

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**THE PASSAMAQUODDY TRIBE'S  
PLEASANT POINT HEALTH CENTER  
DID NOT ALWAYS MEET FEDERAL AND  
TRIBAL HEALTH AND SAFETY  
REQUIREMENTS**

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# *Office of Inspector General*

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## Report in Brief

Date: July 2018

Report No. A-01-17-01500

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
**OFFICE OF INSPECTOR GENERAL**



### Why OIG Did This Review

Longstanding challenges, including insufficient oversight and limited access to specialists, likely impact the quality of health care services provided to American Indians and Alaskan Natives. In certain cases, the Federal government permits Tribes to administer their own health care programs through Federally Qualified Health Centers (FQHC), which receive Federal funding but limited Federal oversight in recognition of the independent nation status of the Tribes. An initial OIG analysis of the Passamaquoddy Tribe's Pleasant Point Health Center (PPHC), a Medicare FQHC, identified potential concerns about quality of care provided to its members which warranted a more detailed review.

Our objective was to determine whether the Passamaquoddy Tribe at Pleasant Point met Federal and Tribal health and safety requirements for the quality of health care provided at PPHC.

### How OIG Did This Review

We reviewed the scope of services identified in the Indian Health Service's contracts with the Passamaquoddy Tribe at Pleasant Point, requirements for Medicare FQHC, and Tribal requirements for calendar years 2014 through 2016 and compared services that were required to be provided to actual services rendered at PPHC.

## The Passamaquoddy Tribe's Pleasant Point Health Center Did Not Always Meet Federal and Tribal Health and Safety Requirements

### What OIG Found

The Passamaquoddy Tribe at Pleasant Point did not always meet Federal and Tribal health and safety requirements for the quality of care at PPHC. Specifically, we found that PPHC did not always have a physician who provided medical direction for the health center, clear lines of authority and responsibility between medical and administrative decision-making, medical policies and procedures (including pain-management treatment prioritization for opioid prescription and compliance monitoring), and other policies and procedures needed to comply with the requirements.

Because the Passamaquoddy Tribe at Pleasant Point did not provide adequate oversight and implement policies and procedures for its health center, PPHC did not always meet Federal and Tribal requirements, which increased the risk that patients did not always receive quality health care and PPHC may hire unqualified medical providers and administrative staff.

### What OIG Recommends

We made several recommendations to the Passamaquoddy Tribe at Pleasant Point, including that it (1) ensures PPHC is under the medical direction of a physician, (2) establishes clear lines of authority and responsibility between medical and administrative decision-making, and (3) develops and implements medical policies and procedures to comply with health and safety requirements.

The Passamaquoddy Tribe at Pleasant Point concurred with our recommendations. For example, PPHC has solicited assistance from Indian Health Services to recruit a medical director to fulfill the FQHC required physician responsibilities.

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## INTRODUCTION

### WHY WE DID THIS REVIEW

American Indians and Alaskan Natives experience higher mortality rates than all races in the United States in specific categories such as diabetes, drug- and alcohol-induced deaths, chronic liver disease, assault, homicide, and suicide. The Office of Inspector General (OIG) has identified longstanding challenges, including insufficient oversight and limited access to specialists that likely impact the quality of health care services provided to American Indians and Alaskan Natives. Tribes may operate their own clinics with Indian Health Service (IHS) funds. Tribal clinics also may enroll as Medicare Federally Qualified Health Centers (FQHCs). An initial OIG analysis of the Passamaquoddy Tribe's Pleasant Point Health Center (PPHC), a Tribal FQHC, identified potential concerns about quality of care provided to its members, which warranted a more detailed review.<sup>1</sup>

### OBJECTIVE

Our objective was to determine whether the Passamaquoddy Tribe at Pleasant Point met Federal and Tribal health and safety requirements for the quality of health care provided at PPHC.

### BACKGROUND

Within the U.S. Department of Health and Human Services, IHS's mission is to partner with American Indians and Alaskan Natives to elevate their physical, mental, social, and spiritual health to the highest level. The goal of IHS is to ensure that comprehensive, culturally acceptable personal and public health services are available and accessible to all of the approximately 2.2 million people of the 573 federally-recognized Tribes.

In 1975, Congress recognized the importance of Tribal decision-making in Tribal affairs and the nation-to-nation relationship between the United States and Tribes through the passage of the Indian Self-Determination and Education Assistance Act (ISDEAA) (Public Law 93-638). Under Title I of the ISDEAA, federally-recognized Tribes can contract annually with IHS for funding to administer their own health care programs and services that IHS would otherwise provide.

#### **Tribal Medicare Federally Qualified Health Centers**

While most FQHCs are outpatient primary care facilities that provide care to primarily low-income individuals and receive grants under section 330 of the Public Health Service Act, health centers that are funded by IHS may apply to become Medicare FQHCs. For purposes of

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<sup>1</sup> This review focused on the health care services provided at PPHC. We are conducting a second, ongoing review of health care for Tribal patients referred by PPHC to external health facilities for services that are purchased by the Tribe in a program known as Purchased and Referred Care.

Medicare Part B, the Social Security Act considers an FQHC to be (1) a 330 grantee, (2) a facility that meets the requirements of a 330 grantee, (3) an entity that was treated as a federally funded health center for purposes of Medicare part B as of January 1, 1990, or (4) a facility operated by a Tribe, Tribal organization, or urban Indian organization receiving IHS funding. PPHC is a Tribal health center that is funded by IHS and is covered by the definition in 1861(aa)(4)(D) of the Social Security Act.

By obtaining certification from the Centers for Medicare & Medicaid Services (CMS) as an FQHC for Medicare, a clinic certified under Medicare will be deemed to meet the standards for certification under Medicaid (42 CFR 491.3). Tribally-operated health centers may receive reimbursement for health services provided to qualifying individuals.

