WISHA & HIPAA in the Dental Office

WISHA: Old Game; New Rules
HIPAA: Protecting Your Patients & Your Practice
Hello,

Today we’re going to discuss issues relating to WISHA, Infection Control, and HIPAA in the dental industry. We are now enjoying our 30th year assisting dental practices cope with compliance issues. Thanks to dental offices such as yours, and thousands of dental care professionals throughout the U.S., we’re recognized as one of the country’s leaders in the field of dental regulatory compliance. We work hard to respond to the needs of the industry and appreciate those who refer to us as “The Compliance Company.”

The fact that you’re here this morning is testimony that you are committed to the safety and good health of both your employees and your patients. Whether it’s been preparing written programs, providing staff training, or just answering questions that come up on a daily basis, we thoroughly appreciate the opportunity to work with you in realizing the benefits of that commitment.

As of February 1st, we’ll have prepared written more than 8000 WISHA programs and nearly 5700 HIPAA programs for dental offices across the country and provided training to nearly 190,000 dental professionals. Our seminars and in-service training programs are rated among the best in the industry. We field more than 8000 telephone requests for information and/or assistance each year.

As we settle in to 2019, we want to assure you that we will continue to respond to your daily and long-term compliance needs. We are dedicated to providing you with the information, understanding, and programs needed for you to continue to keep in step with, and more often than not, ahead of the regulatory curve. We are called the “Compliance Company” because that’s who we are; and we thank you for it.

Terre L. Harris,
President/C.E.O.
April 28, 2016

Dear Mr. Harris:

Thank you for emailing the Dental Quality Assurance Commission (commission) regarding sterilization of slow speed hand pieces. The commission discussed your email on April 22, 2016.

The commission determined that reusable equipment like the removable portion of a slow speed hand piece falls under WAC 246-817-620 and must be sterilized. The motor portion of the slow speed hand piece typically does not enter the mouth and does not have to be processed through an autoclave but should be disinfected. The commission recognizes there are three parts to a typical slow speed hand piece, the disposable tip, the reusable attachment, and the motor. Dispose of tip, sterilize reusable attachment, and disinfect the motor.

Please contact Jennifer Santiago at 360-236-4893 or Jennifer.santiago@doh.wa.gov

Sincerely,

Charles Hall, D.D.S., Chairperson
Dental Quality Assurance Commission
PO Box 47852
Olympia WA 98504-7852

*NOTE: This letter was received in response to our inquiry asking the Commission’s position on the CDC’s recommendation to sterilize low-speed handpiece motors between each patient.

**This requirement is currently included in the DQAC’s draft to adopt the CDC’s 2003 guidelines and 2016 “Summary”. If adopted, it will not be required until late 2020 or early 2021.
THE WISHA MANDATE

The Washington Industrial Safety and Health Act (WISHA) is the collection of regulations that are administered and enforced in the State of Washington by the Division of Occupational Safety and Health (DOSH) to ensure employee safety and good health. Its mandate is to ensure that employers provide safe and healthful working conditions for all Washington employees (e.g., dental professionals).

DOSH’s responsibility is to oversee private and public sector worker safety and health throughout the state. It has adopted rules to reduce or eliminate workplace hazards, provides education and training materials to employers, conducts on-site inspections and consultation to help employers identify and fix workplace hazards.

WISHA INVESTIGATIONS

WISHA representatives are authorized to investigate any workplace and all pertinent conditions relating to employee safety and health.” Inspections identify unsafe workplace conditions and determine if rules and regulations are being followed.

CITATIONS AND PENALTIES

"General" (non-serious) citations are issued without monetary penalty but "Serious" now include penalties in the several thousands of dollars. The top three dental office citations are for violations of the Bloodborne Pathogens standard.

