The mission of the National Network for Oral Health Access (NNOHA) is to improve the oral health of underserved populations and contribute to overall health through leadership, advocacy, and support to oral health providers in safety-net systems.
Executive Summary

Risk management is an important component of the overall operation of the Health Center. It aids organizations in providing quality services while reducing liabilities, and protects both the providers and patients from negative consequences. This chapter explores topics related to clinical risk management in Health Center oral health programs, including:

- Definitions of risk management;
- Risk management tools;
- High risk areas;
- Addressing practitioner mistakes and patient complaints; and
- The Federal Tort Claims Act.

The first step in risk management is avoiding risks. Knowing common mistakes and high risk areas enables providers to prevent errors and make sure that the services are provided with utmost care. When mistakes are made, providers should address them properly in order to ensure not only the protection for the Health Center, but also the safety of patients. NNOHA provides this chapter so that these key points are at the fingertips of the Health Center oral health program team.
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1. Introduction

Risk management is important for organizations to understand and apply in order to reduce liabilities while providing quality services. For Health Centers\(^1\), this concept is especially vital, because they provide services and care to underserved populations who tend to have more complex dental needs and more opportunities for risk. Most risks are preventable, and identifying the potential areas of risk for an oral health program protects the providers and their patients. This chapter provides an overview of the elements of clinical risk management that are relevant to Health Center oral health programs. Clinical practice and malpractice issues are only one type of risk facing Health Centers. Other types of risk may include legal, financial, or operational, but the purposes of this chapter will mainly be to address the clinical issues that face Health Center Dental Directors. Knowing relevant regulations and standards, as well as common problems and errors, will empower Dental Directors and other oral health providers to manage risks and provide quality care to patients in a safe environment.

2. Learning Objectives

Upon completing this chapter, the reader will gain a better understanding of:

- What risk management is;
- Common risks involved in the practice of oral health care;
- Ways to prevent common risks;
- How the Federal Tort Claims Act (FTCA) can protect Health Centers and their providers; and
- How ethics and risk management work together.

\(^1\) Terminology: “Health Center” is the term commonly used to refer to Community Health Centers, migrant and seasonal worker health centers, health centers that treat the homeless, and centers that treat residents of public housing. Authorizing Section 330 legislation has officially changed the term “Community Health Center” to the accepted term “Health Center” and that is the term used throughout this manual to refer to these listed types of grant-supported entities.
3. Relevant Documents

**AUTHORIZING LEGISLATION - SECTION 330 OF THE PUBLIC HEALTH SERVICE ACT**
Section 330 is the authorizing legislation for Health Centers. It provides the legal basis for the Health Center program, including definitions, information on grants, populations of focus, audits, and other requirements. The entire text is available at the link above.

**HEALTH CENTER PROGRAM REQUIREMENTS**
http://bphc.hrsa.gov/about/requirements/index.html
This page contains a summary of Health Center program requirements on the need, services (including staffing), management and finance, and governance, based on the statute and regulations.

**THE FEDERAL TORT CLAIMS ACT (FTCA)**
http://bphc.hrsa.gov/FTCA/
FTCA is the federal legislation that allows parties claiming to have been injured by negligent actions of employees of the United States to file claims against the federal government for the harm they suffered. The FTCA also provides authority for the federal government to defend against such claims.

**POLICY INFORMATION NOTICE 2011-01: FEDERAL TORT CLAIMS ACT (FTCA) HEALTH CENTER POLICY MANUAL**
http://bphc.hrsa.gov/policiesregulations/policies/pin201101.html
This document consolidates and incorporates ten (10) older policy documents into one notice and serves as BPHC’s primary source of FTCA information.

**THE FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT (FSHCAA)**
Later codified as 42 U.S.C. Section 233 (a) – (n), the FSHCAA makes federal employees of deemed Health Centers, which includes their employees, officers, directors, and certain contractors. The purpose of defining specific Health Center staff as employees is to provide medical/dental malpractice insurance, thereby, conferring FTCA protections on these organizations and individuals.
4. **What Is Risk Management?**

**Risk management** is the identification, assessment, and prioritization of risks (*the effect of uncertainty*) and the application of resources to minimize, monitor, and control the probability or impact of adverse events. It specifies information needed by providers, leaders, and staff to minimize risks for their oral health programs, and next steps if an error occurs.

This chapter will deal primarily with risk management to prevent and mitigate adverse events in relation to clinical practice and patient outcomes. However, risk management is much more than addressing clinical errors—it has broader applications. At an organizational level, many types of risks are being managed. Examples include compliance with *Health Insurance Portability and Accountability Act of 1996* (HIPAA) regulations to avoid the risk of improper disclosure of personal information, risks resulting from facility operations that could cause injury to patients and employees, and inadequate or improper personnel policies and procedures that put the organization at risk. For Health Center-wide issues that do not relate directly to clinical practice in the oral health program, Dental Directors should be working in conjunction with other staff (e.g. Chief Executive Officers, HIPAA compliance officers, privacy officers, Chief Operations Officers, office managers etc.) to develop and implement center-wide risk management policies and procedures in the dental clinic.

Successful risk management involves developing and implementing systems that minimize the probability of adverse events in all aspects of providing care. Dental Directors should insure that the oral health program is in compliance with all aspects of the HIPAA regulations and is following Health Center policies and procedures regarding release of records. Those policies should be consistent with state and federal laws and regulations.

Physical facilities are another area of risk management. This includes compliance with relevant regulations regarding the American Disabilities Act (ADA) access and establishment and implementation of policies and procedures to prevent work-related injuries and illnesses. Another area of concern is provision of appropriate translation services in compliance with Culturally and Linguistically Appropriate Services (CLAS) standards. Again, these activities are conducted on a Health Center-wide basis, but are implemented in the oral health program.

Most Health Centers, as part of their quality improvement plan, have an incident reporting system in place which can be utilized when adverse incidents occur in all aspects of Health Center operations. Through this process, lessons are learned to prevent future similar incidents. These lessons become part of future risk management activities.

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2 A sample Incident Form can be found on NNOHA’s website at http://tinyurl.com/incdForm.
**ADDITIONAL DEFINITIONS**

- Risk management includes any activity, process, or policy to reduce liability exposure.
  

