

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE PENOBSCOT INDIAN NATION DID
NOT MEET ALL FEDERAL AND TRIBAL
HEALTH AND SAFETY REQUIREMENTS**

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Office of Inspector General

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief

Date: November 2018

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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 (FQHCs), which receive Federal funding but limited Federal oversight in recognition of the independent nation status of the Tribes. Other audits of the quality of health care at tribally-run health care facilities have identified areas where Tribes may improve the quality of health care.

Our objective was to determine whether the Penobscot Indian Nation (Penobscot Nation) on Indian Island, Maine, met Federal and Tribal health and safety requirements for the quality of health care provided at the Penobscot Nation Health Department (PNHD).

How OIG Did This Review

We reviewed the scope of services identified in the Penobscot Nation Title V Compact and Multi-year Funding Agreement with Indian Health Service and identified health service requirements for Medicare FQHCs and Tribal requirements in effect for calendar years 2015 through 2018.

The Penobscot Indian Nation Did Not Meet All Federal and Tribal Health and Safety Requirements

What OIG Found

The Penobscot Nation did not meet all Federal and Tribal health and safety requirements for the quality of health care at PNHD. Specifically, we found that PNHD did not have a physician who provided the medical direction for the health center and performed all of the required oversight duties, written patient care policies and procedures (including pain-management and opiate-dependency treatment and compliance monitoring), and other policies and procedures needed to comply with the requirements.

Because the Penobscot Nation did not provide adequate oversight and implement policies and procedures for its health center, PNHD did not meet all Federal and Tribal requirements, which increased the risk that (1) patients may not have always received quality health care, (2) PNHD may have hired unqualified medical providers and administrative staff, and (3) PNHD may have missed opportunities to improve its delivery of health care services.

What OIG Recommends and Penobscot Nation Comments

We made several recommendations to the Penobscot Nation, including that it (1) ensures PNHD is under the medical direction of a physician who performs all of the required duties; (2) develops, approves, and implements written medical policies and procedures with the advice of the required group of professional medical staff; and (3) develops and implements policies and procedures to comply with health and safety requirements.

The Penobscot Nation concurred with our recommendations and described actions that it has taken or planned to take to address them. For example, PNHD is currently standardizing its policies and procedures to provide proper clinical oversight of provider healthcare and to better monitor pain management and opiate dependency treatment. Additionally, Penobscot Nation will work with external entities to perform annual quality assurance evaluations of patient care and to update its Tribal-wide emergency preparedness plan.

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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. Other audits of the quality of health care at tribally-run health care facilities have identified areas where Tribes may improve the quality of health care.

OBJECTIVE

Our objective was to determine whether the Penobscot Indian Nation (Penobscot Nation) on Indian Island, Maine, met Federal and Tribal health and safety requirements for the quality of health care provided at the Penobscot Nation Health Department (PNHD).

BACKGROUND

Within the U.S. Department of Health and Human Services, the Indian Health Service's (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 the 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 V of the ISDEAA, federally-recognized Tribes can enter into compacts with the IHS, which set forth the general terms of the nation-to-nation relationship, and multi-year funding agreements to assume full funding and control over health care programs, services, functions, and activities that IHS would otherwise provide.

Tribal Medicare Federally Qualified Health Centers

While most Federally Qualified Health Centers (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 the purposes of 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. PNHD 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 a Medicare FQHC, a clinic 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 only the specific grievance.

Tribal Medicare FQHCs are not required to obtain medical accreditation or undergo periodic inspections and evaluations by medical accrediting organizations. 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.

Penobscot Indian Nation

The Penobscot Nation is one of four American Indian Tribes that make up the Wabanaki Confederacy. For over 10,000 years, these Tribes have resided in regions now located within the boundaries of the State of Maine. The Penobscot Nation is governed by a chief, a vice chief, and a 12-member Tribal council who are elected for 4-year terms by Tribe members. The Tribal government has entered into a Title V compact agreement with IHS, and operates health care programs and services that IHS would otherwise provide. The Penobscot Nation receives approximately \$4 million annually from IHS to support the health care programs and services it provides.

There are approximately 2,400 Tribe members, including 430 members who reside on the Penobscot Indian Island Reservation, located on Indian Island, Maine.

Penobscot Nation Health Department

PNHD operates the Penobscot Nation's health center. PNHD provides readily available, comprehensive, quality care to members of the Penobscot Nation, and other eligible persons.¹ In addition to IHS funding, PNHD is funded through various local, State, and Federal grants and contracts and reimbursements from Medicare, Medicaid, and third-party insurance. PNHD offers a range of outpatient medical services including family medical care, family planning, prenatal, pharmacy, medical laboratory, dental, community health case management, nutrition

¹ Other eligible persons include persons of Indian descent who belong to the community served by the facility, and non-Indian women pregnant with an eligible Indian's child during her pregnancy through 6 weeks after delivery (42 CFR § 136.12).

counseling, health promotion and disease prevention, diabetes control and prevention, mental health counseling, substance abuse counseling and prevention, and environmental health services. PNHD was certified as a Medicare FQHC by CMS in 1994 and serves approximately 1,300 patients. CMS did not have any record of a complaint filed against PNHD.