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Penalty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop and implement a written exposure control plan You must &quot;develop, implement, and maintain a written Exposure Control Program”</td>
<td>$3,000</td>
</tr>
<tr>
<td>Provide training BBP to your employees (combined with) Maintain training records You must “document and maintain training records for three years”</td>
<td>$3,000</td>
</tr>
<tr>
<td>Provide Hepatitis B vaccinations You must &quot;provide hepatitis vaccinations to all employees who have occupational exposure to blood or other potentially infectious materials”</td>
<td>$3,000</td>
</tr>
</tbody>
</table>

WRITTEN PROGRAMS

“Each employer must develop formal, written Safety and Health programs based on (WISHA) rules and any associated Washington regulations”

WISHA requires written programs for Accident Prevention, Bloodborne Pathogens, and Hazard Communication. In Washington, programs are based on federal WISHA regulations and must be written to the activities of your practice.

COMPLIANCE CATEGORIES

Ultimately, there are four basic categories into which most requirements fall; Written Programs, Hazard Assessments, Staff training, and Documentation.
ACCIDENT PREVENTION PROGRAM – GENERAL SAFETY STANDARDS

“Each employer must develop a formal, written Accident Prevention Program”

The Accident Prevention Program was the first WISHA requirement to ensure safe working conditions for the men and women of Washington. It is a requirement of every dental industry employer. Program elements include:

SAFETY ORIENTATION

Each employee must receive a description of your safety program and your office policies and procedures at the time of initial employment and annually, thereafter.

STAFF TRAINING

WISHA requires training programs that are specific to the activities of your practice and effective in practice. Training must be provided at the time of initial hiring, annually, thereafter, and as the employer deems necessary.

FIRST AID TRAINING

Employers must ensure trained first-aid personnel are available in the office or close by at all times employees are present. Documentation of the first-aid training and the names of certified employees should be maintained within the office.

FIRST AID SUPPLIES

A first aid kit must contain sufficient and necessary first-aid supplies for your office size (number of employees). First-aid kits from your local retailer or safety supplier are adequate for most dental offices.

REPORTING ACCIDENTS

WISHA requires timely reporting of all work-related accidents, illnesses and injuries requiring outside medical attention. Investigations should be conducted immediately and an “Accident Report” recorded and documented.

FIRE EXTINGUISHERS

All fire extinguishers located in your practice must be available and functional. Each must be visually inspected monthly for access and physically inspected annually for operational soundness.

EMERGENCY EVACUATION

All employees must receive training on procedures to successfully evacuate the office in the event of fire, earthquake, bomb threat, or medical emergency including designation of an outside location at which all will assemble upon evacuation.

EMERGENCY EYEWASH

All offices must provide a functional emergency eyewash when there is potential for eye exposure to corrosives, strong irritants, or toxic chemicals. Employees must be informed where the eyewash station is located and how to use it.

WISHA POSTERS

WISHA posters which inform employees of their job safety and health protection rights must be displayed in an area in the office that is easily accessible to all employees. You can obtain free posters from WISHA at www.WISHA.gov.
EXPOSURE CONTROL PROGRAM - BLOODBORNE PATHOGENS STANDARD

“You must prepare a written Exposure Control Program designed to eliminate or minimize employee exposure in your workplace”

ANNUAL REVIEW AND UPDATE

The Exposure Control Program must be reviewed and updated annually to ensure its continued effectiveness and to reflect new/modified tasks and procedures, changes in technology, and document an annual review of safer medical devices.

WRITTEN PROGRAM ELEMENTS

Your written program must identify exposure-potential tasks and activities that might occur, the positions of employees whose duties include those activities, and be available and accessible to all employees at all times the office is open.

EXPOSURE DETERMINATION

You must identify employees have occupational exposure to blood or other body fluids - without regard to the use of PPE. All employees who have exposure-potential assignments during the performance of their duties are considered to be at risk.

METHODS OF COMPLIANCE

Standard Precautions is the infection control concept that all body fluids are to be considered potentially infectious. The three primary compliance methods - Administrative, Engineering, and Work Practice Controls – must be implemented:

HEPATITIS B VACCINATIONS

The hepatitis B vaccination series must be offered to employees who have potential exposure to bloodborne pathogens. Hep B vaccination status of each clinical employee must be documented in the employee’s personal, confidential file.

PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment must be worn in all activities in which there is a reasonable likelihood that blood or other potentially infectious body fluids will reach the employee’s skin or clothing. General work clothes are not acceptable.

GLOVES

Patient care gloves are “single use” and discarded when removed for any reason. Utility gloves are required during sterilization procedures and may be reused so long as the glove has not been compromised.

FACE MASKS

Face masks must cover the nose and mouth to protect the mucous membranes. Masks that become compromised should be discarded and a clean mask substituted. *Masks are always changed between patients.*

EYE PROTECTION

Eye protection which may be glasses or goggles with solid side shields or chin-length face shields must be worn during exposure-potential procedures. Personal glasses with solid side shields may be worn if they cover the orb of the eye.

PROTECTIVE BODY CLOTHING

Protective body clothing must shield employee street clothing and skin from exposures to body fluids. Knee-length lab coats, lab jackets with long, cuffed sleeves and scrub pants are commonly accepted PPE in dental settings.
POST EXPOSURE MANAGEMENT
The employer must have written protocols to encourage employees to have an “immediate” post-exposure evaluation any time skin is broken resultant in the performance of their duties even if the incident does not produce the presence of blood.

HAZARD ASSESSMENT
A "Hazard Assessment" must be conducted each year to identify and correct any facility hazards and/or procedural deficiencies that are present, or are likely to be present, which necessitate the use of personal protective equipment.

HAZARD COMMUNICATION PROGRAM - “THE RIGHT TO KNOW ACT”
You must prepare and implement a Hazard Communication Program, tailored to the activities of your practice, that addresses employee protection from exposure to hazardous chemicals used in the performance of their duties.

WRITTEN PROGRAM
Written Program policies and procedures, based on federal WISHA regulations and the activities of your practice, must address and include attention to hazardous chemical identification, SDS maintenance, and container labeling.

LABELS AND WARNINGS
Hazard warning labels convey a product’s specific chemical(s) and hazard information. Each container must be labeled, tagged, or otherwise marked with the product name, “signal” word, hazard statement, and pictogram, or words, pictures, symbols, or a combination, thereof to provide “at least general information” regarding the hazards of the product.

SAFETY DATA SHEETS (SDS) [MSDS]
The Material Safety Data Sheet [MSDS] has historically been used to identify a product’s chemical hazard information and to train employees about the hazards and safe use of products which contain hazardous chemicals. In 2013 WISHA renamed the MSDS to SDS (Safety Data Sheets) and required replacing existing MSDSs with SDSs. All SDS and labeling changes were to be in place by June of 2016.

EMPLOYEE INFORMATION AND TRAINING
All employees must receive training about hazardous chemicals at the time of hire; with the introduction of a new or unfamiliar products product containing hazardous chemicals; and at least once yearly as reinforcement training.

Training should include location of the Hazard Communication Program, SDS book, and spill kit; methods to detect the presence/release of a hazardous chemicals; associated hazards of chemical products, and necessary protective measures.

GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELING OF CHEMICALS
In 2013, WISHA adopted the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). It amended the Hazard Communication Standard and became effective on April 15, 2013. New and more detailed labels on containers of chemicals displaying the GHS information are required and the MSDS is being phased out and replaced by newly SDS sheets.

SAFETY DATA SHEET (SDS)
The name “Material Safety Data Sheet” (MSDS) has been changed to “Safety Data Sheet” (SDS) and unlike the MSDS, the SDS has standard format that must be implemented by all manufacturers in countries signatory to the GHS.