- Risk management: creating and applying a system of procedures to reduce exposure to various types of liability.


- Risk management is something you do to provide the best possible care for your patients; it is not about avoiding a lawsuit.

  – David Rosenstein, DMD, MPH

5. **RISK MANAGEMENT AND QUALITY ASSURANCE**

In terms of clinical practice, risk management and quality assurance (QA) are often used synonymously; however, while related, they have conceptual differences. QA refers to activities that help define, design, assess, monitor and improve the quality of health care. QA activities may be integrated with supervising health care providers and other efforts to improve productivity, provider performance, and the overall quality of health services. QA is a means of accomplishing risk management in a specific area – clinical practice. It certainly is not, on its own, the equivalent of a risk management program.

Risk management, as described by The Indian Health Service, has proactive and reactive components. Proactive activities prevent adverse occurrences or losses, help to improve the quality of patient care, and reduce the probability of an adverse outcome turning into a medical malpractice claim. Efforts that prevent and minimize risks contribute to QA, which is one area where QA and risk management overlap. Reactive actions include responses to adverse occurrences or claims.

Most importantly, risk management and QA are both essential elements of patient safety. Providers are responsible for assessing and controlling risks, as well as monitoring and improving quality of services, which ensure their patients receive the best treatment possible.

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6. STANDARD OF CARE

In common law, a tort is a wrong that involves a breach of duty owed to someone else, that causes injury. The person who suffers injury is entitled to receive damages from the person or people responsible. In health care/dentistry, the most prominent tort liability is negligence or malpractice. In order for negligence to exist, the following four elements must be found:

1. A duty (standard of care) was owed by the dentist to the patient.
2. The dentist violated the applicable standard of care.
3. The plaintiff suffered a compensable injury.
4. Such injury was caused in fact and proximately caused by the substandard conduct.

Standard of care is an important concept of risk management and is defined in court case Blair vs. Eblen (and adapted here for dentists) as: “[A dentist is] under a duty to use that degree of care and skill which is expected of a reasonably competent [dentist] acting in the same or similar circumstances.” The standard of care can change over time based on emerging clinical practice, prevailing knowledge and court case precedent. Providers are advised to keep abreast of changes in dental practice. As there can also be geographic variations in the standard of care, the American Dental Association (ADA) regularly updates its Principles of Ethics and Code of Professional Conduct but also recommends consulting local counsel regarding the prevailing standard of care in a provider’s community.

7. ETHICAL PRACTICES AND RISK MANAGEMENT

Ethical practices are the foundation of risk management programs, and both ultimately benefit the patients and improve the Health Center’s quality of care. When providers practice ethically, they mitigate many of the Health Center’s risks—it can act as a tool to manage risks.

Ethics in oral health programs apply moral principles to the practice of dentistry and include five general principles expressed in their code of ethics:

1. Patient autonomy (self-governance)
2. Nonmaleficence (do no harm)
3. Beneficence (do good)
4. Justice (fairness)
5. Veracity (truthfulness)

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6 Blair v. Eblen, 461 S.W. 2d 370, 373 (Ky 1970).
Unethical practice causes risks for providers and their patients. The first principle of patient autonomy refers to the patient’s right to be informed about his or her treatment and protection of confidential patient information. Providing full informed consent prior to dental procedures, followed by appropriate documentation, are important elements of risk management in an oral health program. If the first ethical principle is compromised, it violates legal statues and exposes the practice to liability. Protection of patient information, coupled with complete and accurate progress notes, are the best supporting documentation in a malpractice defense. Each of the five principles has a risk management component, providing an effective barometer for a risk management program. While ethical practice is the foundation for risk management, human error can occur even when providers are acting ethically—a complete risk management program provides a framework to control for human error as well.

8. **Top 10 Clinical Practice Risks**

The following list represents the ten most common reasons for FTCA dental torts claims based on a consensus of consulting dentists, which were contracted to review malpractice claims. The list of risk areas is instrumental for Health Center leaders in the process of developing or enhancing their risk management programs.

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**TOP 10 POTENTIAL RISK AREAS FOR HEALTH CENTER ORAL HEALTH PROGRAMS:**

1. Lack of Informed Consent
2. Failure to Diagnose
3. Lack of a Thorough Exam
4. Failure to Follow-Up on Emergencies
5. Treatment of the Wrong Tooth
6. Surgical Complications
7. Removable Prosthetics
8. Lack of/Inadequate Treatment Plan
9. Incomplete Treatment
10. Inappropriate Procedures
1 Lack Of Informed Consent:

The American Medical Association (AMA) defines informed consent as the process of communication between a patient and a physician that results in the patient’s authorization or agreement to undergo a specific medical intervention. Providers may find it helpful to think of informed consent as the process of getting the patient’s permission to pursue a certain course of treatment.

It is important to have a signed informed consent form, as well as: 1) a statement of the diagnosis in the treatment record; 2) proposed treatment options; 3) procedure to be performed, and 4) a statement that risks and benefits were discussed with the patient. Detailed information that is shared with patients and well documented helps patients understand exactly what is involved in their treatment, and minimizes conflicts later. If the patient is non-English speaking, the communication should be provided in his or her preferred language. It is the provider’s responsibility to ensure the form is signed and dated by the patient, the dentist, and a witness. According to the UDS data 37% of patients are pediatric. Refer to the AAP website for their latest guidance on informed consent in children: http://pediatrics.aappublications.org/content/119/2/405.full.pdf

Providers also realize that having a signed consent does not completely protect them from a lawsuit. Employing best practices of quality care, providers listen to what is important to the individual. They use clear and culturally-sensitive terminology when discussing the patient’s expectations, the risks and benefits of specific procedures, and alternative treatment options regardless of the ability to pay for procedures. At the end of the discussion, it is always good practice to ask if there are additional questions. The conversation is then documented in the chart notes and indicates that all questions were answered and understood by the patient. It should be documented that the patient verbalized an understanding of the nature of the treatment/procedure, including the risks and benefits.