PNHD is staffed by approximately 19 medical professionals, including 3 primary health care providers, and 13 administrative professionals. In January 2017, PNHD's health director, who oversees PNHD and supervises all medical and non-medical staff, including PNHD's medical director, left the health center. For approximately 10 months, the assistant health director took over many of the health director's responsibilities while the health director position remained vacant. In October 2017, the Penobscot Nation hired a new health director to oversee its health center.

HOW WE CONDUCTED THIS REVIEW

We reviewed the scope of services identified in the Penobscot Nation Title V Compact and Multi-year Funding Agreement (MFA) with IHS and identified health service requirements for Medicare FQHCs and Tribal requirements in effect for calendar years (CYs) 2015 through 2018. We interviewed PNHD staff and reviewed medical, pharmacy, and personnel records to obtain an understanding of medical and administrative operations at PNHD. We observed the physical conditions of PNHD's health care facility 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 Penobscot Nation did not meet all Federal and Tribal health and safety requirements for the quality of health care at PNHD. Specifically, we found that PNHD did not have:

- a physician who provided medical direction for the health center and performed all of the required oversight duties;
- written patient care policies and procedures, which include pain-management and opiate-dependency treatment 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 screenings for all of its employees, which includes fingerprinting employees who come in contact with Indian children;
- a preventative-maintenance program for patient care equipment and medical supplies; and
- an emergency preparedness plan that was updated and tested annually.

These findings occurred because PNHD and the Penobscot Nation's human resources department experienced staff turnover, PNHD did not have adequate written policies and procedures that ensured that it complied with Federal requirements, and PNHD's management was not always aware that Tribal policies and procedures existed. Furthermore, PNHD's management did not know that the health center was a certified Medicare FQHC and required to follow Federal regulations for FQHCs. As a result of these deficiencies, PNHD did not meet all Federal and Tribal requirements, which increased the risk that (1) patients may not have always received quality health care, (2) PNHD may have hired unqualified medical providers and administrative staff, and (3) PNHD may have missed opportunities to improve its delivery of health care services.

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 and 491.8).

At PNHD, the medical director has overall responsibility for the medical clinic, including the pharmacy, laboratory services, home health services, and nutrition. According to the medical director's job description, the medical director coordinates with and provides consultation to the community health, dental, and substance abuse and counseling services programs. Additionally, the medical director supervises the full- and part-time nurse practitioners, the pharmacist, and registered dietitian and diabetes coordinator (PNHD Medical Director Job Description, dated February 2010).

PNHD hired a physician on staff who served as its medical director throughout the period we reviewed. The medical director provided medical care to health center patients, consulted with

other PNHD medical staff about patient care, and reviewed patients' medical records as part of the patient referral process. However, the medical director did not perform the additional FQHC-required and PNHD job description duties, such as providing routine medical supervision to health care staff or developing, executing, and reviewing PNHD's written policies and health care services provided to its patients. During our fieldwork, we found evidence that the medical director monitored and eventually terminated an underperforming medical assistant, but the medical director told us that supervising health care staff was not part of his regular activities.

PNHD was not always under the medical direction of a physician who performed all of the FQHC-required duties because PNHD's former health director did not provide the necessary oversight and supervision to ensure that the medical director performed all federally-required duties included in the job description and because of turnover of the health director position at PNHD. As a result, PNHD may have missed opportunities to improve patient health care because all FQHC physician responsibilities were not performed.

INADEQUATE WRITTEN PATIENT CARE POLICIES INCLUDING POLICIES AND PROCEDURES FOR OPIOID PRESCRIBING AND COMPLIANCE MONITORING

An FQHC's policies and its lines of authority and responsibilities must be clearly set forth in writing (42 CFR § 491.7). Additionally, FQHCs must (1) develop patient care 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; (2) provide health services in accordance with appropriate written patient care policies which comply with applicable Federal, State, and local laws; and (3) review their patient care policies at least annually. Patient care policies must include (1) a description of the services the health center provides either directly or through arrangement with external providers, (2) guidelines for the medical management of health problems, (3) procedures for the periodic review and evaluation of services provided by the health center, and (4) rules for storing, handling, and administration of medications (42 CFR § 491.9).

Since January 1, 2017, Maine prescribers are required to check prescription monitoring information for records related to the patient when initially prescribing a benzodiazepine or an opioid medication and every 90 days for as long as that prescription is renewed (22 MRSA § 7253).

With the exception of its dental department, PNHD did not have adequate written patient care policies that were developed with medical staff and reviewed annually. PNHD had some written policies and procedures, but they were incomplete and in some cases outdated. For example, there were no written policies for reporting and investigating medical accidents. PNHD's pharmacy had a policy and procedure manual, but it hadn't been updated since April 2003, and the pharmacist, who was hired in 2016, was unaware of the manual's existence. Additionally, the procedures for pharmacy technicians using the pharmacy's prescription software had not been updated since 2005.