**GHS REQUIRED FORMAT**

<table>
<thead>
<tr>
<th>SECTION</th>
<th>Identification</th>
<th>Includes product identifier; manufacturer or distributor name; address, phone number; emergency phone number; recommended use; restrictions on use.</th>
</tr>
</thead>
<tbody>
<tr>
<td>SECTION 2</td>
<td>Hazard(s) Identification</td>
<td>Includes all hazards regarding the chemical; required label elements.</td>
</tr>
<tr>
<td>SECTION 3</td>
<td>Composition/information on ingredients;</td>
<td>Includes information on chemical ingredients; trade secret claims.</td>
</tr>
<tr>
<td>SECTION 4</td>
<td>First-aid measures;</td>
<td>Includes important symptoms/effects, acute, delayed; required treatment</td>
</tr>
<tr>
<td>SECTION 5</td>
<td>Firefighting measures;</td>
<td>Lists suitable extinguishing techniques, equipment; chemical hazards from fire.</td>
</tr>
<tr>
<td>SECTION 6</td>
<td>Accidental release measures;</td>
<td>Lists emergency procedures; protective equipment; proper methods of containment and cleanup.</td>
</tr>
<tr>
<td>SECTION 7</td>
<td>Exposure controls/personal protection;</td>
<td>Lists precautions for safe handling and storage, including incompatibilities.</td>
</tr>
<tr>
<td>SECTION 8</td>
<td>Handling and storage;</td>
<td>Lists WISHA’s Permissible Exposure Limits (PELs); Threshold Limit Values (TLVs); appropriate engineering controls; personal protective equipment.</td>
</tr>
<tr>
<td>SECTION 9</td>
<td>Physical and chemical properties;</td>
<td>Lists the chemical’s characteristics.</td>
</tr>
<tr>
<td>SECTION 10</td>
<td>Stability and reactivity;</td>
<td>Lists chemical stability and possibility of hazardous reactions.</td>
</tr>
<tr>
<td>SECTION 11</td>
<td>Toxicological information;</td>
<td>Includes routes of exposure; related symptoms, acute and chronic effects; numerical measures of toxicity.</td>
</tr>
<tr>
<td>SECTION 12</td>
<td>Ecological information;</td>
<td>Ecological information</td>
</tr>
<tr>
<td>SECTION 13</td>
<td>Disposal considerations;</td>
<td>Disposal considerations</td>
</tr>
<tr>
<td>SECTION 14</td>
<td>Transport information;</td>
<td>Transport information</td>
</tr>
<tr>
<td>SECTION 15</td>
<td>Regulatory information;</td>
<td>Regulatory information</td>
</tr>
<tr>
<td>SECTION 16</td>
<td>Other information, including date of preparation or last revision.</td>
<td>Includes the date of preparation or last revision.</td>
</tr>
</tbody>
</table>

**HAZARD CLASSIFICATIONS**

Chemical manufacturers must determine the hazard classes of each chemical according to the requirements established in the Hazard Communication Standard (HCS). There are three primary hazard classifications:

**PHYSICAL HAZARDS**

Physical hazards include explosives, flammable, oxidizing, and under pressure gases and aerosols; flammable liquids and solids, self-reactive and solid self-heating substances, pyrophoric liquids, water-sensitive solids substances on that emit flammable gases, oxidizing liquids and solids, organic peroxides, and substances corrosive to metal.

**HEALTH HAZARDS**

Health hazards include Acute Toxicity, Skin Corrosion, Skin Irritation, Eye Irritation, Serious Eye Damage, Respiratory Sensitizer, Carcinogenicity, Reproductive Toxicity, Specific Target Organ Toxicity, (Aspiration Hazard).
Environmental hazards include Acute Aquatic Toxicity and Chronic Aquatic Toxicity.

**SDS PICTOGRAMS**

The Hazard Communication Standard now requires pictograms on labels to alert users of the chemical hazards. Each pictogram is determined by the chemical hazard Classification(s) and consists of a symbol within a red border and represents a distinct hazard(s).