In some cases, the best treatment is no treatment. Most dental problems can be safely postponed until the patient demonstrates a full understanding of what the provider is proposing or until after the patient receives another opinion. However, if a patient has a serious acute emergency, providers ensure he or she understands the ramifications of delaying definitive care. Having a patient sign an informed refusal of care form, similar to a hospital’s against medical advice discharge, and documenting it in the chart notes is a tactful precaution. Each organization needs to have procedures in place that adhere to the regulations of individual States. Informed consent gives the patient the opportunity to weigh and respond to risks. It allows the patient to understand the nature of the treatment or procedure and to be a part of the decision-making process regarding his or her own health.

When treating a patient who is a minor, providers assume that, in most situations, minors are legally unauthorized to give consent and parent or guardian authorization is necessary. Health Centers are required to have policies regarding consent for minors taking into account state laws and regulations, with documented potential exceptions, and ensure providers are aware of these policies. In addition to age, there should also be some consideration of obtaining consent from individuals with decreased competency for other reasons such as mental or developmental disability. Informed consent needs to be geared towards the individual patient to assure that they understand the procedures, the risks, and any other options.
Failure To Diagnose:

Failure to diagnose and document periodontal disease status is the leading problem in this area. Documentation of pocket depth is insufficient. Additionally, it is important to document diagnoses. There are some cases where providers confuse treatment procedures with diagnoses. For instance, it is common to find “tooth #9, MIF composite,” instead of “MIF dental caries on tooth #9.”

b. Missing signs of early oral cancer lesions or other oral pathology are other common diagnostic failures. Dental providers are responsible for performing a comprehensive oral cancer examination, including a review of the patient’s medical and dental history. Comprehensive examinations enable providers to avoid potential legal liability and, more importantly, provide the best care for their patients. Suspicious lesions that persist longer than a week should be biopsied. Such a referral is followed up to ensure the patient presented for biopsy. If not, follow-up procedures are documented clearly in the patient record. There should be a “protocol” regarding referrals and follow-up care, similar to the medical follow-up for a positive pap smear.

c. Failure to diagnose X-ray anomalies, which may require additional investigation. Patients are informed and the conditions noted, even if care is not immediately indicated (for example, asymptomatic supernumerary teeth). With the availability of electronic health records, intraoral and extra-oral photographs of pathology lesions are recommended as part of the patient’s health record, because they document baseline comparison for future exams.

d. Increasingly, failure to refer a patient to a medical provider or social services can place dental practitioners at risk. This includes a patient who may present with the oral manifestation of a systemic illness (HIV infection, bulimia, diabetes, etc.), or for an individual who needs follow up for management of a chronic disease (high blood pressure etc.). Dental radiographs may also detect individuals with poor bone density, which may be a sign of osteoporosis. A patient who presents with evidence of physical and mental problems and signs of abuse, that are obvious to an observant practitioner, also receives appropriate referrals. The patient is asked if he or she is seeing a provider for these problems, and the answers are documented.

e. Failure to diagnose other common conditions, such as, cracked tooth syndrome, temporal mandibular joint dysfunction, orthodontic conditions, and endodontic pathology can also be a source of claims in this area.
3 Lack of a Comprehensive Exam:

Providers are responsible for conducting a detailed examination and documenting it. This includes a medical history, all diagnoses, a periodontal exam and charting, evaluation of the patient’s occlusion, soft tissue/oral cancer evaluation, and a sequential treatment plan. All findings are recorded.

A complete medical history is documented and updated at each visit. The patient is asked if there were any changes since the last visit in medical history, new medications, allergies, and pain assessment. Explanations for all yes responses are included. The ADA recommends taking a patient’s blood pressure at every visit based upon findings of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure.8

Appropriate x-rays and any other diagnostic tests are performed and documented. Providers always obtain appropriate diagnostic x-rays. This recommendation includes pregnant patients. It is considered negligence if x-rays are not taken before providing treatment. If the patient is concerned about the cost or radiation exposure, a signed waiver for refusal to take x-rays may be an inadequate defense in a malpractice suit. The best risk management strategy is for providers to communicate with the patient and encourage consent to what is necessary for a diagnosis. If that strategy fails, then providers may politely tell the patient they cannot provide care without adequate diagnostic information.

A comprehensive treatment plan is developed, discussed and documented for conditions noted during the exam. For some conditions no treatment will be the desired option. Other conditions may require referrals to outside providers for care beyond the clinic’s scope of service.

4 Failure to Follow Up on Emergency Cases:

A well-managed Health Center has a policy and protocol to deal with emergency patients. Not every individual needs a post-op visit, but some follow-up is required for every patient; patients with acute infections especially require careful observation. Calling patients 24 to 48 hours after a surgical procedure is considered a best practice for quality care. It allows providers to catch any complications early, and assures patients that the Health Center prioritizes their health. An effective strategy used by providers is a pre-printed post-procedure follow-up form for the chart. Emergency patients are always cautioned to go to the emergency room if their condition worsens or fails to improve after office hours. A hospital-like emergency discharge form is both retained in the records and given to patients when they leave, in addition to any post-op instructions. The form includes information about the procedure performed, a need for follow-up care, and risks for the patient, if care is delayed.

Even patients who require off-site referrals for acute emergency care benefit from follow up. A best practice is to schedule the referral appointment with the patient present in the Health Center dental clinic. It is equally important to ensure the information is discussed with the patient using a literacy level appropriate to the patient’s cognitive level and to document patients verbalization of understanding.

“A provider’s first line of defense is thoroughly documenting a patient’s history. If it is not in the record, you have not done it. It is not enough that the patient writes it down. There has to be an indication that you have looked at that. You have to have everything that you have found in the mouth in your records…. You need to note everything, not just what you are going to do.”

— David Rosenstein, D.M.D., M.P.H.

8 More information on blood pressure protocols can be found on the ADA’s website at http://www.ada.org/.
TREATMENT OF THE WRONG TOOTH/WRONG SITE:

A frequent malpractice claim filed against providers is for treating the wrong tooth or site. Instituting operational procedures coupled with patient education can mitigate these risks. First, providers ensure there is a documented diagnosis for every tooth considered for extraction, and the informed consent process is completed on the day of the procedure. This is followed by a verification procedure by the patient, surgical assistant, and oral surgeon to reconfirm which tooth will be extracted. Both the surgeon and the assistant again confirm the tooth before its actual removal. When providers reaffirm verbally the procedure and location with their patients before it is performed, it is known as a Time-Out period.