Additionally, PNHD did not have complete written policies and procedures for prescribing and monitoring patients with prescriptions for medications with a high risk for abuse. PNHD has a policy requiring patients to sign a controlled substance agreement, which patients sign agreeing to comply with their opioid and suboxone treatment plan, random urine drug testing, and pill counts, but the agreement does not specify how frequently medical providers and patients should review and sign the agreement. PNHD does not have written monitoring procedures to verify that all patients sign agreements or written policies outlining when a high-risk medication prescription requires additional medical review by PNHD medical staff. Additionally, PNHD does not have guidelines outlining and prioritizing all of the pain management options available to patients. Written policies and procedures provide the framework for patient care by establishing guidelines and processes for medical treatment, including policies and procedures for prescribing and monitoring patient use of opioids. The lack of written policies and procedures could result in inconsistencies in the quality of patient health care.

For example, based on a judgmental selection of medical records for 36 patients who received high-risk opioid² and suboxone³ prescriptions, we found inconsistencies in the monitoring of those patients, including:

- Three of the 36 patients did not have a signed controlled substance agreement in their medical files. For the 33 patient medical files with a signed controlled substance agreement, we found that 9 patients signed the agreements more than 3 years prior to the date the pharmacy filled the prescription, with 1 patient signing her agreement nearly 9 years prior.
- One of the 35 patients⁴ who received opioid or suboxone prescriptions did not have evidence in his medical file that the provider reviewed the Maine State Prescription Monitoring Program (PMP) database.

² For the purposes of this audit, we define “high-risk opioids” as 11 of the prescription opioid medications the National Institute on Drug Abuse lists as commonly abused drugs because they can cause euphoria and are often used nonmedically, leading to overdose deaths. Those medications are Hydrocodone/Ibuprofen 7.5-200MG, Hydrocodone/Ibuprofen 10-200MG, Hydrocodone/APAP 5-325MG, Hydrocodone/APAP 7.5-325MG, Hydrocodone/APAP 10-325MG, Oxycodone/APAP 5-325MG, Oxycodone/APAP 7.5-325MG, Oxycodone/APAP 10-325MG, Oxycodone HCL 5MG, Oxycodone HCL 10MG, Oxycontin 10 MG.

³ Suboxone is an FDA-approved drug used in medication-assisted treatment to help people reduce or quit their use of heroin or other opiates, such as pain relievers like morphine.

⁴ One of the patients in our sample received a prescription for opioids prior to the January 1, 2017, implementation of Maine’s law requiring prescribers to consult the PMP database.

- Four of the 28 patients⁵ who received urine drug tests to verify their compliance with their treatment plan did not have documentation that medical providers reviewed the test results.⁶

PNHD did not have adequate written patient care policies and procedures because its management did not know that PNHD is an FQHC that is required to follow Federal regulations.

Without written patient care policies and procedures, medical staff did not have sufficient guidance to facilitate day-to-day decision-making relating to patient care, including opioid prescribing and monitoring practices.

NO WRITTEN POLICIES AND PROCEDURES FOR MEDICAL DOCUMENTATION

An FQHC must maintain a medical record system in accordance with policies and procedures that requires 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).

PNHD did not have policies and procedures for (1) requiring medical providers to complete and sign medical notes for patient visits within a specified time and (2) monitoring open patient visit records to ensure that medical staff completed patient records in a timely manner.

PNHD did not have written policies and procedures for medical documentation requirements because its management did not know that PNHD was an FQHC and is required to follow Federal regulations to ensure that medical providers complied with medical documentation requirements.

Without written policies and procedures to ensure that medical documentation is completed in a timely manner, subsequent providers may not have had adequate documentation when reviewing patients' medical histories to make accurate diagnoses of time-sensitive medical conditions. Additionally, medical providers may not accurately remember the details of a patient's visit when completing progress notes weeks or months after the visit.

We also found that PNHD did not monitor open patient visit records to ensure that medical staff completed patient records in a timely manner. Of PNHD's three primary care medical

⁵ PNHD's Medication Agreement for Prescribed Controlled Substances and Patient Contract for Buprenorphine Treatment of Opiate Addiction or Opiate Withdrawal Using Suboxone agreements inform patients that they may be subjected to blood or urine drug screenings to monitor drug levels and to screen for drugs that were not prescribed by a medical professional. However, PNHD does not have policies outlining which patients must be tested or the frequency of these tests. Eight of 36 patients did not receive urine drug tests, resulting in 28 patients that received urine drug tests.

⁶ Medical providers documented their review of the urine drug test results for the remaining 24 of the 28 patients.

providers, one completed patients' medical documentation in a timely manner, including a description of the patient's condition, a diagnosis, and a treatment plan. However, the remaining two medical providers did not always complete medical progress notes. For example:

- One medical provider had 26 open patient visit records that did not include medical progress notes or an electronic signature. These patient visit records had been open for an average of 28 days, with the longest being 53 days.
- Another medical provider had five open patient visit records that took an average of 8 days to close, with the longest being 11 days.

In May 2017, PNHD requested that IHS review its medical records for coding and documentation compliance issues. IHS's review of a random sample of medical records reported similar findings, such as patient medical records not completed timely and missing medical progress notes for PNHD's primary care medical providers and other medical staff.

NO ANNUAL PROGRAM 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 review of 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).