<table>
<thead>
<tr>
<th>PICTOGRAMS/SYMBOLS</th>
<th><strong>Health Hazard</strong></th>
<th><strong>Flammable</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>* Carcinogen</td>
<td></td>
<td>* Flammables</td>
</tr>
<tr>
<td>* Mutagenicity</td>
<td></td>
<td>* Pyrophorics</td>
</tr>
<tr>
<td>* Reproductive Toxicity</td>
<td></td>
<td>* Self-Heating</td>
</tr>
<tr>
<td>* Respiratory Sensitizer</td>
<td></td>
<td>* Emits Flammable gas</td>
</tr>
<tr>
<td>* Target Organ Toxicity</td>
<td></td>
<td>* Self-reactives</td>
</tr>
<tr>
<td>* Aspiration Toxicity</td>
<td></td>
<td>* Organic Peroxides</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th><strong>Irritant</strong></th>
<th><strong>Compressed Gas</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>* Irritant (skin and eye)</td>
<td></td>
<td>* Gasses Under Pressure</td>
</tr>
<tr>
<td>* Skin Sensitizer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Acute Toxicity (harmful)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Narcotic Effects</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Respiratory Tract Irritant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Hazardous to Ozone Layer</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th><strong>Corrosion</strong></th>
<th><strong>Explosive</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>* Skin Corrosion</td>
<td></td>
<td>* Explosives</td>
</tr>
<tr>
<td>* Skin Burns</td>
<td></td>
<td>* Self-Reactives</td>
</tr>
<tr>
<td>* Eye Damage</td>
<td></td>
<td>* Organic Peroxides</td>
</tr>
<tr>
<td>* Corrosive to Metals</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th><strong>Oxidizing</strong></th>
<th><strong>Toxic</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>* Oxidizers</td>
<td></td>
<td>* Acute Toxicity (fatal or toxic)</td>
</tr>
</tbody>
</table>

|                  | **Environmentally Damaging** (Non-Mandatory) | |
|------------------|---------------------------------------------| |
|                  | * Aquatic Toxicity                          | |
SAFETY DATA SHEET (SAMPLE)


Printing date 03/07/2014
Reviewed on 03/07/2014

(Not an actual SDS)

1 Identification

- **Product identifier**
  - Trade name: piperidine
  - **CAS Number:** 110-88-4
  - **EC number:** 203-813-0
  - **Index number:** 613-027-00-3
- **Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:** NuGeneration Technologies, LLC (dba NuGenTec)
    1155 Park Avenue, Emeryville, CA 94608
    salessteam@nugentec.com
    888-996-8436 or 707-826-4080 for product information
  - **Emergency telephone number:** Infotrac: 1-800-535-5053, 1-352-326-2510

2. Hazard(s) identification

- **Classification of the substance or mixture**
  - Flammable
    - Highly flammable liquid and vapor
  - Acute Toxicity
    - Toxic in contact with skin / Toxic if inhaled
  - Skin Corrosion and Burns
    - Flame
      - Highly flammable liquid and vapor.
      - Sku and crossbones
      - Toxic in contact with skin.
      - Toxic if inhaled.
    - Corrosion
      - Causes severe skin burns and eye damage.
    - Label elements
    - GHS label elements
    - Classified and labeled according to the (GHS).
    - Hazard pictograms
    - OHS02 OHS05 OHS06
    - Signal word Danger
    - Hazard statements
      - Highly flammable liquid and vapor.

3. Personal Protective Equipment

**Respiratory protection**
Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

**Hand protection**
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove’s outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
GHS LABELING CLASSIFICATIONS

The HCS has “performance-oriented” labels that allows almost any method of conveying hazards while the GHS has specific, “harmonized provisions” for pictograms, hazard statements, and signal words, and precautionary statements.