TIME-OUT

The Joint Commission, an independent, not-for-profit organization that provides accreditation and certification for health care organizations, established the Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery. One principle is to perform a Time-Out before the procedure (UP.01.03.01). All clinics accredited by the Joint Commission are required to follow this guideline.

The purpose of the Time-Out is to conduct a final assessment that the correct patient, site, and procedure are identified. This requirement focuses on those minimum features of the time-out. Some believe that it is important to conduct the time-out before anesthesia for several reasons, including involvement of the patient. An organization may conduct the time-out before anesthesia or may add another time-out at that time. During a time-out, activities are suspended to the extent possible so that team members can focus on active confirmation of the patient, site, and procedure.

A designated member of the team initiates the time-out and it includes active communication among all relevant members of the procedure team. The procedure is not started until all questions or concerns are resolved. The time-out is most effective when it is conducted consistently across the organization.

Source: http://www.jointcommission.org/assets/1/6/2011_NPSGs_OBS.pdf

Allegations of removing the wrong tooth are also particularly common when a patient comes in with an emergency and points to a particular tooth as the source of pain. Providers educate patients on the possibility of referred pain, or that adjacent teeth may be involved. For example, a provider advises the patient that the tooth in question has a problem and should be extracted; however, there may be other teeth with problems that can contribute to the pain he or she is experiencing. After this tooth is extracted, the patient may notice pain from the other teeth. That does not necessarily mean the wrong tooth was removed; it usually indicates there is more than one problem. This is why it is important to document the subjective and objective diagnostic information that led to the decision to extract or treat a particular tooth.
6 Surgical Complications:

The only sure way to completely avoid surgical complications is to never perform any surgical procedures. Eventually, providers encounter surgical complications regardless of how carefully they practice. The best strategy to manage these risks is to discuss them with the patient before the procedure is started, and include these discussions in the informed consent documentation. Written and verbal post-operative instructions are given to the patient in his or her preferred language. Possible surgical complications include:

- **Infection** – Many teeth extracted at Health Centers are extracted due to the presence of infection. The patient may not understand that the severe caries or periodontal disease necessitating a tooth extraction is due to a pre-existing infection. Providers need to inform the patient that they are extracting a tooth in the presence of an infection. Most times, removing the source of infection resolves the problem, but there is a chance that infection may worsen. Providers are advised to prescribe antibiotics judiciously when indicated, and inform the patient to return immediately if the swelling worsens, particularly when it involves the infraorbital area, or the submandibular space. The patient is instructed to go to the emergency room when a provider is unavailable. This information should be included in the post-op instructions.

- **Sinus Perforation** – X-rays should be carefully examined before extracting teeth in the posterior maxilla for sinus floor proximity. Referral to an oral surgeon is an option. When the tooth needs to be removed but the sinus may be exposed because of the tooth’s close proximity to the sinus, it is recommended that providers show the patient the x-ray and help him or her to visualize the potential risks. Providers also communicate to the patient that additional procedures and costs may be incurred in association with closing a sinus exposure, should one occur. If providers are willing and able to perform this type of extraction, they also should be familiar with how to close an oral-antral communication or have a location where patients can be referred immediately.

- **Fractures** – Providers are alert for conditions that may make the patient more susceptible to fracture, and look for signs of osteoporosis or tooth position that increase this risk. An angular lower third molar impaction or isolated terminal maxillary tooth is approached with care and requires good surgical techniques, or referral to a specialist.

- **Nerve Damage** – Most often, nerve damage is a result of removing the lower third molars with close proximity to the inferior alveolar nerve, although there have been cases associated with nerve block local anesthetic injections. This requires careful examination of the radiographs. If a patient develops paresthesia after an extraction or the administration of a local anesthetic, the patient must be followed-up and referred to an oral surgeon is indicated if the paresthesia does not resolve within a certain time frame.

- **Miscellaneous** – If a patient experienced elevated blood pressure before or during the procedure, blood pressure is taken post-extraction as well. Every tooth extracted is visually examined with care to ensure the entire root structure was removed. When in doubt, providers can take a post-operative x-ray to verify. If providers discover they extracted the wrong tooth or made any error that can potentially harm a patient, they first talk to the patient, contact their compliance officer, and then document the events appropriately.
With all these possible surgical complications, anticipation is the key to mitigating risks, and patients appreciate the knowledge and expertise in correctly diagnosing the potential problem. Providers always give patients the option of referral to a specialist, and only attempt these types of extractions if they have proper training and experience in performing the procedures. Any time a surgical complication is faced it is important to have a close relationship with the oral surgeon and based on the severity of the event, to call them, explain the complication in a detailed way, and follow their recommendation. Most times the surgeon will validate the general dentist’s management of the situation, and all the times they will make recommendations that align with the standards of practice of the specialty. It is very important that the provider document that conversation in the patient’s record.

**Removable Prosthetics:**

The most common risks when providers create or repair dentures for their patients are mitigated through effective communication and patient education. Patients often have unrealistic expectations about the end results, and the provider needs to determine the patient’s expectations before starting. Patient satisfaction increases when providers set expectations of what dentures can and cannot accomplish in practical and understandable terms, and explain that functionality of dentures is dependent on patient anatomy, ridge morphology, and adaptive capacity. The provider can remind the patient that dentures are not a substitute for teeth; they are a substitute for NO teeth. Attitude is critical. Talk about the possible need for adhesive, acclimation time for speaking and eating with “new” teeth, anticipated life expectancy for the prosthetic, etc. When repairing or replacing a set of deteriorating dentures that a patient has worn for many years, providers take time to explain that the repaired set may feel differently and require a period of adjustment, and may never feel like the “old set.” These conversations are also documented in the patient’s chart. Providers are also responsible for educating their patients on new technologies such as implants, which may improve denture function, even if the patient cannot afford this intervention or this service is not offered. Providers should be cautious about taking on cases that might not work or are beyond the scope of their competency and should always have a signed consent form.