PNHD did not carry out or arrange for an annual program evaluation to review the quality of health care services provided during the period of our review or in prior years. In 2017, PNHD performed an organizational assessment, which focused on financial, administrative, technology, and equipment issues. However, the scope of the assessment did not include reviews of the utilization of PNHD's health care services, active and closed patient health records, or PNHD's missing and outdated policies and procedures.

PNHD did not conduct annual program evaluations because its management did not know that the health center is an FQHC that is required to follow Federal regulations that require annual program evaluations, and PNHD did not designate a qualified medical staff member to carry out, or arrange for, an annual evaluation of its total program.

As a result, PNHD 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 for the patients it served during the period of our review or in prior years.

INCOMPLETE PREEMPLOYMENT SCREENING CONTROLS

Not All Employees Who Come in Contact With Indian Children Had an FBI Fingerprint-Based Background Check

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

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)).

Tribal requirements state that a thorough character investigation, including fingerprinting as required by the Indian Child Protection and Family Violence Protection Act, shall be completed on all applicants for any position that involves direct contact with or control over children (Penobscot Nation Personnel Policies and Procedures 2016 § I.B.5 "Character Investigations").

PNHD did not comply with Federal and Tribal requirements for all employees whose positions involve regular contact with Indian children. Of the 19 employees who had regular contact with Indian children, 16 employees did not have evidence of a fingerprint-based FBI background check prior to being hired in their personnel records. However, we found evidence in the personnel files that PNHD did perform a nonfingerprint background check for 9 of the 16 employees sometime after they were hired.

Not All Employees Had Evidence of Preemployment Screenings

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 §§ 1128 and 1156).⁷

Providers that participate in MaineCare, Maine's Medicaid program, are required to ensure that excluded individuals or entities are not employed or utilized to provide services, receive payments, or submit claims, to the program (MaineCare Benefits Manual chapter I, § 1.03-3 W). Maine's Department of Health and Human Services recommends that providers screen all new potential employees prior to hire and routinely screen all staff at set time intervals (i.e., annually, quarterly, etc.).

⁷ While not required, the 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 (see <https://oig.hhs.gov/exclusions/tips.asp>).

PNHD did not verify that its 36 employees were not included in the LEIE database and that its 21 medical staff were not included in the MaineCare excluded providers list before hiring them. When PNHD learned of this lapse in oversight, it verified that none of its employees were excluded from federally funded health care programs by consulting the LEIE database and the MaineCare excluded providers list. We also confirmed that none of the employees were in the LEIE database and the MaineCare excluded providers list.

Personnel Files Did Not Always Include Current Medical and Professional Licenses

An FQHC's staff must be licensed, certified, or registered in accordance with applicable State and local laws (42 CFR § 491.4(b)).

PNHD's personnel files did not always include current licensing documentation for medical staff who are required to be licensed. Specifically, for 7 of its 21 medical staff, the personnel files included either an expired license or did not include a copy of a medical license. When PNHD learned of this oversight, it obtained updated licenses for five medical staff. PNHD could not obtain licenses for the remaining two medical staff because they had been terminated. We also confirmed that all of the medical staff, including the two terminated employees, were appropriately licensed during our audit period by consulting the relevant certifying bodies' or State board's website.

Not All Employees Were Screened for Other Tribal Preemployment Requirements

Tribal personnel policies require that all individuals who are offered employment complete an employer-sponsored physical examination and drug test. Employment is contingent upon acceptable results of the physical examination and a negative drug test (Penobscot Nation Personnel Policies and Procedures 2016, "Drug Testing Procedure," § D "Preemployment Testing").

Applicants will be interviewed after the information provided on their application is verified, checks from previous employers and personal references are completed, and favorable results from character investigations or criminal background checks are secured by the human resources specialist (Penobscot Nation Personnel Policies and Procedures 2016 § I.E "Screening and Hiring Procedures").

PNHD did not always comply with Tribal requirements for preemployment screening of applicants. Specifically, we found that for the 36 employees:

- 17 employee files did not have evidence of preemployment drug testing,
- 7 employee files did not have evidence of a preemployment physical examination, and

- 4 employee files did not have documentation of a previous employer and personal reference checks.

PNHD did not always comply with Federal and State personnel requirements because Tribal staff were not always aware of the preemployment screening and documentation requirements, including verifying that applicants are not listed in the LEIE database or the MaineCare excluded parties list. PNHD was aware of the Tribal personnel requirements, but did not comply with them because of employee turnover in the Penobscot Nation human resources department.

As a result, Indian children and other patients faced an increased risk of substandard treatment or unsafe care provided by health care staff who were not properly screened prior to employment or who did not have current licensing information in their employee files after hire.

PNHD DID NOT HAVE A PREVENTATIVE MAINTENANCE PROGRAM FOR PATIENT CARE EQUIPMENT AND MEDICAL SUPPLIES

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).

PNHD generally provided a safe, clean, and accessible facility for its patients and staff. However, PNHD did not comply with medical equipment requirements to regularly inspect and maintain its clinical equipment and medical supplies (see Appendix B for photographs of instances of noncompliance). Specifically, we found:

- rusted medical instruments and medical instruments in expired sterilization packs; and
- expired medical supplies, such as individually packaged hypodermic needles, sterilized wound dressings, and ultrasound gel.