CMS certifies tribally-operated health centers as Medicare FQHCs based on the Tribe's written self-attestation that the health center will comply with specific health and safety requirements. CMS performs monitoring site visits at these health centers only when it receives a patient complaint and limits its investigation to address the specific grievance.

Tribal Medicare FQHCs are not required to obtain medical accreditation or undergo periodic inspections and evaluations by medical accrediting organizations.<sup>2</sup> Government oversight agencies do not conduct an initial inspection of the health center when it begins operation and perform limited facility inspections to ensure compliance with health and safety requirements.

### **Passamaquoddy Tribe**

The Passamaquoddy Tribe resides on two separate reservations in Maine: Indian Township and Pleasant Point. Each reservation has its own distinct Tribal government consisting of a chief, a vice chief, and a Tribal council who are elected for varying terms by Tribe members who live on or near their respective reservation. Each Tribal government separately contracts with IHS under Title I of the ISDEAA to operate a health center located on its reservation. The Passamaquoddy Tribe at Pleasant Point has a total population of approximately 2,200.

### **Pleasant Point Health Center**

The Passamaquoddy Tribe at Pleasant Point, which owns and operates PPHC, provides outpatient health care to approximately 1,000 of its members. Specifically, PPHC provides general medicine, diabetes care, behavioral health, general dentistry, nursing, laboratory services, optometry, podiatry, chiropractic medicine, and pharmacy services. PPHC also assists eligible members to obtain referrals for contracted health care services from off-site providers and local hospitals. The Passamaquoddy Tribe at Pleasant Point receives about \$3.4 million under its annual Title I contract with IHS to operate its health center.

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<sup>2</sup> In this report, all references to "FQHC" pertain solely to a Tribal Medicare FQHC.

Through the IHS contract, the Tribal chief and council hire and employ PPHC's health director, who is in charge of administration and works under the immediate supervision of the chief. The health director administers and manages the PPHC programs, provides supervision to the various health program supervisors, including the medical director, and supervises the PPHC staff to ensure the delivery of quality health care. The medical director participates in the medical care of ambulatory patients, provides direct supervision of all medical providers, and provides direction for the medical laboratory, nursing, pharmacy, dental, medical records, and other PPHC medical programs.

Since certifying PPHC as an FQHC in 1991, CMS has received one complaint and addressed the complaint through telephone conversations with the health director and the individual who made the complaint.

## **HOW WE CONDUCTED THIS REVIEW**

We reviewed the scope of services identified in the IHS contracts with the Passamaquoddy Tribe at Pleasant Point, requirements for Medicare FQHC, and Tribal requirements for calendar years (CYs) 2014 through 2016 and compared services that were required to be provided to actual services rendered at PPHC. We interviewed PPHC staff and reviewed medical, pharmacy, and personnel records to obtain an understanding of medical and administrative operations at PPHC. We observed the physical conditions of the PPHC as well as selected medical equipment, instruments, and supplies and reported our observations. We limited our review of internal controls to those relating to our audit objective.

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. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains the details of our scope and methodology.

## **FINDINGS**

The Passamaquoddy Tribe at Pleasant Point did not always meet Federal and Tribal health and safety requirements for the quality of care at PPHC. Specifically, we found that PPHC did not always have:

- a physician who provided the medical direction for the health center and performed the required oversight duties;
- clear lines of authority and responsibility between medical and administrative decision-making;



- written medical policies and procedures, which include pain-management treatment prioritization requirements for opioid prescription and compliance monitoring;
- written policies and procedures for medical documentation and complete patient health records;
- an annual quality assurance evaluation of patient health care;
- complete preemployment screening, which includes fingerprinting of employees who come in contact with Indian children; and
- a safe, clean, and accessible environment and a preventative-maintenance program for the health care facility and medical equipment.

Because the Passamaquoddy Tribe at Pleasant Point did not provide adequate oversight and implement policies and procedures for its health center, PPHC did not always meet Federal and Tribal requirements, which increased the risk that (1) patients did not always receive quality health care and (2) PPHC may have hired unqualified medical providers and administrative staff.

#### **FEDERALLY QUALIFIED HEALTH CENTER PHYSICIAN RESPONSIBILITIES NOT ALWAYS PERFORMED**

An FQHC must be under the medical direction of a physician. In addition to providing medical care to patients, this physician provides medical direction for the center's health care activities, consultation for and medical supervision of the health care staff, and reviews of the health center's patient records. Furthermore, the physician participates in the development, execution, and periodic review of the health center's written policies and the services provided to patients that benefit from Federal programs (42 CFR 491.7 & 491.8).

PPHC had at least one physician on staff who provided medical care to health center patients throughout the period we reviewed. However, PPHC was not under the medical direction of a physician who performed the additional FQHC-required duties beyond patient care for the entire period. PPHC could not provide evidence that a physician provided medical direction for the health center's activities. Specifically, PPHC could not demonstrate that a physician provided medical supervision of the health care staff,<sup>3</sup> reviewed patient records, or participated in the development, execution, and periodic review of PPHC's written policies and the services provided to patients that benefit from Federal programs.

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<sup>3</sup> Although physicians hired as "medical director" were contractually required to perform supervision of the medical staff, PPHC could not provide evidence that its physician "medical director" had actually supervised medical staff. We further note that contract physicians hired for short periods were required to work cooperatively with medical and support staff, but were not required to supervise the medical staff at PPHC.

For example, a physician did not develop and implement medical policies and procedures for reporting medical errors or for ensuring the supervision, retraining, and monitoring of clinical staff to prevent a reoccurrence of medical errors.