**Lack Of Or/Inadequate Treatment Plan:**

Treatment planning is defined as the process of formulating a rational sequence of treatment steps designed to eliminate disease and restore efficient, comfortable, esthetic masticatory function to a patient. A complete treatment plan, based on a thorough assessment and discussion with the patient, is critical in assuring the quality of care; it is the road map for the next steps. An inadequate or absent treatment plan creates risk for the Health Center as does a plan that is undocumented. While providers may understand the next steps and processes for their patients, not having it documented in the chart raises issues if another provider unfamiliar with the case reviews the charts. Providers are also responsible for reviewing the treatment plan with the patient and documenting the review in the chart.

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**9 Failure To Complete Procedures:**

Treatment started in good faith is sometimes not completed for a variety of reasons. For example, a patient does not understand multiple visits are needed to complete the treatment or fails to attend follow-up appointments or referrals. Often, a patient believes that the absence of pain means further treatment is unnecessary, or fees become barriers to care. Providers are responsible for ensuring the patient follows the proposed treatment once it has been initiated. In the interest of providing the best care while being conscious of potential risks, providers should develop a system that follows up on patients’ care once they leave the Health Center. A good system includes documenting the communication of which patients are aware their treatment is incomplete and know the recommended next steps; documentation of all follow-up communication, such as, phone calls and letters is also kept in the chart.

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**MALPRACTICE SCENARIOS**

- Dr. A at Best Care Health Center gave his patient, who presented with a carious lesion extending into the pulp, the options of extraction, endodontic care, or no treatment. The patient decided to start endodontic treatment, and Dr. A removed the pulp and referred the patient to an endodontist. Dr. A informed the patient verbally and on the written referral slip (a copy of which was placed in the chart) that if the endodontic treatment was not completed, there could be further complications. When the patient learned of the cost for the endodontic treatment, coupled with currently being out of pain, he chose not to continue with endodontic treatment. A year later, the patient’s tooth became symptomatic and broke off below the gum line, and the patient required a surgical extraction to remove the tooth. The oral surgeon asked the patient, “Who started the root canal and did not finish it?” The patient sued Dr. A. A review of the case showed that the patient had selected to start endodontic treatment and there was documented evidence that the patient had been informed of the possible complications of non-treatment in both verbal and written form. The case did not proceed.

- Dr. B, a Health Center dentist, extracted tooth #17 on a patient. The patient was scheduled to return the following week for suture removal but did not attend the appointment. The patient returned 5 months later stating that his lip was numb. Dr. B told the patient to return in two months for follow-up, but the patient did not return. Approximately 2 years after the extraction, the patient went to an oral surgeon for a consult regarding the numbness. By this date, too much time had elapsed from the date of injury for successful nerve reconstruction surgery to be performed. The patient sued Dr. B. A review of the case by the insurance/dental consultant revealed that the provider was at fault because of improper follow-up within the appropriate time-frame after the adverse outcome had been identified.
AVOIDING ABANDONMENT CLAIM

Dentists can be charged with allegations of abandonment if they terminate the doctor-patient relationship without reasonable notice or reasonable opportunity for their patients to arrange for dental care with a new provider. Providers are legally responsible to continue care for their patients until services are no longer required, the patients terminate the relationship, or providers give sufficient notice for their patients to withdraw from care. Dentists are required to follow their Health Centers’ policies before deciding to withdraw from care.

INAPPROPRIATE OR UNNECESSARY PROCEDURES:

Inappropriate or unnecessary procedures such as unnecessary endodontic treatment, excessive bleaching, or other questionable care, can leave providers at risk for malpractice claims. For example, a provider should be careful when deciding to remove functioning silver fillings to be replaced with composites. Be cautious if the patient believes that dental amalgams are the source of ongoing medical problems. If the medical condition fails to improve, the patient may find fault with the work, develop dental hypersensitivity, or become upset that they have incurred an unnecessary expense. Providers may want to exercise caution with any procedures whose primary function is not about improving oral health.

PATIENT FEE DISPUTES

Fee disputes are not professional negligence and are not covered by the FTCA. However, fee disputes can be a source of patient complaints and could lead to malpractice claims. It is worth considering ways to avoid fee disputes with patients.

If oral health program policies and procedures regarding fees, billing and collection are followed, and patients understand what their financial responsibilities will be, fee disputes are often avoided. Part of that discussion is to ensure patients understand the fee is an estimate for planned services, and to prepare for unexpected issues that arise, which incur additional charges. This documented discussion also becomes part of the signed treatment estimate. After a patient complains about charges, it is more challenging to diffuse the situation and may not be worth the money or effort to engage in a confrontation.

If a provider has started an irreversible procedure on the patient (endodontic or fixed prosthetic care, for example), he or she cannot refuse to complete the case, even if the fee has not been paid in full. Refusing to complete the procedure is a potential legal risk, because a claim of patient abandonment can be filed. When providers satisfactorily complete the procedure, they can remind the patient about the outstanding balance before beginning other treatment.
9. **Documentation and Clinical Risk Management**

The purpose of an electronic or written chart is to maintain a patient’s records and treatment. When a chart is legible, minimizes the use of abbreviations, and thoroughly documents a patient’s case, it makes successive treatment for the patient more efficient and appropriate and increases quality of care. Additionally, there are connections between documentation and risk to the Health Center/practitioner. Many malpractice cases are lost as a result of poor documentation hindering the ability to defend a malpractice suit, rather than poor care. Poor documentation may also result in an inability to substantiate billing, posing risk of the appearance of fraud.

The following recommendations can mitigate risk from documentation errors in paper and electronic dental records:

- Make sure each entry is dated and signed clearly (in blue or black ink if paper record) with appropriate identifier for the treating provider as required by state or organizational requirements (initials, last name, numerical identifier etc.).

- Include any discussions with the patient in the progress note.

- Record amount, quantity, and names of materials used in procedures performed. For surgical extractions document and explain the specifics. For example, indicate if flap reflected, bone removed, number and type of sutures placed, etc.

- Developing electronic templates for every procedure code takes time initially, but the investment makes the process more efficient later. It is more difficult in offices with more than two providers.

- If a patient is on Coumadin, aspirin, or other medication that affects the delivery and outcome of treatment, identify that condition for medical alerts (for example the yellow flag in some EDR systems).