PNHD did not always follow health center best practices because it did not have policies and procedures in place to regularly inspect and maintain its clinical equipment and medical supplies.

As a result, there is an increased risk of compromised safety, infections, and transmitted diseases related to patient care.

PNHD DID NOT HAVE AN UPDATED EMERGENCY PREPAREDNESS PLAN

An FQHC must establish and maintain an emergency preparedness program that includes an emergency plan, policies and procedures to implement the emergency plan, an emergency communications plan, and an annual emergency training program for all staff. At a minimum,

an FQHC must review, update, and test its emergency plan annually. Beginning November 15, 2017, health care providers and suppliers must be in compliance with CMS's emergency preparedness regulations to participate in the Medicare or Medicaid program. The Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers regulation outlines four core elements: (1) Risk Assessment and Emergency Planning, (2) Communication Plan, (3) Policies and Procedures, and (4) Training and Testing (42 CFR § 491.12).⁸

The Penobscot Nation will update its emergency plan no less than every 5 years, and each Tribal department is responsible for reviewing and updating its standard operating procedures and mutual aid agreements on an annual basis (Penobscot Indian Nation Emergency Operations Plan Update 2009-2014, dated June 29, 2009, § 1.2 "Plan Monitoring, Evaluation, and Update Procedures").

The Penobscot Nation has a 5-year emergency operations plan that covers all Tribal departments and functions, including PNHD. The section of emergency operations plan that addresses PNHD includes policies and procedures to implement and update the plan and an emergency communications plan. However PNHD's portion of the plan, which was last updated between August 2008 and June 2009, expired in 2014. PNHD had not updated its standard operating procedures or tested its emergency plan annually since June 2009.

PNHD's portion of the emergency preparedness program was not regularly updated and tested because PNHD management was not aware that the Penobscot Nation's reservation-wide emergency operations plan existed prior to our fieldwork. Additionally, PNHD's management did not know that the facility was an FQHC and required to follow Federal regulations to maintain an emergency preparedness program for PNHD and update it annually.

Without an up-to-date emergency preparedness program for PNHD that is reviewed, updated, and tested annually, PNHD may not be prepared to aid its community and provide medical care in the event of a human-made or natural disaster.

RECOMMENDATIONS

We recommend that the Penobscot Nation:

- ensure that PNHD is under the medical direction of a physician who performs all of the duties required in the job description and in accordance with Federal and Tribal requirements;

⁸ These requirements took effect November 16, 2016, and CMS stated that all providers affected by the rule must comply and implement all regulations by November 15, 2017 (Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 81 Fed. Reg. 63860 (Sept. 16, 2016)).

- develop, approve, and implement written medical policies and procedures, with the advice of the required group of professional medical staff, 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, review the results of the program evaluations, and take corrective actions as appropriate;
- implement Federal and Tribal preemployment screening controls for employees who have not been fully screened prior to employment and for new staff hired at PNHD, including the performance of fingerprinting and FBI background checks for all staff currently working with Indian children, and maintain complete employee personnel files that include current licensing information when applicable;
- establish a preventative maintenance program for the facility and medical equipment to ensure that it provides a safe, clean, and accessible environment; and
- work with the Penobscot Nation’s Tribal government to ensure that its emergency preparedness program is reviewed, updated, and tested annually, in accordance with Federal requirements, and review and update PNHD’s standard operating procedures in accordance with Tribal requirements.

PENOBSCOT INDIAN NATION COMMENTS

In written comments on our draft report, the Penobscot Nation concurred with our recommendations and described actions that it has taken or planned to take to address them. For example, PNHD is currently standardizing its policies and procedures to provide proper clinical oversight of provider healthcare and to better monitor pain management and opiate dependency treatment. Additionally, Penobscot Nation will work with external entities to perform annual quality assurance evaluations of patient care and to update its Tribal-wide emergency preparedness plan. The Penobscot Nation’s comments are included in their entirety as Appendix C.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed PNHD's operations relative to Federal and Tribal health and safety requirements for CYs 2015 through 2018. We limited our review of internal controls to those applicable to the delivery of health care.

We conducted our fieldwork at the Penobscot Indian Island Reservation and PNHD located in Indian Island, Maine, from August 2017 through March 2018.