LABEL EXAMPLE

![Label Example](image)

IMPLEMENTATION SCHEDULE

<table>
<thead>
<tr>
<th>Implementation / Enforcement Date(s)</th>
<th>Requirements</th>
<th>Who</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 1, 2016</td>
<td>Update alternative workplace labeling and Hazard Communication Program as necessary, and provide additional employee training for newly identified physical or health hazards.</td>
<td>Employers</td>
</tr>
</tbody>
</table>

INFECTIOUS WASTE MANAGEMENT

“You must handle regulated waste properly and safely and dispose of all regulated waste according to applicable city, county, and state regulations”

WISHA’s bloodborne Pathogen standard refers to infectious wastes as “regulated wastes” and requires that you must “handle regulated waste properly and safely”. Dispose of regulated waste according to state and county and/or city regulations.

SHARPS WASTES

Contaminated instruments and objects or devices that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires are considered sharps waste.

SHARPS WASTE CONTAINERS

Sharps wastes containers must be leak proof, rigid, puncture resistant and "be located as close as feasible to the immediate area where used". WISHA enforces this to mean IN the operatory; observe the “Do Not Fill Above This Line” mark.

INFECTIOUS WASTE DISPOSAL

Most counties have regulations which require that you segregate infectious wastes from the regular waste stream. Even those that don’t have specific rules, require that all infectious wastes be placed in containers identified as infectious waste.
HIPAA

HEALTH INSURANCE PORTABILITY & ACCOUNTABILITY ACT

“The usual stuff — a new virus from the Joker, spyware from the Penguin, malicious code from Cat Woman, another phishing scheme from the Riddler.”
HIPAA PRIVACY

The rules called HIPAA established a national set of “basic privacy standards” that provide a new level of protection to patients and, at the same time establish a balance between the needs of the individual and the needs of society. Until HIPAA, there were virtually no federal rules that protected the individual’s private health information and simultaneously guaranteed access to their own information.

PRIVACY MANDATE

HIPAA rules are dedicated to the fundamental principle that dental and medical patients have an absolute right to expect their personal health information to be used judiciously by those who collect it. Under HIPAA, patient dental care information is to be protected as personal and sensitive and patients have a right to expect that dental care professionals will safeguard their private, personal information against improper use or disclosure.

DENTAL OFFICE PROGRAMS

All Covered entities must prepare, implement, and enforce written policies and procedures, tailored to the activities of their practice, that address the HIPAA Privacy, Security, Breach Notification, and Omnibus Rules and ensure the protection of patient protected healthcare information (PHI).

All HIPAA programs must include as a minimum, an organizational practice GAP/Risk Analysis; written privacy protection protocols, employee training, complaint management systems, and Business Associate Agreements.

KEY TERMINOLOGY

Covered Entity
Any medical or dental healthcare provider, practice, clinic, hospital or other healthcare facility; insurance companies that process medical and dental claims, and the clearing houses involved in that process.

PHI – Protected Health Care Information
Any patient information – in any form – whether oral, recorded, or written that identifies, or can readily be associated with the identity of a patient

TPO – Treatment, Payment, Operations
The operational activities necessary to provide the patient services and conduct the practice business

MNS – Minimum Necessary Standard
The minimum amount of information that is necessary to accomplish an intended purpose
VIOLATIONS AND PENALTIES

HIPAA has identified two violation categories: Civil and Criminal. Penalties, based on intent and severity of damages to the patient, can range vary from $100 to 1.5 million dollars per event. Under HIPAA, the individual who violates the standard is the individual who is cited, pays any penalties and, if of the more serious nature, goes to jail.

STATEMENT OF PRIVACY PRACTICES

Each practice must have and offer a Statement of Privacy Practices to each patient at the time of his or her initial visit to the office. The “Statement” is the written promise to each patient that their private and personal information will be used exclusively for their dental care and related services. It must also be posted and available in the office for patient reference and on the company’s web site.

ACKNOWLEDGEMENT OF RECEIPT

You must make a best faith effort to have each patient receiving the “Statement of Privacy Practices” sign the “Acknowledgement of Receipt of Notice of Privacy Practices” form. This signature is important because it is also often used to document the patient’s authorization to share their private information with other family members.