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**Top Types of Errors in Record Keeping**

1. Treatment plan is not documented.
2. Health history is not clearly documented or updated regularly.
3. Informed consent is not documented.
4. Informed refusal is not documented.
5. Assessment of patient is incompletely documented.
6. Words, symbols, or abbreviations are ambiguous.
7. Telephone conversations with patient are not documented.
8. Treatment rendered is not clearly documented.
9. Subjective complaints are not documented.
10. Objective findings are incompletely documented.
11. Illegible documentation (paper records).
12. Lack of signatures or illegible signatures (paper records).

(Adapted from the American Dental Association, CMIRP Malpractice Survey, 2005.)

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10 Providers can use the following resources to organize the charts and ensure patient safety: The Joint Commission Official “Do Not Use” List of Abbreviations: http://www.jointcommission.org/assets/1/18/Official_Do_Not_Use_List_6_111.PDF, American Dental Association “Dental Abbreviations, Symbols and Acronyms”: http://www.ada.org/sections/professionalResources/pdfs/dentalpractice_abbreviations.pdf
■ Scan all documents that contain necessary information that cannot be recorded in electronic dental records.

■ Additions or amendments to records must be documented appropriately to avoid the appearance of surreptitiously altering treatment records to cover up adverse incidents. In paper charts additions must be dated and initialed. In EDR, providers should use the append notes function (or similar) to add to their notes.

■ Invest time and resources to configure the electronic system or paper forms (exam charts, consent forms, post-op instructions) to maximize compliance with good recordkeeping and risk management practices.

■ Follow Health Center policies and procedures regarding creation of medical records. Those policies should be consistent with state and federal laws and regulations.

■ Remember, if it is not documented, it didn’t happen.

 СоАР PROGRESS NOTES

 СоАР notes can serve as a useful tool when organizing progress notes in the patient record. Typically, СоАР progress notes include the following components:

Subjective – the patient’s experience of the condition
Objective – the physical findings during clinical examination
Assessment – the updated diagnosis and current status
Plan – the list of interventions to be performed for the patient now and in the future

10. Working Outside Of Competency

There is a fine line between getting training in performing some procedures and being proficient at them. Health Centers must be extremely careful whenever a decision is made to expand services, especially in specialty fields. Health Centers employ very competent dentists who generally have a heart for serving the underserved. Both providers and administrators want to make services available to patients that would not be able to afford them otherwise. Before expanding services CEOs should be educated about the standards of care for the specific specialty and the minimum requirements to designate a provider as proficient in a specific area.

Dentists may find themselves in situations where they feel they are obligated to perform various procedures, some of which may be outside their expertise or competency. When a dentist is inexperienced or uncomfortable with specific procedures, the patient should be referred to a specialist. Dentists employed at Health Centers are in a unique situation. They are aware that they may be the only dental providers in a community of great need.
and that many of their patients will experience financial hardship by having treatment performed by a specialist. This may cause a provider to try and perform procedures beyond their level of competency and experience in order to "help" a patient, out of a sense of altruism. This places both the dentist and the patient at risk. The first duty as a dental professional is to safeguard the patient. In addition, dentists should not work outside of the privileges granted to them by the Health Center regardless of their competency to perform the procedure. Doing so would jeopardize FTCA coverage in the event of a claim.

11. **Informed Refusal**

When a patient disagrees with the recommended procedure and refuses treatment, providers should fully disclose to the patient the risks associated with the refusal and document that the risks associated with the decision were fully discussed with the patient and the patient refused treatment.

The online Safety Net Dental Clinic Manual provides guidelines on handling the informed refusal process:11

- If the patient refuses the recommended care, the provider asks about the reasons for doing so.
- If the patient states, or if it appears, the refusal is due to a lack of understanding, the provider re-explains the rationale for the procedure or treatment, emphasizing the probable consequences of the refusal.
- Use of audiovisuals, such as brochures, dental models, videos, or flip charts is helpful.
- The provider documents that: the patient refused the recommended care; the patient’s reasons for refusal; the consequences of refusal were re-explained in terms the patient understands, and the patient still refused the recommended treatment. Emphasis is placed on the point that the patient understood the risks of refusing care.
- The provider attempts to obtain the patient’s signature on the form or in the chart, which attests he or she was fully aware of the risks and refused the care.
- If the patient is uncooperative, the signature or initials of a witness to this discussion and refusal is entered in the chart or on the form as an alternative.12
- The dentist should follow Health Center policies and procedures regarding informed refusal. Those policies should be consistent with state and federal laws and regulations.

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12 NNOHA’s Dental Forms Library hosts various forms related to Health Center Oral Health Programs. For examples of refusal forms, visit: http://www.nnoha.org/dentallibrary.html
Q: How do I document a patient’s refusal to undergo a necessary intervention?

A: Your documentation of a patient’s refusal to undergo a test or intervention should include:

- an assessment of the patient’s competence to make decisions;
- a statement indicating a lack of coercion;
- a description of your discussion with him (or her) regarding the need for the treatment;
- alternatives to treatment;
- possible risks of treatment, and potential consequences of refusal; and
- a summary of the patient’s reasons for refusal.

12. DEALING WITH PATIENT COMPLAINTS

Providers can avoid escalation of a difficult situation or outcome by listening to patients and offering them opportunities to voice their concerns. The best way to deal with patient complaints is to listen, address and satisfy their concerns, learn from the experience, and implement a plan to avoid similar complaints in the future. Providers should follow Health Center policies and procedures regarding patient complaints.

“A patient complaint can be seen as a complaint, and something you have to deal with, or it can be seen as a gift—information that we can use to improve the quality of our patient care."

– Martin Lieberman, DDS
13. **Professional Peer Review**

Peer review can have several applications in terms of risk management. When performed for quality assessment within a Health Center, peer review generally involves review of dental charts and clinical observation by other providers. This process can identify areas of improvement in documentation and clinical practice in a collegial environment.