We noted that during 15 of the 36 months in the review period, PPHC had a physician serving in the position of “medical director” with defined duties that corresponded to that required of an FQHC physician; this physician worked under the supervision of the health director. Although the physician performing the medical director role may have provided direct care to patients, PPHC did not demonstrate that this individual satisfied the additional requirements of an FQHC physician.

PPHC was not always under the medical direction of a physician because the health director did not provide the necessary oversight and supervision to ensure the performance of all federally required duties. In addition, the reliance on contract physicians to provide direct care for limited time periods at the health center did not satisfy the additional responsibility requirements of an FQHC physician. Because all FQHC physician responsibilities were not performed, PPHC patients did not receive long-term continuity of care and faced an increased risk of compromised health care.

#### **CLEAR LINES OF AUTHORITY AND RESPONSIBILITY LACKING BETWEEN MEDICAL AND ADMINISTRATIVE DECISION-MAKING**

A health center must be under the medical direction of a physician (42 CFR 491.7(a)(1)). This physician must provide medical direction for a center’s health care activities and consultation for, and medical supervision of, the health care staff (42 CFR 491.8(b)(1)).

A health center’s physician assistant or nurse practitioner participates in the development, execution, and periodic review of the policies governing the services of the health center and participates with a physician in a periodic review of patient health records. To the extent the following functions are not performed by a physician, a nurse practitioner or physician assistant provides services in accordance with the health center’s policies, refers patients to external facilities for services not available at the health center, and assures adequate maintenance of patient health records (42 CFR 491.8 (c)).

An FQHC must clearly set forth in writing its policies and its lines of authorities and responsibilities (42 CFR 491.7 (a)(2)).

PPHC lacked written medical policies that identify medical and nonmedical staff roles in determining patient care. During our audit period, PPHC had a single health director, who did not have a medical education or medical training, but exercised some roles reserved for a physician or other licensed medical provider. For example, the health director was tasked with supervising PPHC’s health care staff. In some cases, he wrote their performance evaluations and had influence in the decision-making process for the continuation of their employment at PPHC. In certain circumstances, he also intervened with medical providers on the behalf of

patients dissatisfied with their pain-management treatment. In certain instances, medical staff indicated that they felt pressured by the health director to change a patient's prescription, which they felt was inappropriate because the health director did not have medical training.

Additionally, in 2016 while fulfilling his job responsibility to manage PPHC within budget constraints, the health director placed significant limits on patient lab testing. Specifically, we noted a significant reduction in specific compliance monitoring urine drug tests for patients on an opioid treatment plan in November 2016, and no evidence that patients received this test in December 2016.<sup>4</sup> One PPHC provider indicated that the health director limited urine drug testing because of funding restrictions and not based on medical need.

PPHC's lines of authorities and responsibilities were not clearly defined because the health center (1) lacked written medical policies that identify medical and nonmedical staff roles in determining patient care and (2) the health director's written responsibilities did not ensure that only qualified medical staff with the appropriate clinical education and training address patient medical complaints. Further, the position description did not specifically require that the health director incorporate medical staff input in prioritizing relative patient medical care based on available funding. Without clear lines of authority and responsibility between medical and administrative decision-making at PPHC, patients faced an increased risk of compromised care and decreased effectiveness in detecting diversion and potential opioid abuse.

#### **NO WRITTEN MEDICAL POLICIES AND PROCEDURES FOR OPIOID PRESCRIBING AND COMPLIANCE MONITORING**

FQHCs must (1) provide health services in accordance with applicable Federal, State, and local laws; (2) develop policies with the advice of at least one physician, at least one mid-level provider, and with one medical professional who is not a member of the staff; and (3) furnish health services in accordance with its written policies, including rules for the administration of drugs (42 CFR 491.9).

With the exception of its behavioral health department, PPHC did not develop policies with the advice of at least one physician, at least one mid-level provider, and one medical professional who was not a member of its staff. PPHC also did not furnish services in accordance with its written policies, including rules for the administration of drugs.

PPHC did not have written medical policies and procedures because PPHC was not under the medical direction of a physician, who could develop and implement medical policies and procedures, and because of health care staff turnover. We noted that 11 of 14 medical providers worked at PPHC for less than 1 year during our review period. Some health care staff

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<sup>4</sup> One provider noted that the specific type of testing restricted was extremely useful for compliance monitoring. The test results yielded not only whether the patient's urine contained illicit substances and medications not on the patient's medication regimen, but also indicators as to whether the patient had tampered with the specimen in order to affect the accuracy of the test.

expressed concerns that patients with opioid prescriptions made threats of violence against them.

Written policies and procedures provide the framework for provider medical decision-making and patient care by establishing priorities and processes for medical treatment, including pain-management policies and procedures for prescribing opioids to patients and monitoring patient use of opioids. The lack of written policies and procedures could result in inconsistencies in quality of care. For example, we found inconsistencies in the medical providers' pain-management treatment plans used to monitor patients with opioid prescriptions. Based on a judgmental selection of medical records for 30 patients who received both opioid prescriptions and urine drug tests, we found that 6 of the patients had not signed a Controlled Substance Agreement, which is an agreement to comply with their opioid treatment plan. Additionally, we found that:

- for 23 of the 30 patients who received urine drug tests, medical providers documented both their review of the test results and their discussions with patients about the test results, and incorporated any drug test findings into the patients' treatment plans;
- for 6 of the 30 patients who received urine drug tests, medical providers did not document their review of the test results and their discussions with patients about the test results, and did not incorporate any drug test findings into the patients' treatment plans; and
- for 1 of the 30 patients who received a urine drug test, the medical provider documented his review of the test results, but did not document any discussion of the test results with the patient or incorporate the findings in the patient's treatment plan.

