dix from other institutions. If these inmates had tests ordered that did not fall within the 30-day time frames utilized by the HITs, they would not be tested. There were no safeguards in place to automatically review new inmates transferring to FCI Fort Dix from other facilities to ensure that all previously ordered tests were completed.
- The doctors did not always review lab documentation when examining patients to determine if there were outdated tests that had not been completed.
- There were a number of duplicate tests ordered for the same patients. For example, if the initial test was determined to be outdated a new test was ordered. In some cases, the initial test, no longer in the prescribed time frames, would not be cancelled and would still show as pending.

Dr. Pradip Patel said there has been a problem getting blood tests completed since "at least" the spring of 2010. Patel said the BOP implemented the use of BEMR in April of 2007. He said changing from a paper documentation system to an electronic system could account for a delay in the reporting of laboratory work dating back to 2008, but said there was still a "tremendous" backlog of tests waiting to be completed. Patel opined this delay adversely affected his ability to appropriately treat his patients.²

Patel said that he addressed this issue in writing via emails in September 2010, and orally in meetings prior to 2010. Patel said the response from the administration was always that "they were working on it" by trying to get another laboratory technician. Patel said he suggested to the administration (CD Abigail LaSalle and HSA Michelle Baker) that they utilize nurses, Physicians Assistants (PAs), and EMTs to assist in collecting these samples. Patel said he was aware that those staff members had been used in the past for specific "mass draws" (usually related to DNA

² As an example, Dr. Patel cited the following:

The patient was seen on 4/29/11 by me. I noted in my disposition for patient to be scheduled for labs due 4/4/11. They were not done till 8/1/11. This inmate's Creatinine jumped from 1.34 to 1.62. This is a decline in his measure of kidney function. If his Creatinine had gone up to 1.7 then he is at high risk for lactic acidosis from taking Metformin which is one of the medications he is on. Now I have to let him know about this and also consider discontinuation of Metformin and consider Insulin for his Diabetes. This is a time consuming process that has to be done out of pocket from the normal scheduling of patients. And when labs are not done timely it leads to delay in treatment and patient safety concerns. This is an example why patient safety is key [sic] concern to me and for the BOP.

samples). Patel said that although the collection of blood for medical diagnoses and treatment is more complex than the draw required for DNA, there could still be a significant impact on the number of pending lab collections by utilizing other staff.

During an interview on August 2, 2011, Patel said there was currently one Laboratory Technician at FCI Fort Dix and said this has been the case since another technician left "less than a year ago." However, Patel said that FCI Fort Dix experienced a significant backlog of laboratory tests even when two lab technicians were in place. Patel said he orders laboratory work for stable patients to be conducted one month prior to their next regularly scheduled visit. Patel said if the laboratory work is not done in a timely fashion he cannot effectively monitor a patient's progress. Patel said if he sees a patient and there is no evidence that the requested laboratory work has been done, he will ask the patient if he recently had blood work done. If a patient says that he has had recent blood work, Patel will call the United States Medical Center for Federal Prisoners in Springfield, MO, (where the laboratory work samples are tested) to try and obtain the results. Patel said if the patient indicates he has not had recent laboratory work done, he may cancel the previous laboratory work, depending on the circumstances, and place a new order. Patel said this is not a desirable course of action since the records would show that he canceled blood work. Patel said that FCI Fort Dix needs to get all laboratory work up to date and then maintain timely draws and collections.

Patel said he has, on occasion, taken patients to the phlebotomist to have laboratory work done when he noticed that ordered work had not been completed. Patel said these tests are completed because of the phlebotomist's willingness and said he cannot mandate the testing. Patel also added that because of time constraints, he can only take patients to the lab technician occasionally.

Patel said it is his perception that the Warden, HSA, and the CD "do not care" if the laboratory work is done in a timely manner. Patel said he feels this way because in the spring of 2011, these officials changed the assignments of all the doctors and gave them new caseloads. Patel said these changes resulted in not only having to learn and research health records for new patients, but also required them to treat new patients without adequate laboratory work.