The process of *professional* peer review in organized dentistry provides a means for resolving differences of opinion or dispute between a dentist and patient or between a dentist and a third party, and is meant to resolve issues before entering the legal system. There are many different models across the country; the reviewers may be State dental societies, State agencies, State dental examiners, dental quality assurance entities, etc. The ADA’s peer review process includes each constituent (State) or component (local) dental society organizing a committee, which consists of dentists, dental specialists, and sometimes laypersons, who volunteer their time and expertise to consider questions about the appropriateness or quality of care, fees and other issues.13

14. **Next Steps Following a Mistake**

Everyone makes mistakes. Having an organized chart and good communication with the patient can help prevent errors, but does not grant immunity from errors. What happens after an error determines the probabilities of the best outcomes for all parties. The professional puts the patient first and everything else second. If a provider becomes aware of an error or problem during the appointment, they are encouraged to not be defensive, remain calm and seek immediate assistance from colleagues or help from an appropriate, evidence-based source, including referral to the appropriate specialist if indicated. It is advisable to stop the procedure, and check references to make sure the situation is being handled as currently recommended. The provider acknowledges the error and documents everything in the chart or electronic dental record. Error disclosure is not easy to do, but is important to the patient and can be a good risk management strategy.

The provider involves the Health Center risk manager, QA department, Health Center management and clinical leadership, or other similar responsible party in the process from the beginning. The patient should not be blamed. A professional provider lives up to their mistakes and is forthright throughout the process.

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13 American Dental Association “Peer Review Resources”: http://www.ada.org/1623.aspx
15. **The Health Center FTCA Medical Malpractice Program**

The Federal Tort Claims Act (FTCA) is the federal law that waives the sovereign immunity of the United States, which permits parties claiming to have been injured by negligent actions of employees of the United States to file claims against the federal government for the harm they suffered. The FTCA also provides authority for the Federal government to defend against such claims.

The Federally Supported Health Center Assistance Acts (i.e. FSHCAA) of 1992 and 1995 stipulate that deemed Health Centers and certain persons, referred to as “covered individuals”, are to be treated as employees of the U.S. Public Health Service for purposes of medical malpractice liability coverage. These covered individuals include governing board directors and officers, employees, and certain individual contractors of deemed Health Centers.

Covered individuals are defended by the Federal government against medical malpractice claims for covered activities (acts or omissions) in the performance of medical, surgical, dental, or related functions resulting in personal injury occurring within the scope of employment and within the approved scope of project of a deemed Health Center. A Health Center’s scope of project defines the approved service sites, services, providers, service area(s), and target population.\(^\text{14}\)

Only Health Centers that are funded under Section 330 of the Public Health Service Act (not look-alikes) are eligible to be deemed. Health Centers must demonstrate in the deeming application that they conduct complete and thorough credentialing and privileging of their providers, that they have implemented appropriate policies and procedures to reduce the risk of malpractice and lawsuits arising out of any health or health-related functions performed by the covered entity including a quality assurance program. Health Centers must submit an application annually to continue to be covered entities in the Health Center FTCA Medical Malpractice Program.

**Benefits of FTCA Program Coverage:**

- Health Centers no longer have to purchase commercial malpractice insurance. Because of this, these savings can be used to increase patient care.
- Coverage is similar to occurrence-based rather than claims-made insurance and does not have a specific coverage limit with a monetary cap. Therefore, any coverage limits required by other organizations, such as hospitals, are met under the FTCA.
- Covered individuals are immune from personal liability for claims of medical malpractice arising from their deemed employment, contract for services, or duties as an officer or director of the deemed Health Center.
- Suits are brought against the Federal government rather than the provider. Claimants must first seek an administrative remedy by presenting the claim to the Health and Human Services (HHS) Office of the General Counsel within two years after the claim accrues, generally the date of the injury. Cases that make it to trial are heard in federal district court with the plaintiff defended by U.S. Department of Justice attorneys.

Who is covered under FHSCAA and the FTCA?

- Medical malpractice protection applies to employees and certain individual contractors of deemed Health Centers. Dentists who are the Health Center’s employees (i.e. receive a W-2 form) may be full-time or part-time and receive coverage. There is no requirement on the minimum number of hours or percentage of full-time equivalent (FTE) for part-time employees if they are on the organization’s payroll.

- Dentists who are individual contractors (i.e. receive Form 1099) and work more than 32.5 hours per week (i.e. full-time) for the period of the contract for the deemed Health Center.

- Part-time individual contractors who provide family practice, obstetrics and gynecology, general internal medicine, or general pediatric services are covered.

Who is not covered under FHSCAA and the FTCA?

- Volunteer physicians and part-time contract dentists are not covered. In the case of non-covered individuals, such as volunteer physicians and part-time (i.e., averaging less than 32.5 hours per week) contract dentists providing services within the scope of the approved Federal section 330 grant project, the covered entity remains covered, while the individual is not.

- Students or residents training in a Health Center are not covered by FTCA. Malpractice protection for these individuals should be provided through a means other than FHSCAA and the FTCA (generally carried by the academic institution). Health Center oral health programs participating in residencies and other training programs must have clear contracts with the residency sponsoring organization defining malpractice coverage for attendings and preceptors, students and trainees.

If a patient files a claim under the FTCA, the process includes:

- A complaint filed with HRSA
- A review of the complaint by experts
- A decision by the Department of Health and Human Service (HHS), Office of General Counsel regarding the claim (pay, deny, attempt to settle)
- If there is no payment or settlement of the claim, there is potential for the claimant to file suit against the United States

FTCA coverage is restricted to acts or omissions of a covered entity that are within the scope of employment of a covered individual. Providers should consult with the appropriate individual within the center (CEO, Risk Manager, Medical/Dental director) regarding FTCA questions. Providers can also call the FTCA Hotline at 1-866-FTCA-Help (382-2435) with questions or concerns.
Payments for settlements and judgments come from an account funded with money taken from the section 330 appropriations, funds that would have otherwise been used to make grants to Health Centers. Additional information about Health Center FTCA Medical Malpractice Program is available in Policy Information Notice 2011-01, “Federal Tort Claims Act (FTCA) Health Center Policy Manual” at http://bphc.hrsa.gov/policy/pin1101/.

16. **National Practitioner Data Bank**

National Practitioner Data Bank (NPDB) was enacted because the U.S. Congress believed that the increasing occurrence of medical malpractice litigation and the need to improve the quality of medical care had become nationwide problems that warranted greater efforts than any individual State could undertake. The intent is to improve the quality of health care by encouraging State licensing boards, hospitals, other health care entities, and professional societies to identify and discipline those who engage in unprofessional behavior; and to restrict the ability of incompetent physicians, dentists, and other health care practitioners to move from State to State without disclosure or discovery of previous medical malpractice payment and adverse action history. Adverse actions can involve licensure, clinical privileges, professional society membership, and exclusions from the Medicare and Medicaid programs.