METHODOLOGY

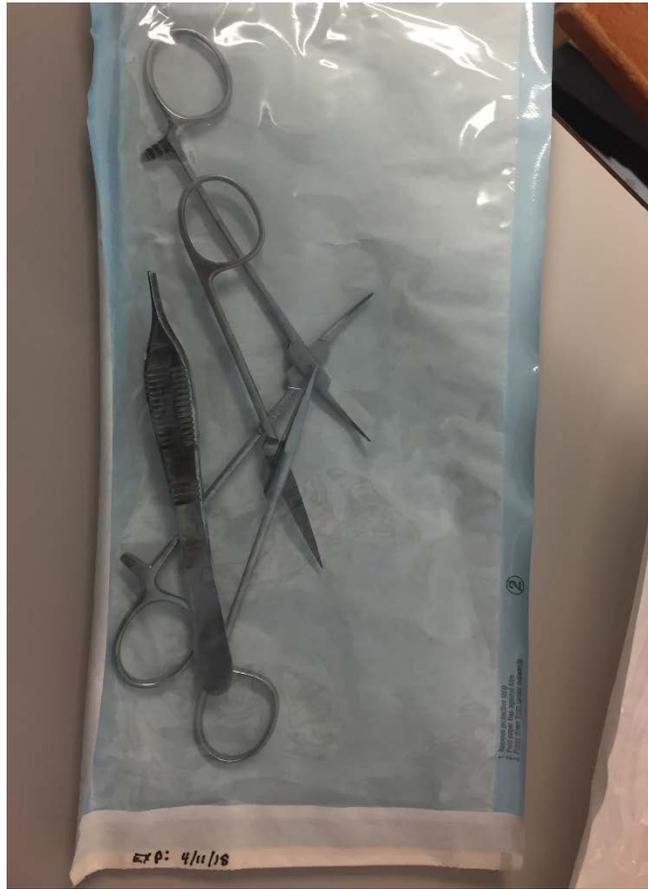
To accomplish our objectives, we:

- reviewed applicable Federal and Tribal requirements for health care delivery at PNHD;
- 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 V Tribes;
- reviewed the Penobscot Tribe's Title V Compact dated July 10, 2003, and its Multi-year Funding Agreement (MFA) for FYs 2014 through 2018 for PNHD to identify health services contracted with IHS;
- reviewed the organizational chart and job descriptions for PNHD employees;
- reviewed health care provider verification processes prior to employment;
- verified medical licenses for health care providers at PNHD 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 PNHD to verify safety, functionality, and cleanliness of its facility and selected patient care equipment and researched manufacturer's maintenance requirements;
- performed a walkthrough of PNHD laboratory and reviewed the overall operation, services provided, and the care, maintenance, and service of the lab equipment;

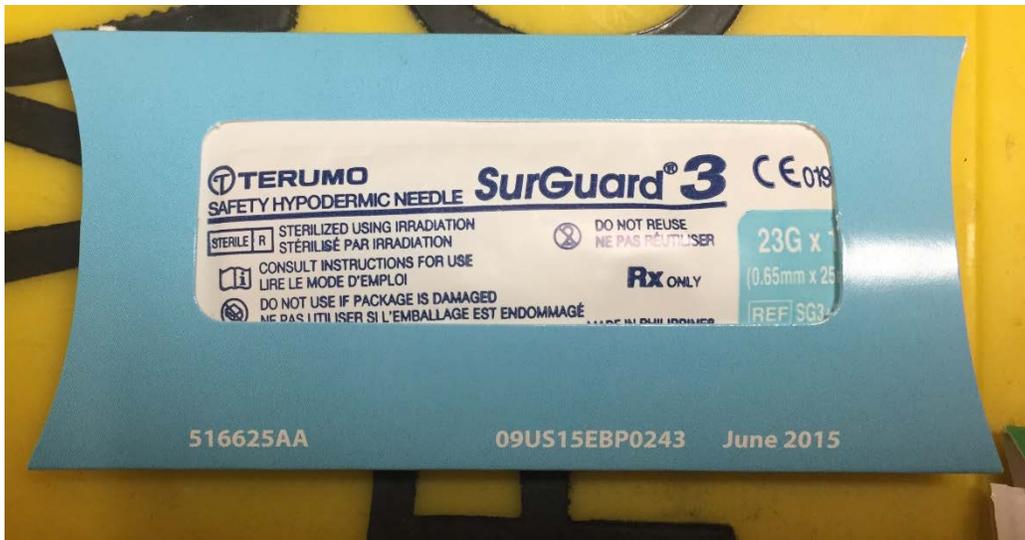
- obtained an understanding of the electronic health records system used for the documentation of health care services at PNHD and reviewed and analyzed the records;
- generated reports to document and quantify health service related issues;
- reviewed contractor monitoring reports to identify provider usage of medication compliance testing results;
- assessed the security controls and processes for ordering, receipt, inventory, and dispensing of pharmaceuticals in the PNHD pharmacy;
- confirmed that a judgmental selection of medications in the pharmacy did not exceed the labeled expiration date;
- met with State officials, PNHD, and pharmacy staff to understand the State requirements for the use of the prescription drug monitoring program and PNHD's usage of the system to monitor medications prescribed and pharmaceuticals dispensed at the Tribal health facilities;
- reviewed written emergency plans for non-medical emergencies;
- 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.