Patel said he did not provide the Warden, HSA, or CD with the document he had retrieved from BEMR that reflected the extent of delinquent laboratory requests, but advised them orally on several occasions that the labs were not completed timely. Patel also added that the HSA and CD have access to BEMR and could have gotten the records after his numerous complaints. Patel said he also sent emails on either September 22 or September 23, 2010, detailing the delinquent labs and the need to complete these labs.³

³ On September 23, 2010, Patel sent an email to CD LaSalle, HSA Baker and Assistant Health Services Administrator (AHSA) Linda Angrisani noting, "A lot of the current CCC's that I'm seeing presently have no current labs because they are not being done on time. This makes our clinic unproductive and hence we will end up seeing the patients again for abnormal labs which should and can be avoided. We need to do something to catch up with labs. So that they are available when we see patients." On the same date HSA Baker responded, "I am aware and understanding of your frustration and unfortunately we only have 1 lab Tech and she can only do so much. I have been working in an attempt to secure another Lab Tech. Although we have had several candidates that are interested, they either cannot pass the background or are not US citizens. If you identify someone who is in need of labs with an

Dr. Nicoletta Turner-Foster said she was aware there was a problem getting laboratory results collected and submitted at FCI Fort Dix. Turner-Foster said it was her belief this problem has existed for the past six years and stemmed primarily from having only one laboratory technician. Turner-Foster said the institution previously had two laboratory technicians and said that, although the problem was not as severe, the facility still had a backlog.

Turner-Foster said most of the laboratory requests at FCI Fort Dix are driven by patients with conditions such as hypertension, diabetes, elevated cholesterol, etc. She said, "We are mandated to see these patients on a regular basis and need lab work to appropriately treat these patients." Turner-Foster opined that 50% of the patients she sees have not had ordered laboratory work completed, and approximately 15% of those scheduled for a second visit still have not had these tests completed.

Turner-Foster said she has voiced her concerns about the untimeliness of lab work to no avail. She said one idea that was put forth was to have doctors take laboratory specimens and thinks one solution would be to hire more laboratory technicians. Turner-Foster said another approach would be to utilize MLPs, EMTs, and nurses to collect samples to assist in alleviating the problem. Turner-Foster said she spoke with HSA Baker and CD LaSalle and was told that they were trying to hire someone for the laboratory technician position, but that two previous applicants were not able to be hired because of "credit issues."

Turner-Foster said that when she and Dr. Patel reported this matter to OSC, they provided OSC with a "stack" of BEMR rosters indicating over 1,000 delinquent lab tests. Turner-Foster said they did not provide this data to the Warden, Associate Warden, Health Services Administrator, or Clinical Director, but did advise these staff members on several occasions that lab work was not being done. Turner-Foster said she may have also contacted these staff members by email.

Turner-Foster said she could recall only one patient that was impacted by delinquent lab work. This patient was a Stage 4 Kidney Disease patient who could have been treated sooner if the requested blood work would have been completed. Turner-Foster said this patient had to be sent to an outside hospital for several days to be stabilized. She said the patient is now Stage 3 and is being treated at FCI Fort Dix.⁴

urgency, let Dr. Lopez or I know so that we can work with Ms. Jackson to get it done." Later that day Patel responded, "Most patients who are on CCC have previously scheduled labs usually one month prior to their next visit and there are a lot. They are not considered urgent so I can't point them out nor have time to screen all the future CCC's. They need to be done prior to their CCC. Then the CCC can be done completely. It is not a matter of what is urgent. It is a matter of what should take place in a timely manner so the CCC can be complete."

⁴ A patient was referred to an outside hospital on July 21, 2011 because of a July 5, 2011 potassium level of 7.1 mmole/L. It was noted: "He has stage 4 CKD (Chronic Kidney Disease) and...requires normalization of his potassium and stabilization of his CKD." The laboratory tests on this patient were scheduled for October 21, 2010, but were not completed until July 5, 2011. A review of this case was also conducted by Dr. Jeffery D. Allen, Chief of Health Programs in Central Office. Dr. Allen noted the inmate was seen on 10/14/10 and lab work was ordered for 10/21/10, but the work was not completed until 7/5/11. When Dr. Turner-Foster saw that patient on 4/12/11 for a routine CCC visit, she noted the labs ordered for 10/21/10 were pending collection, and ordered new labs with a due

Carolyn Johnson is a contract phlebotomist assigned to FCI Fort Dix by her employer, Interactive Medical Specialists. Johnson said she usually collects 25 to 32 laboratory specimens per day.