The NPDB is primarily an alert or flagging system intended to facilitate a comprehensive review of health care practitioners’ professional credentials. The information contained in the NPDB is intended to direct discrete inquiry into, and scrutiny of, specific areas of a practitioner’s licensure, professional society memberships, medical malpractice payment history, and record of clinical privileges.

What is reported to the NPDB? If one of the following occurs, a report to NPDB is warranted:

- A provider’s practice is limited in any way as a result of disciplinary actions
- A payout is made to a patient
- Any action of the Department of Health

Individuals protected by the FTCA may be reported to the NPDB if a payment is made on their behalf. When a provider applies for a position at a Health Center, the provider is subject to a credential search. (This is not the case in most private practice situations.) A listing in the NPDB does not mean a dentist is barred from practicing or employment, but may require follow-up and explanation.

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15 National Practitioner Data Bank: http://www.npdb-hipdb.hrsa.gov/resources/aboutLegsAndRegs.jsp
17. **Summary**

Risk management is an important part of managing a Health Center oral health program. Risk management is not only about avoiding claims. It is about developing systems that facilitate providing safe, quality, evidence-based care to Health Center patients by reducing organizational and individual provider risk.

For many areas of risk management, the oral health program will be implementing and/or adapting policies and procedures that are being followed by the entire Health Center organization. As related to clinical dental practice however, the Dental Director is the leader in developing and maintaining the risk management program. This includes:

- Establishing a peer review system
- Keeping current with changes in treatment guidelines and the standard of care
- Understanding the primary areas of clinical risk
- Developing standards and systems for documentation of paper or electronic records
- Analyzing adverse events that occur in the clinic as part of a quality improvement process
- Creating a patient-centric environment

Risk management is an ongoing process that yields continuing benefits for the provider, organization, and patients.

18. **Frequently Asked Questions**

Q: **If a new patient who is pregnant comes into the clinic and refuses x-rays for fear of harming the baby, but she is in pain, what should I do?**

A: Do not treat this patient without an x-ray. It is beneath the standard of care to provide treatment without proper diagnostic information. Explain about the safety of x-rays and the need to have them for proper diagnosis and treatment. The California Dental Association Foundation released, *Oral Health During Pregnancy and Early Childhood: Evidence-Based Guidelines for Health Professionals* in 2010. It can be downloaded from: www.cdafoundation.org/guidelines.

Q: **Should we take full-mouth x-rays on all non-emergent, new patients?**

A: Take the necessary x-rays that enable you make a complete and comprehensive diagnosis and treatment plan. Panoramic and bite-wings would suffice the definition of FMX. The ADA has developed guidelines on the type and frequency of x-rays suggested throughout the life cycle: *The use of dental radiographs: Update and recommendations*. It can be downloaded from: www.ada.org/sections/professionalResources/pdfs/report_radiography.pdf

Q: Are part-time dentists covered by FTCA?

A: Part-time dentists who are employees of the Health Center (i.e., receive a W-2 form) are covered. Part-time dentists who are contractors are not covered unless they are contracted for at least 32.5 hours per week.

Q: Are volunteers covered by FTCA?

A: Volunteers are not covered by FTCA at the time of this writing.

Q: Are visits made to a patient's home covered under our “scope”? 

A: Both the site and service must be covered under the organization’s scope of project to be covered and considered under “scope”16. “Home visits” may be added to a Health Center's scope of project. A Health Center need not add each patient’s individual home as a site (they likely would not qualify as sites).

Q: A patient desires a fixed bridge but does not want a full exam or any other treatment due to financial concerns. Should I make the bridge?

A: You cannot provide treatment without first conducting the appropriate exams. This is beneath the standard of care.

Q: What if I work for an organization that does not do quadrant dentistry, but encourages providers to spread out treatment into multiple appointments?

A: NNOHA recommends quadrant dentistry should be practiced whenever possible. Although there are scenarios and patients where different treatment sequences are advised, splitting treatment out into multiple visits for non-clinical reasons is unethical and not consistent with the standard of care. This may also violate encounter-based billing rules.

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19. Links

- ECRI Institute (ECRI): www.ecri.org/clinical_RM_program
- The Joint Commission: http://www.jointcommission.org/
16. HEALTH CENTER FINANCIALS WORKSHEET

1. Who is covered by FTCA coverage?
   a. Volunteers
   b. Part-time employees
   c. Students

2. What is the number one potential clinical risk area in Health Center dentistry?
   a. Dentures
   b. Lack of informed consent
   c. Sexual harassment
   d. Poor charting

3. List ways that you can avoid errors in charting and record-keeping:
   ______________________________________________________________________________________
   ______________________________________________________________________________________
   ______________________________________________________________________________________

4. In what area do you think your Health Center is most at risk?
   ______________________________________________________________________________________
   ______________________________________________________________________________________
   ______________________________________________________________________________________

5. Explain the “standard of care.” How does this fit in your practice?
   ______________________________________________________________________________________
   ______________________________________________________________________________________
   ______________________________________________________________________________________

6. How do ethics relate to risk management?
   ______________________________________________________________________________________
   ______________________________________________________________________________________

7. Which of these is an example of a practice that increases risk?
   a. Completing a small O on tooth #20, and a small O on tooth #21 in one visit.
   b. Completing a small O on tooth #20 on one visit, and completing a small O on tooth #21 on a separate visit.
   c. Completing sealants on teeth #s 2 and 3 in one visit.
   d. Completing a sealant on tooth #2 on one visit, completing a sealant on tooth #3 on a separate visit.
   e. (b.) and (d.) above
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The National Network for Oral Health Access (NNOHA) is a nationwide network of dental providers in safety-net settings. These providers understand that oral disease can affect a person’s speech, appearance, health, and quality of life and that inadequate access to oral health services is a significant problem for low-income individuals. The members of NNOHA are committed to improving the overall health of the country’s underserved individuals through increased access to oral health services.

For more information on NNOHA, visit www.nnoha.org, send an Email to info@nnoha.org, or call 303-957-0635
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