Without written policies in place, PPHC did not have sufficient guidance to facilitate day-to-day decision-making related to patient care and opioid prescribing practices.

## **INCOMPLETE PATIENT HEALTH RECORDS**

An FQHC must maintain a medical record system in accordance with policies and procedures that require providers to maintain separate records for each patient that include all physician orders, reports of treatment and medications, medical providers' progress notes, pertinent information to monitor a patient's progress, and the signatures of the providers or other health care professionals (42 CFR 491.10).

An FQHC must conduct or arrange for an annual program evaluation which includes a review of active and closed patient health records (42 CFR 491.11).

PPHC did not always comply with medical documentation requirements. Specifically, we found that medical providers did not always complete medical progress notes that included a description of the patient's condition, a diagnosis, and a treatment plan. For example, we

found that for three judgmentally selected providers:

- one medical provider did not write notes for 526 out of 1,762 patient visits (or approximately 30 percent) during a 11-month period;
- a second medical provider did not write notes for 23 out of 36 patient visits (or approximately 64 percent) during a 2-week period; and
- a third medical provider did not write notes for 67 out of 1,382 patient visits (or approximately 5 percent) during an 8-month period.

These issues occurred because PPHC did not have written policies and procedures that required medical providers to complete and sign progress notes for patient visits within a specified time and did not have a physician providing medical direction to coordinate the development of those policies and procedures and to oversee provider compliance with medical documentation requirements. In addition, as discussed in the next report section, these issues resulted because the PPHC did not conduct annual program evaluations, which should include a review of active and closed patient health records.

As a result, subsequent providers may not have had adequate documentation to make accurate diagnoses of time-sensitive medical conditions, and PPHC staff could not process referrals to medical specialists and external providers without the documentation of the medical concern identified by the clinician in the initial patient visit.

## **NO ANNUAL QUALITY ASSURANCE EVALUATIONS OF PATIENT HEALTH CARE**

FQHCs must conduct or arrange for an annual program evaluation that includes (1) an evaluation of the number of patients served, the volume of services, and whether the utilization of services was appropriate; (2) a sample of both active and closed patient health records; and (3) an evaluation of the health center's health care policies and whether they were followed. The health center staff consider the findings of the program evaluation and take corrective action if necessary (42 CFR 491.11).

PPHC did not carry out or arrange for an annual program evaluation to ensure quality assurance of health services provided during the period of our review, nor could PPHC provide evidence of any annual evaluations conducted in the 25 years since it was certified as an FQHC.

At PPHC's request, IHS performed in 2016 a simulated evaluation to show how the health center could improve its health care processes.<sup>5</sup>

PPHC did not conduct annual program evaluations because it did not designate a qualified medical staff member to carry out, or arrange for, an annual evaluation of its total program.

As a result, PPHC did not identify findings and take corrective actions to improve health care in areas, such as opioid prescribing and compliance monitoring, and had no assurance that the utilization of health care services was appropriate.

## **INCOMPLETE PREEMPLOYMENT SCREENING CONTROLS**

Federally funded Indian organizations must conduct background investigations on all employees and contractors that have regular contact with Indian children (section 408 of the Indian Child Protection and Family Violence Prevention Act).

A criminal history background check includes a fingerprint check through the Criminal Justice Information Services Division of the Federal Bureau of Investigation (FBI), under procedures approved by the FBI, and inquiries to State and Tribal law enforcement agencies for the previous 5 years of residence listed on the individual's application (42 CFR 136.406(b)).

OIG has the authority to exclude individuals and entities from federally funded health care programs and maintains a list of all currently excluded individuals and entities called the List of Excluded Individuals and Entities (LEIE). Entities receiving Federal health care program funds may not hire an individual or entity on the LEIE. Anyone who hires an individual or entity on the LEIE may be subject to civil monetary penalties (Social Security Act Section 1128 and 1156).<sup>6</sup>

Tribal requirements state each employee who will be working with children or have contact with children will go through a State Bureau Investigation (SBI) background and security investigation. These background checks will be done by the police and personnel departments (Passamaquoddy Tribal Government Personnel Handbook: Employment Reference Checks).

As part of the prescreening process, an applicant who applies for a position with the Pleasant Point Passamaquoddy Tribal Government (PPPTG) will be subject to substance-abuse testing. PPPTG will review the results of substance abuse testing for each applicant before making an

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<sup>5</sup> In December 2016, an IHS team of medical professionals completed a review of PPHC health services. This survey simulated an inspection and evaluation by an external medical accreditation agency of a health center in order to obtain medical accreditation. The simulated survey provided an objective process of review and feedback of medical services at PPHC should the facility seek to obtain medical accreditation in the future.

<sup>6</sup> While not required, OIG recommends that providers maintain documentation of the initial name search and any additional searches conducted in order to verify results of potential name matches (<https://oig.hhs.gov/exclusions/tips.asp>).

offer of an interview (Passamaquoddy Tribal Government Personnel Handbook: Substance Abuse Testing Policies and Procedures).

Applicants must submit a completed application form and resume, which must include three written references with at least one being from their most recent employer (Passamaquoddy Tribal Government Personnel Handbook: Reference Checking).

Of the 27 employees who had regular contact with Indian children, none had evidence of fingerprinting or an FBI background check per Federal requirements, and 20 did not have evidence of an SBI Criminal Check per Tribal policies and procedures.

PPHC could not provide evidence that it accessed the OIG/Excluded Parties list before hiring any of its 53 employees, although the assistant health director maintained he did perform this validation but did not document his review. We confirmed that none of the employees were on the OIG/Excluded Parties list.