Johnson said she was aware there was a backlog of laboratory draws but said she was not aware there were possibly over one thousand tests not completed. Johnson said that her "call-outs" are scheduled by HITs. She said that when tests are scheduled, she "pulls up BEMR" to determine the kind of test(s) needed. Johnson said she looks at any tests scheduled for up to three months in the future, and looks back to see tests scheduled since the date of her arrival at FCI Fort Dix in February 2010. Johnson said she never looked at tests scheduled before that date because "that wasn't the way I was trained." (Johnson said she was trained by a former contract phlebotomist at FCI Fort Dix and not by any BOP staff member.)

Johnson said her patients are always scheduled for 8:00 a.m. and she collects specimens until lunch. She said that "more often than not, I am not able to complete all the patients by that time." The patients who are not completed by lunchtime are not returned in the afternoon, but have to be rescheduled for another day.

HITs Robert W. Curran, Kayle Palmisano, and Charron Smith said that approximately one year ago, the Health Services administration made the decision the HITs would do the lab scheduling and would use a range from 30 days in the past to 30 days in the future to determine the pending laboratory tests. Curran, Palmisano, and Smith agreed this system worked well for new entries, but did nothing to address the backlog. They said the doctors consistently contact the HITs in the case of any laboratory requests that need to be done immediately. Curran said this is not necessarily the case for routine laboratory work, but for more urgent situations and/or after a clinician review indicates a need for a quick return on laboratory tests.

Palmisano said that when she began her employment at FCI Fort Dix on April 5, 2010, the laboratory technician, Carolyn Johnson, chose the laboratory tests she wanted completed since she knew how long each test was going to take, whether it was fasting or non-fasting, and whether they were viral load⁵ collections. Palmisano said Johnson would pull the laboratory requests from BEMR and would email her a list of inmates from whom she was going to draw laboratory specimens. She said that her only responsibility was to enter the laboratory tests into SENTRY.⁶ Palmisano said this type of scheduling of laboratory tests was ineffective and the HITs were

date of 9/12/11. Although Turner-Foster acknowledged a long past due date, she put a 5-month due date on her lab order, suggesting no urgency.

⁵ Viral load is a measure of the severity of a viral infection and can be calculated by estimating the amount of virus in an involved body fluid. For example, viral load can be measured in RNA copies per milliliter of blood plasma. Viral load tracking is used to monitor therapy during chronic viral infections and in immuno-compromised patients such as those recovering from bone marrow or solid organ transplantation. Currently, routine testing is available for HIV-1, cytomegalovirus, hepatitis B virus, and hepatitis C virus.

eventually given the responsibility of pulling the pending laboratory requests off BEMR and scheduling the lab work.

Palmisano said she believes the delinquent laboratory requests at FCI Fort Dix resulted in part from duplicate laboratory requests being entered by the clinicians and from clinicians not checking to see if the laboratory work had been previously ordered. She said she believes there were over 200 duplicate laboratory requests in the system.

Palmisano said the clinician would logically be the only person responsible for canceling out an old request in the event that the request was determined to be outdated. She said the PAs/MDs see each new inmate within 14 days of arriving at the institution. Palmisano said that in their review they should look and review any pending laboratory requests and decide if the laboratory requests should stand or be canceled.

Dr. Abigail LaSalle (referred to as Dr. Abigail Lopez de LaSalle or Dr. Lopez at FCI Fort Dix) said she was aware FCI Fort Dix was significantly behind in getting laboratory work drawn and processed. She said she was not aware of the exact number of delinquent laboratory requests because of many outdated and duplicate requests in the system. LaSalle said she has requested that her clinicians review and delete these duplicate and outdated entries when they come across them in BEMR. LaSalle said that on December 18, 2009, she sent a memorandum to her doctors giving them the procedure to eliminate the duplicate laboratory orders and also that she discussed this process at the December monthly staff meeting.

LaSalle said the process for ordering laboratory work is that the doctors enter a clinical note in BEMR, then open the "task" and select the work they need completed. She said the clinician then specifies the date and the routing of the test and then finalizes the laboratory test selection. LaSalle said that at this stage, the doctors are able to review and eliminate any duplicate or outdated test. LaSalle said the task then goes to the laboratory technician's box for completion. She said the tests are then scheduled by the HITs.

LaSalle said attempts to recruit lab technicians for FCI Fort Dix have been ongoing, and said that, although they have had some prospects, the applicants were unable to pass the background investigations. LaSalle said that she had also proposed supplementing the lab technician with EMTs, MLPs, and RNs, but said this did not "pan out" since those staff members were constantly being called for other duties. LaSalle said her expectation is that her clinicians will order lab tests as indicated by the patient's condition. She said she also expects her clinicians to communicate to the lab technician or HIT if they need to prioritize their requests.