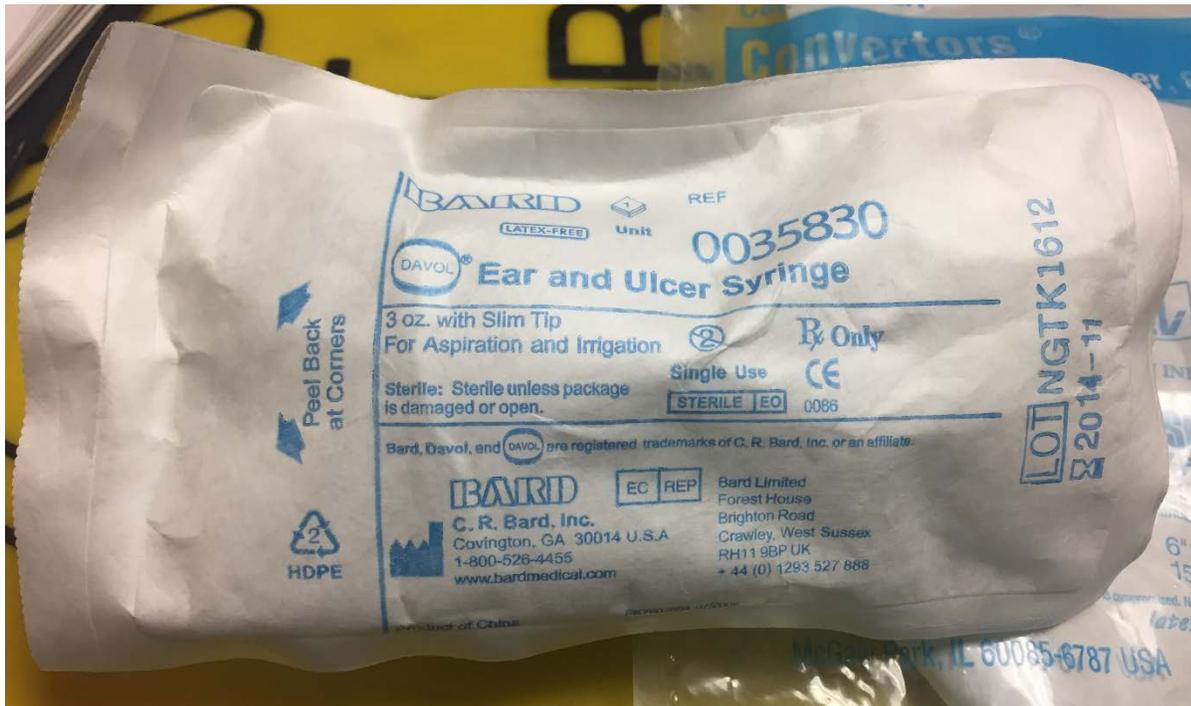
APPENDIX B: PHOTOGRAPHS OF INSTANCES OF NONCOMPLIANCE



Photograph 1: Unsterilized and rusted instrument pack. (Instrument pack as photographed on February 23, 2018.) The use of rusted or unsterilized medical instruments increases the risk of infection or medical injury to patients.



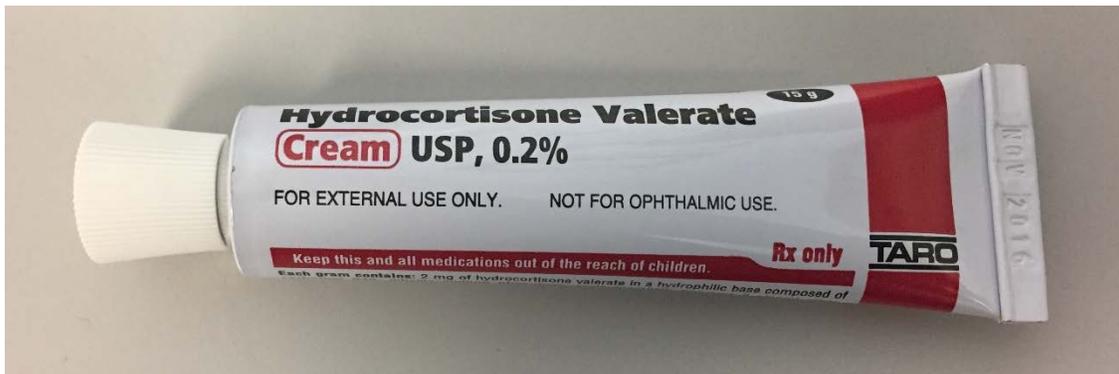
Photograph 2: Safety Hypodermic Needle expired in June 2015. (Hypodermic needle photographed on February 23, 2018.) Using expired medical supplies increases the risk of infection or injury to patients.



Photograph 3 (package front): Ear and ulcer syringe expired in November 2014. (Syringe photographed on March 23, 2018.) Using expired medical supplies increases the risk of infection or injury to patients.



Photograph 4 (package back): Ear and ulcer syringe expired in November 2014. (Syringe photographed on March 23, 2018.) Using expired medical supplies increases the risk of infection or injury to patients.



Photograph 5: Hydrocortisone Valerate cream expired in November 2016. (Cream photograph on March 23, 2018.) Using expired medical supplies increases the risk of infection or injury to patients.