PPHC did not always comply with Federal and Tribal requirements for preemployment screening of applicants. Specifically, we found that for the 53 employees:

- 44 employee files did not have evidence of preemployment drug testing as required by Tribal policies and procedures and
- 32 employee files did not have documentation of 3 reference checks per Tribal policies and procedures.

PPHC did not comply with Federal and Tribal personnel requirements because Tribal staff were not always aware of preemployment screening and documentation requirements, including fingerprinting or FBI background checks, for employees in contact with Indian children.

As a result, Indian children and other patients faced the risk of substandard treatment or unsafe care provided by health care staff who were not properly screened prior to employment.

#### **PPHC DID NOT ALWAYS PROVIDE A SAFE, CLEAN, AND ACCESSIBLE ENVIRONMENT AND HAVE A PREVENTATIVE MAINTENANCE PROGRAM FOR THE PROVISION OF HEALTH CARE**

An FQHC must provide a safe, clean, and accessible environment for the provision of direct health services, and must have a preventive maintenance program to keep patient care equipment in safe operating condition (42 CFR 491.6).

PPHC did not meet Federal requirements for safety, cleanliness, and access to care. Specifically, we found:

- cracked linoleum flooring, ripped vinyl on an exam table, rusted medical instruments, expired medical supplies, and an unclean medical instrument tray (Appendix E);

- telehealth equipment, which is supposed to provide patients with access to care from distant locations for specialized health services such as behavioral counseling or dermatological consultations, was not operational; and
- patient care areas with nonfunctioning alarms that are meant to alert emergency responders of agitated patients whose behavior compromises the safety of other patients or health care providers.

PPHC did not comply with facilities and medical equipment requirements because it did not have policies and procedures and adequate staffing to regularly inspect and maintain its facilities, clinical equipment, and medical supplies. In addition, telehealth equipment was not operational because PPHC did not maintain its technical support and software contracts.

As a result, patients had an increased risk of compromised safety, injury from falls, infections, transmitted diseases, and delayed assistance by emergency responders. In addition, patients with limited transportation resources could not receive specialized health care from remote locations via telehealth services.

## **RECOMMENDATIONS**

We recommend that the Passamaquoddy Tribe at Pleasant Point:

- ensures PPHC is under the medical direction of a physician, in accordance with Federal and Tribal requirements;
- establishes clear lines of authority between the health director's administrative duties and the medical staff's duties to provide care by defining job responsibilities as well as policies and procedures that ensure:
  - medical complaints are resolved by staff with the appropriate clinical training who can assess and evaluate patient-care decisions and
  - patient-care decisions are prioritized with appropriate input from medical staff during periods of limited funding;
- develop, approve, and implement with the advice of the required group of professional medical staff written medical policies and procedures that include:
  - pain-management treatment prioritization requirements for opioid prescription and compliance monitoring and
  - requirements for timely completion, signature, and review of patient health records;



- conduct annual program evaluations in accordance with Federal requirements;
- implement Federal and Tribal preemployment screening controls for employees who have not been fully screened prior to employment and for new staff hired at PPHC, including the performance of fingerprinting and FBI background checks for all staff currently working with Indian children; and
- provide a safe, clean, and accessible environment with a preventative maintenance program for the facility and medical equipment for the provision of health care.

### **THE PASSAMAQUODDY TRIBE AT PLEASANT POINT COMMENTS**

In written comments on our draft report, the Passamaquoddy Tribe at Pleasant Point concurred with our recommendations and described actions that it has taken or planned to take to address them. For example, PPHC has solicited assistance from IHS to recruit a medical director to fulfill the FQHC required physician responsibilities. Additionally, PPHC stated it has updated its position descriptions for health director and medical director to emphasize the separate administrative and medical roles. The Passamaquoddy Tribe at Pleasant Point's comments are included in their entirety as Appendix C.

## **APPENDIX A: AUDIT SCOPE AND METHODOLOGY**

We reviewed PPHC's operations relative to Federal and Tribal health and safety requirements for CYs 2014 through 2016. We limited our review of internal controls to those applicable to the delivery of health care.

We conducted our fieldwork at the Pleasant Point Reservation and PPHC located in Sipayik, Maine, from September 2016 through April 2017.

### **SCOPE**

To accomplish our objectives, we:

- reviewed applicable Federal and Tribal requirements for health care delivery at PPHC;
- reviewed annual performance Audit Reports (A-133) for Tribal health facilities;
- interviewed program officials to understand the CMS certification process for an FQHC;
- reviewed the IHS contracting process with Title I Tribes;
- reviewed the Passamaquoddy Tribe's Title I Contracts for CYs 2014 through 2016 for PPHC to identify health services contracted with IHS;
- reviewed the organization chart and job descriptions for PPHC employees;
- reviewed health care provider verification processes prior to employment;
- verified medical licenses for health care providers at PPHC on State websites and reviewed preemployment screening control processes and documentation;
- interviewed health providers at the Tribal health facilities to understand health care delivery processes for services provided;
- performed an inspection of PPHC and select patient care equipment and researched manufacturer's maintenance requirements;
- obtained an understanding of the electronic health records system used for the documentation of health care services at PPHC and reviewed and analyzed the records;
- generated reports to document and quantify health service related issues;

- reviewed contractor monitoring reports to identify provider usage of medication compliance testing results;
- assessed the security controls and processes for ordering, receipt, inventory, and dispensing of pharmaceuticals in the PPHC pharmacy;
- selected and compared to the pharmacy's inventory count a judgmental selection of medications in the pharmacy;
- confirmed that a judgmental selection of medications in the pharmacy did not exceed the labeled expiration date;
- met with State officials and PPHC and pharmacy staff to understand the State requirements for the use of the prescription drug monitoring program and PPHC's usage of the system to monitor medications prescribed and pharmaceuticals dispensed at the Tribal health facilities;
- summarized results of our review; and
- discussed audit results with the Tribal chief, health director, and assistant health director.