LaSalle said that whenever a doctor advises her that they need to see a patient for follow-up but do not have laboratory test results, she requests they contact or visit the appropriate HIT, schedule the laboratory work as soon as possible, and then re-schedule the patient.

HSA Commander Michelle Baker (Public Health Service) said she was assigned as HSA

⁶ SENTRY is the on-line information system used by the Bureau of Prisons to provide most of its operational and management information requirements.

at FCI Fort Dix on August 20, 2010. Baker says that since that time she has been aware of a backlog of laboratory tests not completed and that Warden Zickefoose has expressed her frustration with the situation and has been adamant the situation should be resolved.

Baker said that in an effort to resolve the situation she requested other medical staff assist the laboratory technician, but said, "Sometimes this worked, and sometimes it didn't." She said that when other staff would take leave, those staff members would have to be assigned to cover the vacant positions.

Baker said she looked for various solutions to the problem of delinquent laboratory work to no avail. She said she constantly was in contact with Human Resources in an attempt to hire another laboratory technician. Baker said she also requested assistance from other institutions in an effort to have laboratory technicians assigned temporarily to FCI Fort Dix, but said after initial discussions she heard no further response.

Baker said that during a meeting on April 7, 2011, which included regional staff members, executive staff members, and Health Services staff members, it was suggested that doctors and other qualified medical personnel assist the laboratory technician, and, although everyone agreed, this never occurred.

Baker said she also attempted to use her Commissioned Officer Student Training Extern Program, doctors, EMTs and nurses to determine if there was "state of the art" equipment the facility could purchase to assist in resolving the laboratory work delinquency. Baker said the facility purchased two machines for "point of care" testing. These machines were a Hemoglobin A1c for immediate blood testing and a Urinalysis Analyzer.

Baker said that although she was aware of a backlog issue, none of the doctors ever raised the extent or the specific number of delinquent laboratory requests.⁷ She said the doctors discussed with her that they were unable to see their patients because the laboratory work was not being completed.

Warden Zickefoose said she was aware of an issue involving delinquent laboratory tests at FCI Fort Dix, but said she was not aware of the scope of the problem. She said that to address the issue, she attempted on several occasions to hire more contract staff, but said none of the potential applicants could pass the background check.

Zickefoose said that Turner-Foster met with her on February 10, 2011, and told her that the laboratory tests were not being completed timely, and that the laboratory tests were necessary to treat her patients. Zickefoose said Turner-Foster indicated that because of this issue, she was unable to see and properly treat her patients.

⁷ In an email dated July 12, 2010, and addressed to the HITs, HSA Baker noted, "After a review of where we stand with Labs starting January 2010-present, it was identified that we have 32 pages of pending Labs on the West and 70 on the East." Baker stated she did not pay attention to the number of lab tests pending, but just determined the number of pages.

Zickefoose said Patel came to see her on March 3, 2011, and echoed the sentiments of Turner-Foster about not having laboratory test results for his patients. Zickefoose said neither Patel nor Turner-Foster advised her of a specific number of backlogged pending lab tests.

Zickefoose said that in March 2011, she requested a meeting that involved regional staff, FCI Fort Dix executive staff, and medical staff. She said this meeting took place on April 7, 2011. Zickefoose said the issue of backlogged lab tests was discussed. It was decided that FCI Fort Dix could contact the Metropolitan Detention Center in Brooklyn, NY, and FCI Fairton, NJ, to see if staff could be "borrowed" to assist at FCI Fort Dix. Zickefoose said HSA Baker contacted these facilities to no avail. Zickefoose said it was also suggested by Regional HSA Barbara Cadogan that FCI Fort Dix clinicians (physicians, MLPs, nurses, and EMTs) assist in collecting specimens in an effort to resolve the delinquencies. Zickefoose said this was done on a few occasions; however, due to staff shortages, leave, and other extended absences, this process was never established to occur on a routine basis.

Jeffrey D. Allen, M.D., Chief of Health Programs, Health Services Division, Central Office, accompanied the Office of Internal Affairs Investigator during the first visit to FCI Fort Dix, NJ, during the week of August 1, 2011.