APPENDIX C: PENOBSCOT INDIAN NATION COMMENTS

Office of the Chief and Council

Kirk E. Francis
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October 29, 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-01-17-01502

Dear Mr. Lamir,

This letter represents the official response of the Penobscot Indian Nation to the September 2018 draft Office of the Inspector General (OIG) report titled: *The Penobscot Indian Nation Did Not Meet All Federal And Tribal Health And Safety Requirements*. As the goal of our Health Department is to provide safe, effective, and evidence-based healthcare to our community, we welcome any feedback that informs our decision-making and allows our facility to refine its policies and procedures. With this goal in mind, the Penobscot Indian Nation concur with the report findings and offers the following planned or in-progress corrective actions to address identified deficiencies:

A physician who provided medical direction for the health center and performed all the required oversight duties

The Penobscot Nation Health Department is currently standardizing the policies and procedures required to provide proper clinical oversight of provider healthcare. In-progress initiatives include the Medical Director's periodic case review of staff and contract medical providers. Peer review of the medical care delivered by the Medical Director will also be routinely conducted to ensure that standards of care are well-understood and maintained. The Medical Director, in cooperation with the Health

Director, will play an integral part in the future development and updating of written policies related to service delivery and patient care.

Written patient care policies and procedures, which include pain-management and opiate-dependency treatment and compliance monitoring

Given the current opioid epidemic in Indian Country, a lapse in oversight regarding pain management and opioid-dependency treatment could have serious consequences for the community. Consequently, the Penobscot Nation Health Department is currently developing a strict monitoring program to identify any potential deficiencies in the future. This program will include formal policies regarding PMPs, controlled substance contracts, and provider review of urine drug testing results. Periodic audits of patient records will be conducted by the Medical Director, with oversight from the Health Director, to ensure that providers and support staff are adhering to the policies.

Written policies and procedures for medial documentation and complete patient health records

The Penobscot Nation Health Department understands the importance of complete and accurate medical records and their role in the continuity and coordination of patient care. As such, the development of formal policies regarding the timeliness and accuracy of medical records is currently underway. Since the identification of the deficiency by auditors, periodic audits of incomplete charts have been completed by the Health Director. Audit results have been distributed to providers and medical support staff for correction, and results have been monitored appropriately.

An annual quality assurance evaluation of patient health care

The Penobscot Indian Nation will formally request an annual quality assurance evaluation of patient health care from Indian Health Services to comply with this requirement. The initial evaluation will take place in 2019, and any recommended corrective actions resulting from the evaluation will be the responsibility of both the Penobscot Nation Health Department Director and Medical Director, with oversight from Tribal Administration.

Complete pre-employment screening for all its employees, which includes fingerprinting employees who come in contact with Indian children

The Penobscot Indian Nation has taken corrective action to ensure pre-employment and post-employment screening controls are implemented and proper documentation is maintained to include: Pre-employment screenings that include a Criminal Justice Information Services Division of the Federal Bureau of Investigations (FBI) background screening will be conducted prior to employment for those positions that involve the direct contact with or control over children. Results will be retained as part of an employee's personnel file. In addition, the Human Resources department will be conducting background screening reviews, which include FBI fingerprinting, every 5 years for those positions that involve the direct contact or control over children. The results will be retained as part of the employee's personnel file.

As part of the pre-employment screening process, a review of Office of Inspector General (OIG) Exclusion List (LEIE) as well as Medicaid Excluded Providers list will be conducted on all new hires. Human Resources will also conduct an annual review of both databases thereafter and document the results within an employee's personnel files. Upon discovery of this oversight, all employees were screened through the LEIE list and well as the Medicaid Excluded Providers list. IT has been documented that current employees are not in the LEIE or Medicaid excluded providers list.

Verification of licensure will be conducted upon hire by the Human Resources department, and copies of the verification will be retained within the employee's personnel file and provided to the Penobscot Nation Health Department (PNHD). PNHD will ensure applicable licensure renewals are verified and copy of renewals will be retained with the internal department employee file and Human Resources Department employee file.

Tribal pre-employment required screening records have been reviewed and any missing components will be documented and/or completed and retained in the employee's personnel file.

Tribal Administration will conduct quarterly audits of newly hired personnel to ensure compliance with internal process.

A preventative-maintenance program for patient care equipment and medical supplies

Based on the findings of the OIG draft report, the Penobscot Nation Health Department has already undertaken the development of a robust Risk and Quality Management program that includes the

routine inventory and evaluation of medical supplies, instruments, and sterilized packs. Medical supplies and sterile packs will be checked monthly by medical support staff, under the supervision of the Medical Director, and rotated appropriately based on expiration date. Instruments will be routinely assessed for damage and wear and replaced as needed.

An emergency preparedness plan that was updated and tested annually

The Penobscot Indian Nation is currently working with a vendor to update its Tribal-wide emergency preparedness plan. Plan components specifically concerning Health Department operations will be developed in cooperation between the Health Department Director and the Department of Public Safety. Annual testing will be conducted to ensure that plan operations are well-developed and clearly communicated with staff and community members.

Summary

The Penobscot Indian Nation appreciates the opportunity that this report has provided to address areas of improvement in our Health Department services. We acknowledge the Office of the Inspector General's assessment that transitions in both Health Department administration and Human Resources staff have led to deficiencies in the standard of healthcare delivery. While we recognize the previous lapse in understanding, we are now fully cognizant of the requirements in patient care coordination, standards of operation, documented policies and procedures, and risk and quality measures required of a Federally Qualified Health Center (FQHC). We look forward to further refining our healthcare delivery system to provide the best care possible for our community.



Kirk Francis
Tribal Chief
Penobscot Indian Nation