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. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## APPENDIX B: PHOTOGRAPHS OF INSTANCES OF NONCOMPLIANCE



**Photograph 1:** Cracked linoleum flooring in triage room. Cracked flooring in medical treatment areas increases the risk that staff and patients could trip and fall resulting in injury and that the treatment area cannot be adequately cleaned and sanitized.



**Photograph 2:** Patient exam table with torn cover. Equipment that is not adequately repaired, cleaned, and sanitized increases the risk of infection and disease transmission to staff and patients.

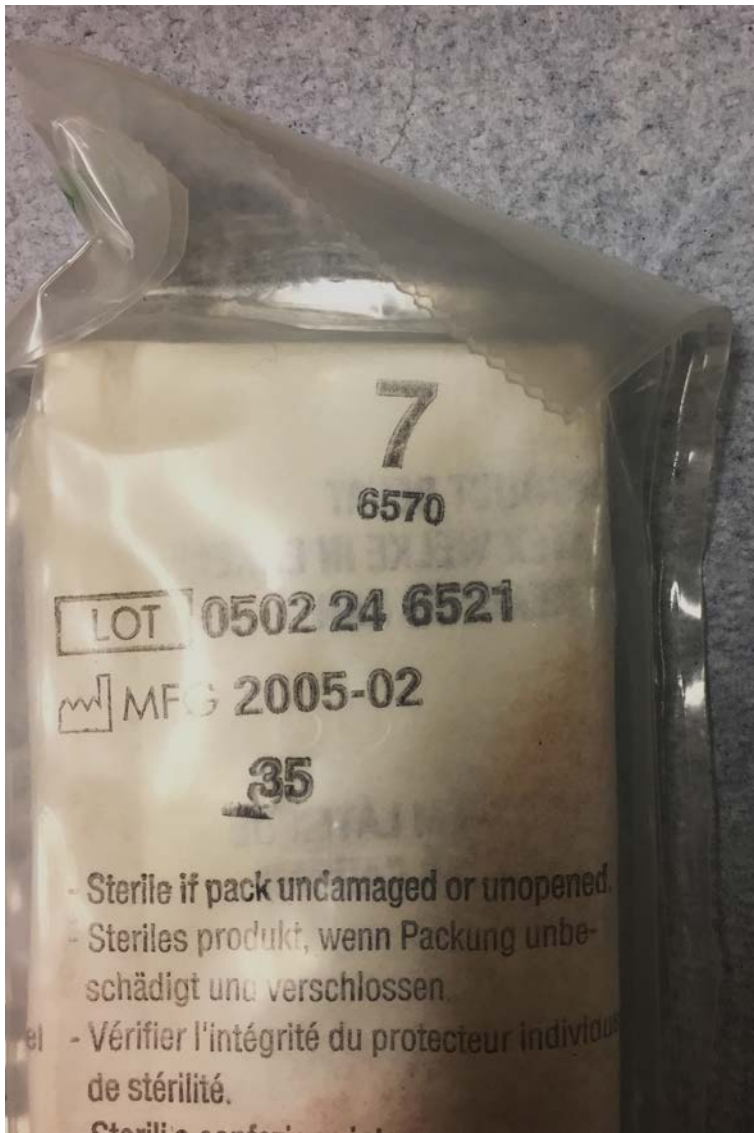


**Photograph 3:** Rusted medical instruments. The use of rusted medical instruments increases the risk of infection to patients.



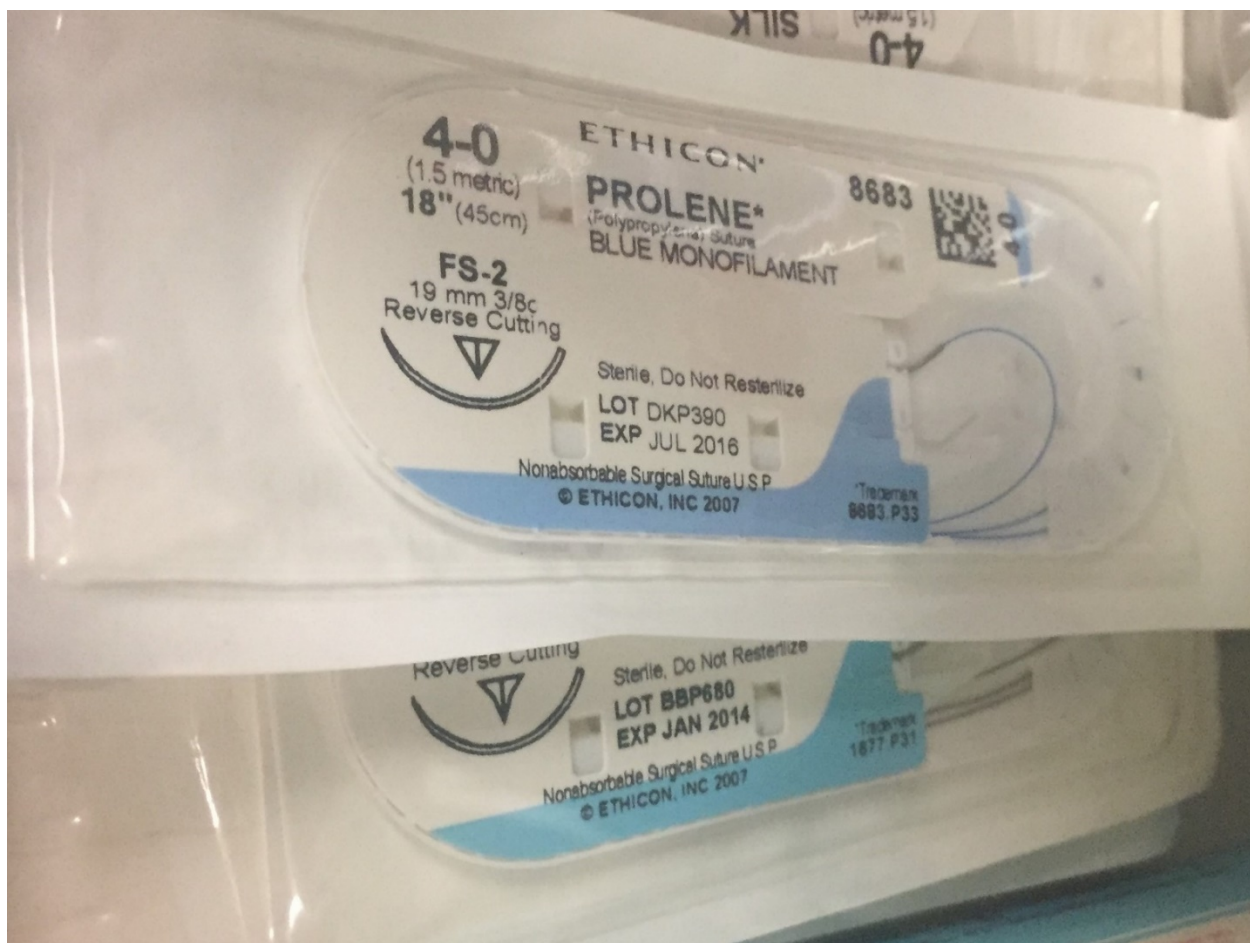
**Photograph 4 (package front):** Expired latex medical gloves manufactured in February 2005. (Note: Latex gloves have an approximate 3 year shelf life from manufacture date. Glove was photographed on December 2, 2016.) Gloves beyond the expiration date have an increased risk of tearing or cracking during use.