Dr. Allen determined there was a significant backlog of pending diagnostic laboratory tests as demonstrated by a BEMR report dated August 2, 2011, which identified 1,141 lab orders that were past due and which dated back to March 2008. Dr. Allen concluded that many of the individual orders included requests for multiple different lab tests. However, he also determined the total number of pending lab orders identified in this BEMR report overestimated the total number of actual lab tests that needed to be drawn. Dr. Allen retrieved a different BEMR report, sorted by inmate name, and found frequent multiple overlapping lab orders for the same inmates. Furthermore, he discovered some of the tests had been done but the order had not been cleared. Finally, Dr. Allen determined that some of the earlier lab tests had been ordered by clinicians at other facilities prior to the inmates' transfer to FCI Fort Dix and were clearly out of date. Dr. Allen said that, with the possible exception on one case of hyperkalemia (elevated potassium level), none of the Health Services staff interviewed were aware of any adverse outcomes resulting from untimely performance of lab tests.

Dr. Allen concluded that there was a significant problem with a large number of pending and past due diagnostic lab orders at FCI Fort Dix. He determined the problem to be complex and caused by a variety of different factors. Dr. Allen said that, although management was aware of the problem and had made efforts to solve the problem, they were not aware of the true magnitude and scope of the problem and their efforts were insufficient to solve it definitively. He said that, although there was no indication that negative patient outcomes had resulted from untimely collection of labs, this problem clearly prevented adequate patient care when labs were not available at the time of the clinical encounters and also posed at least a potential risk to the patients. He said that a solution to the problem needed to include a comprehensive assessment to identify all of the factors contributing to the problem; an accurate assessment of the true magnitude of the problem to include elimination of duplicate, outdated, and previously performed labs; and an assessment of the appropriateness of the labs being ordered.

The investigation revealed numerous efforts to resolve the problems of overdue laboratory requests:

- In a December 18, 2009 memorandum, titled "BEMR House Keeping" and addressed to all clinical staff, LaSalle notes, "Make sure you discontinue old labs, duplicate labs, labs which do not follow the schedule you have assigned for your Pt."
- A March 8, 2010 memorandum from CD LaSalle and HSA Steve Spaulding with a subject line "BEMR Housekeeping" advised all Clinical Staff, "In the process of reviewing your case, if you note the service has already been provided, or is no longer indicated, please remove from the scheduler and indicate in the comment box why the service was canceled." It was also noted, "Before you order labs, look to make sure someone else has not ordered the same labs."
- Minutes from a September 30, 2010 Governing Body Meeting reflect, "Currently looking for an additional Phlebotomist. 1 candidate continues to have issues with EQUIP and is working with Grand Prairie to fix issue. Several previous applicants had difficulties with passing the background clearance and U.S. Citizenship."
- Minutes from a December 13, 2010 Governing Body Meeting reflect, "Phlebotomist (Lab Technician) applicant has completed all required paperwork and the results of the urinalysis (UA) is pending. The estimated start date is planned for January 2011. Once hired there will be a Lab Technician assigned on each compound and alternating at the Camp." (This applicant changed her mind and did not go to work at Fort Dix.)
- Minutes from an April 7, 2011 FCI Fort Dix Administration and Clinical Operations Meeting (attended by Northeast Regional Office Medical Director John Manenti and regional HSA Barbara Cadogan) again addressed the issue, noting:
 - LCDR Baker noted that labs are not completed in a timely manner. Specifically it was discussed FCI Fort Dix has only one Lab Technician. The shortage of manpower results in delinquent labs which ultimately have a negative impact. In an attempt to correct this situation, the Warden has approved to have three (3) contract Lab Technician positions. However, we continue to be challenged in filling the positions due to administrative hiring procedure delays.
 - Warden Zickefoose interjected and reported that there is a second Lab Technician that has been working through some issues that have impacted her start date, but there have been several technicians that have initiated the application process. We note, if not for one reason or another they cannot pass all levels of clearance.
 - Barbara Cadogan recommended that the clinicians (Physicians, EMT/Ps, Nurses) assist with collecting labs in an effort to mitigate the delinquencies. She reminded our staff in the past this has been a plan effectively used at FCI Fort Dix.
- Minutes from an April 29, 2011 Governing Board Meeting reflect, "Currently looking for two (2) Phlebotomists. One (1) candidate continues to work on paperwork issues. Several previous applicants had difficulties with the passing of the background clearance and U.S."

Citizenship."