**Photograph 5 (package back):** Expired latex medical gloves manufactured in February 2005. (Note: Latex gloves have an approximate 3 year shelf life from manufacture date. Glove was photographed on December 2, 2016. ) Gloves beyond the expiration date have an increased risk of tearing or cracking during use.



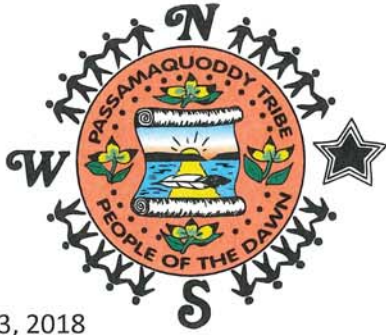


**Photograph 6:** Suture kits expired in January 2014 and July 2016. (Suture materials were photographed on December 2, 2016.) The manufacturer recommends that expired sutures should be used for education, training, and nonclinical research only.



**Photograph 7:** Unclean medical instrument tray. Equipment that is not sanitized properly increases the risk of infection and disease transmission to patients.

## APPENDIX C: THE PASSAMAQUODDY TRIBE AT PLEASANT POINT COMMENTS



*Pleasant Point Reservation*  
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June 13, 2018

David Lamir  
Regional Inspector General  
For Audit Services  
Office of Audit Services, Region 1  
15 Sudbury Street, Room 2425  
Boston, MA 02203

RE: A-01-17-01500

Dear Mr. Lamir

Please consider this letter the official response to letter dated May 7, 2017 regarding draft report number A-01-17-01500 entitled *The Passamaquoddy Tribe's Pleasant Point Health Center Did Not Always Meet Federal and Tribal Health and Safety Requirements*. This draft report was reviewed with members of the Pleasant Point Tribal Council and the Interim Health Director.

As noted in the report, the field work for this audit occurred over a seven month period (September 2016-April 2017). We are a bit perplexed that the report was limited to 12 pages (excluding the attachments). Although we anticipated a much more substantive and detailed report, we take the findings seriously and have been working to correct deficiencies even before this draft report was received.

The Pleasant Point Tribal Government concurs with each of the findings listed in the draft report as written. A description of corrective action, taken or planned, is provided below:

### **Federally Qualified Health Center Physician Responsibilities Not Always Performed**

We are aware of the FQHC requirement to have a Medical Director to oversee patient care and have been actively recruiting to fill the position. Unfortunately, there is a shortage of medical providers across Indian Country. We have solicited assistance from the Indian Health Service, Nashville Area Office to assist us with recruitment efforts as well.

Currently, we have draft medical policies and procedures that can serve as a starting point for the new Medical Director to review/revise. Once they are complete, they will be presented to the Tribal Council for adoption.

### **Clear Lines of Authority and Responsibility Lacking Between Medical and Administrative Decision-Making**



While recruitment efforts are underway, we have also recently revised position description for the Medical Director and the Health Director position. The new descriptions strengthen to position of Medical Director that ensures quality of care and clarifies the administrative role of the Health Director.

In February 2018, PPHC reinstituted the Managed Care Team, which is standard in most IHS and Tribal Health facilities. This team reviews requests for offsite care to ensure that the services fall into current IHS Priority levels (excluding Priority 1 levels of care- life threatening/emergent care) that we are operating within and also to ensure that we have funding to pay for services that are not emergent (Priority 2 and 3). Priority 1 levels of care are automatically processed without review.

### **No Written Medical Policies and Procedures for Opioid Prescribing and Compliance Monitoring**

PPHC will develop and adopt policies and procedures for prescribing and monitoring opioids when permanent medical providers are hired. These procedures will be developed in collaboration with the medical director, mid-level provider, a medical provider not currently on staff, and a member of the behavioral health staff. In the interim, the locum physician is utilizing a contract with patients that was modified from her own clinical practice for use in monitoring usage of controlled substances. Compliance is monitored through urine drug screens, pill counts, and pharmacy utilization reviews.