- Minutes from a July 11, 2011 Governing Board Meeting reflect, "Lab Technicians have financial issues. One LT has significant financial issues and the other although [sic] has financial issues are not as significant."

IV. Violation or Apparent Violation of Law, Rule or Regulation

The investigation revealed no violation of law, rule or regulation by not conducting medical laboratory tests in a timely manner. There is no BOP policy that dictates the timeliness of laboratory tests. In fact, safeguards that exist to ensure compliance to policy (Operational Reviews, Program Reviews, Peer Reviews, and Joint Commission audits) did not contain timeliness of laboratory collections as a line item entry. BOP policy P6370.01 does not specifically address the timeliness of laboratory specimen draws. Although an objective of this policy would be timely and accurate medical laboratory tests, the inaction by the staff members at FCI Fort Dix did not constitute a violation of any policy. Although it was determined that no violation of law, rule, or regulation occurred as a result of the untimely laboratory tests, clinical care guidelines for certain medical conditions do recommend that lab testing occur at periodic intervals, and this did not always occur.

Fort Dix staff members obviously failed to ensure that requested laboratory work was completed in a timely manner. This failure was systemic in nature and involved several different institutional components, and the failure of Health Services' management staff to acknowledge, assess, and remedy the condition that existed negatively reflects on their management abilities. The investigation revealed that the delayed laboratory work spanned several years and included staff who are no longer employed at FCI Fort Dix. Although the efforts of the administration over a period of several months to contract with another phlebotomist were well documented, this action alone does not constitute a realistic effort to address the issue. Unfortunately, management staff focused on this singular solution, and until another phlebotomist could be hired, they continued to operate as usual. It is important to note that if an inmate needed lab work immediately, the health care staff could bring the inmate to the phlebotomist to have labs drawn immediately.

The path to resolving this issue is multi-faceted and is now being addressed by the institution. Although this situation had the potential to negatively impact the health and well-being of the inmate population at FCI Fort Dix, there were no documented Sentinel Events or serious health issues associated to this inaction. Further, although Health Services administrative staff and FCI Fort Dix executive staff members maintain that Drs. Patel and Turner-Foster did not apprise them of the seriousness and extent of the problem, this information was readily available to them. Drs. Patel and Turner-Foster advised administrative staff on several occasions that the problem existed, and they were under no obligation to research the matter in depth to provide evidence of the scope of the problem. When all other avenues to rectify the situation were not effective, they exercised their prerogative to report the matter to OSC.

While we recognize the potential risks posed to the inmates as a result of untimely

laboratory tests, we do not believe management's actions or inaction rose to the level of "gross mismanagement." The staff attempted to hire an additional phlebotomist, and they had the safety valve procedure of bringing an inmate directly to the phlebotomist if there was an immediate need to have his labs drawn. The administration also investigated other avenues to provide relief, such as utilizing other medical staff, and "borrowing" medical staff from other BOP facilities. Our investigation did not reveal any incident of delinquent lab tests related to acute care patients or that resulted in injury to an inmate. Although management could have done more to address the problem, management's efforts were more than perfunctory and were inhibited by some factors beyond management's control, such as the inability to identify additional phlebotomists without credit issues or other issues that rendered them unsuitable for hire.

V. Action Taken or Planned as a Result of the Investigation

On August 17, 2011, Warden Zickefoose implemented a six-phase Corrective Action for FCI Fort Dix Backlogged Inmate Lab Collections. (Note: some of the tasks were completed prior to the formal implementation of the Corrective Action plan.)

Phase I- Training

- A. Train all available clinical staff regarding how to review all pending laboratory requests in BEMR for a specific inmate. **(This component was completed on August 15, 2011.)**
- B. Train all available clinical staff on the operation of the new Hemoglobin A1c, microalbumine/creatinine testing and urinalysis analyzer. These machines will provide a rapid snapshot on diabetic glucose control and nitrates, urobilinogen, protein, pH, blood, specific gravity, ketones, bilirubin, and glucose. These machines were purchased to assist clinical staff with patient care due to the ongoing struggle to hire a phlebotomist. **(This component was completed on August 15, 2011.)**
- C. Review original BEMR "pending lab" report for possible duplicate and triplicate lab entries, as well as removing these unnecessary laboratory entries from BEMR. **(The final "pending lab" count was determined to be 839 backlogged laboratory requests affecting 773 inmates. This component was completed on August 16, 2011.)**

Phase II- Chronic Care Clinic

Determine how many of the 773 inmates were listed in the Chronic Care Clinic. **(This component was completed on August 17, 2011. 433 inmates were determined to be in a Chronic Care Clinic.)**

Phase III- Lab Collections/Review

- A. Implementation of laboratory collection for the backlogged laboratory requests will commence on August 17, 2011, for the inmates housed in the Special Housing Unit,

- approximately 52 "pending labs." **(This was completed on August 17, 2011.)**
- B. Laboratory collection for inmates housed at the Satellite Camp will commence on August 18, 2011, approximately 50 "pending labs." **(This was completed on August 18, 2011.)**
1. Due to FCI Fort Dix's Joint Commission Audit and Operational Review deadline, laboratory collection will be suspended the week of August 22 and resume on August 29, 2011. It should be noted that FCI Fort Dix was reaccredited by the Joint Commission and there were no major concerns noted with patient care.
 2. On August 29, 2011, four teams, consisting of two staff members each (two teams on the east compound and two teams on the west compound) will begin mass laboratory specimen collection. The goal is to draw 40 laboratory specimens per compound for a total of 80 per day. Eighty laboratory specimens per day times four days equals 320 laboratory specimens per week. **(This process was completed as scheduled.)**
 3. Goal completion is scheduled for September 15, 2011. **(On September 15, 2011, it was verified that all delinquent laboratory tests had been completed.)**
- C. A full time lab technician from MCC New York will conduct a staff assist on August 29, 2011, to assist in laboratory specimen collection and training of the medical staff. **(Completed)**
- D. Two staff members have been identified (one on each compound) to receive all lab results for sorting. These results will be sorted into two categories, normal and abnormal. The abnormal results will be immediately scanned into BEMR for physician review. Physicians will review lab results on a daily basis. **(Ongoing)**
- E. Normal lab results will be processed after the abnormal lab results. **(Ongoing)**
- F. While lab results are sorted, scanned, and reviewed daily, our goal is to complete physician review and signature of all lab results by September 21, 2011. **(Not all lab results were co-signed by physicians by September 21, 2011. One physician was delayed in co-signing. That issue was addressed and corrected on September 23, 2011.)**
- G. While physicians will start reviewing labs daily, once the first results are received our goal is to have all backlogged results reviewed and signed by the physician on September 28, 2011. **(All backlogged lab results were reviewed and signed off by September 28, 2011.)**

Phase IV- External Medical Review

Central Office and Northeast Regional Office will establish a medical review team to audit all inmate medical files with abnormal lab results or most severely ill inmates who had backlogged labs. Target date is the first part of October 2011. **(Completed on October 5, 2011.)**

Phase V- Hiring

Phlebotomist Hiring- two additional contract phlebotomists have finally agreed to work at FCI Fort Dix. Three new contract phlebotomists began working at FCI Fort Dix on September 7, 2011, September 26, 2011, and October 4, 2011, respectively. This will give FCI Fort Dix four contract phlebotomists to cover the east and west compounds as well as the Satellite Camp.

Phase VI- Perpetual Audit

It is possible for inmates to be received from another institution with a pending lab showing in the BEMR program. Therefore, starting at the end of September and each month thereafter, the Improving Organizational Performance (IOP) Coordinator will pull the "pending lab" report in order to ensure that any pending or backlogged labs are scheduled in a timely manner. (An email from HSA Baker, dated September 15, 2011, clarified this directive to indicate that the start date used by the IOP Coordinator will always be January 1, 2008, to ensure the report captures inmates who may have transferred in to Fort Dix with pending lab work.)

During a second interview with Drs. Patel and Turner-Foster, both indicated that this particular issue was apparently resolved, and agreed that, if the systemic processes put in place to prevent the delinquency of lab request draws were continued, the matter should be of no further concern.

VI. Other Corrective Action

A) Training

Health Services Management Staff will receive training regarding the need to monitor laboratory tests and the manner by which this manner can be accomplished.

B) Future Monitoring

In order to ensure that labs are taken and processed in a timely manner, the Health Services Branch in Central Office will require submission of a monthly report by the Northeast Regional HAS identifying outstanding lab draws (greater than 30 days for routine labs) at FCI Fort Dix. Finally, to further the BOP's commitment of permanently resolving this issue and to prevent recurrences of this situation, a Performance Expectation will be added to the Performance Work Plan of the institutional HAS requiring the monitoring of the timeliness and submission of laboratory specimens for testing.