### **Incomplete Patient Health Records**

We understand that incomplete medical records negatively impacts quality of care. In addition to developing policies and procedures, we have added several practices to ensure that records are completed and reviewed in a timely manner. These include:

The Medical Records technician regularly reviews encounters to ensure there are notes on each visit. If there are incomplete records, a report is generated and given to the provider and our onsite quality assurance staff person. This practice allows us to monitor record completion and avoid any major incidents regarding documentation.

Consultation reports are all scanned into the Electronic Health Record (EHR) on receipt. Medical providers are tagged in the system to review the consult note. The EHR system requires the medical provider to electronically sign the report to indicate their review. This process ensures that all consult notes are reviewed and the providers can efficiently request any follow-up that is needed for a particular patient.

As of March 2018, lab reports from our offsite lab provider are automatically loaded into our EHR system. This is a long awaited improvement to our system. As the lab reports come in, the lab technician and medical provider are tagged for review.

Urine drug screens are being offered for all patients with a controlled substance agreement. We recently had to find a new lab to provide this service. The last agency stopped providing services unexpectedly. Our new provider seems responsive to our needs and also was able to offer a discounted rate for any uninsured patient. This will help contain cost over time.

We are also exploring the use of medical scribes at PPHC. A medical scribe would participate in each patient encounter and document the discussion and essentially the medical exam within our EHR system as it is occurring. Although this is how EHR intends for documentation to occur, we have found that many medical providers do not have the keyboarding or computer skills that allow this to happen easily. With the use of a scribe, the medical provider would only have to review for accuracy and add any additional comments and diagnosis. This would greatly improve the accuracy of documentation. It would also allow for more timely completion of medical referrals for our patients. We envision this medical scribe to also be an EHR "Super User" that can easily navigate the medical record system and capture necessary elements and significantly improve the quality of information contained in our system and overall utilization data. This is not a practice that many IHS or Tribal Health facilities use but one that is increasingly used in the general health care system. We have identified a tribe in New Mexico that is using scribes in their outpatient clinic and hospital. We are requesting peer technical assistance.

### **No Annual Quality Assurance Evaluation of Patient Health Care**

Annual program evaluations have not been conducted previously. The Tribe staff, will formally request IHS to perform the required annual program evaluation for the Health Center . The request will include an annual evaluation of the number of patients served, a review of active and closed patient records, and a review of current policies. A copy of any findings will be provided to the governing body and PPHC Management. Corrective Actions will be required by the Medical Director and Health Director to address any findings.

### **Incomplete Pre-employment Screening Controls**

Ensuring quality services is a priority for the Passamaquoddy Tribe at Pleasant Point. As part of this commitment, fingerprinting is required for all PPHC new employees that work with children. We are currently working with our tribal law enforcement and Bureau of Indian Affairs (BIA) to determine how best to meet the Federal Bureau Investigation (FBI) Background check requirement. Currently, all fingerprints and back ground checks are conducted by our State Bureau of Investigation (SBI).

The FBI and SBI background checks often take weeks to complete which can impede service delivery. As a result many agencies, including IHS, make provisions to ensure that service delivery is negatively impacted. In some circumstances, a provider may be allowed to provide service to minor patients provided they are supervised at all times. This practice is reflected in our current policies.

As part of our compliance and credentialing process, the Assistant Health Director checks the OIG exclusion list monthly to verify that we are not doing business with any excluded entity or individual. Verification is kept on file.

In order for an application for employment to be considered complete, three written references are required. Our Human Resource Department is checking these references as indicated in our current policies.



The Passamaquoddy Tribe at Pleasant Point recognizes the need for an updated drug screening policy and we have engaged in preliminary discussions at the Tribal Council level to address this. The pre-employment provisions will be incorporated into our overall drug testing policy revisions.

**PPHC Did Not Always Provide a Safe, Clean, and Accessible Environment and Have a Preventative-Maintenance Program for the Provision of Health Care**

We have corrected a number of the deficiencies outlined in the draft report. Policies that ensure a safe, clean and accessible environment have been developed. These policies ensure that expiration dates are checked monthly and equipment and tables are cleaned regularly. Checklists have been developed that track completion of these major safety processes.

In addition, we have also ordered/purchased several new items to improve service delivery. New exam tables have been ordered and will be set up upon delivery. Replacing the floor covering has not occurred due to the lack of a vendor that can install commercial flooring suitable for a health care facility. We are currently seeking a vendor from outside the area that can complete this work in the next 3 months.

PPHC has joined the Maine Rural Health Collaborative that is dedicated to providing telehealth services across rural areas in Maine. As part of this collaborative, new telehealth equipment has been ordered and should be operational by the fall. It is expected we can offer a number of services to our patients including rheumatology, behavioral health services, and cardiology.

Panic alert buttons are currently operational across the Health Center. Once pushed, a panic alert button need to be reset on the button itself and also on the system panel. This process has been outlined in the policies and procedures. Staff has been reminded to reset the alert systems when they are used.

**Summary**

The Passamaquoddy Tribe at Pleasant Point is appreciative of OIG's commitment to the quality of care provided to the Passamaquoddy people. We are committed to improving the health care delivery system at Pleasant Point and will continue our efforts to realign health care operations in order to address any deficiencies and prevent any further occurrence.

If you have any additional questions or require further clarification, please do not hesitate to contact me.

Sincerely,

  
Ralph Dana, Tribal Chief

  
Elizabeth Dana, Vice Chief