PHI DISCLOSURES

HIPAA rules include inherent consent to the use and disclosure of a patient’s protected information for purposes of normal dental operations and associated payment activities without the specific, written permission of the patients. All uses and disclosures not specifically allowed by HIPAA rules require the written authorization signed by the individual patient or his/her legal representative.

AUTHORIZATION OR CONSENT

HIPAA has divided disclosure of patient PHI into two categories: (1) those which can only occur with the patient’s authorization and, (2) those by which consent is established by HIPAA rule. You must honor all patient authorizations to disclose and/or provide a copy of their own protected health information unless there is reason that it should be denied. All denials must be documented.

DISCRETIONARY DISCLOSURES

Patient PHI may be disclosed to a third party without the patient’s authorization at the guarded discretion of the dental professional only when and to the extent that will serve to the benefit of the patient.

REQUIRED DISCLOSURES

Disclosures of PHI authorized by legal demand, governmental directives and compulsory process of law will be released in stick keeping of the authorizing documentation.

DISCOVERY REQUESTS (LEGAL)

Discovery requests for PHI which are generated by attorneys or other parties in response to a discovery request or compulsory process on your office.
TO PARENTS OF MINORS

HIPAA generally gives parents the rights to access PHI of their minor children except when court orders/directives or state law prohibit parents access; when parents agree to confidential relationship between doctor and minor; and when doctor believes parent involvement could endanger the minor.

SECURITY AND PHYSICAL SAFEGUARDS

Security efforts and activities must continually be monitored and reviewed as part of your daily operations. Particular vigilance includes attention to sign-in sheets, schedules, telephone messages, recall cards, open charts, unprotected computers, patient discussions, and locked doors and windows.

BUSINESS ASSOCIATES

It is common that practitioners look outside their practice for support and assistance for activities and functions they cannot or choose not to perform themselves. The entities to which they look are individual contractors, consultants, and other businesses called Business Associates.

When the interaction between the dental office and these service providers requires the disclosure of patient PHI, the information being disclosed is no longer under the supervision of the practitioner. Therefore, a contract to ensure the privacy rights of the patient are not lost in the process must be established between the covered entity and the business associate. Examples of Business Associate companies include:

Examples of entities falling within the definition of Business Associates include, but are not limited to:

<table>
<thead>
<tr>
<th>IT Companies</th>
<th>Janitorial Services</th>
<th>Legal Services</th>
<th>Data Storage Vendors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accounting Services</td>
<td>Practice Mgmt. Firms</td>
<td>Collection Agencies</td>
<td>Live Answering Services</td>
</tr>
</tbody>
</table>

Once a Business Associates signs the Business Associate Agreement, they have the same responsibilities and take the same precautions as a Covered Entity to protect patient PHI. If the BA hires subcontractors, it must have a Business Associate Agreement with the contractor. The Covered Entity does not have to have an agreement with the Business Associate’s subcontractor.

COMPLAINTS

HIPAA allows that disagreements will, from time to time, surface and that every effort should be made to settle issues of discontent and disagreement without having to resort to legal or third party intervention.

EMPLOYEE TRAINING

All employees and all future employees must be provided HIPAA compliance training at the time of initial employment; when the regulations change; whenever deemed necessary by the doctor, and on a “regular” basis. OCR defines “regular” to mean annually.

MARKETING

Because much of the information shared between offices and during the process of providing dental care is done without the patient’s knowledge or permission, HIPAA includes detailed marketing restrictions.
THIRD PARTY MARKETING

Selling a patient’s Protected Health Information to a third party for their use and reuse is not allowed without the patient’s express written authorization.

INTERNAL MARKETING

The doctor and/or staff are allowed within the permissions of HIPAA to suggest dental-related products and treatment remedies to their patients while they are receiving dental care in this office.

BUSINESS ASSOCIATE MARKETING

HIPAA does not allow Business Associates to use patient PHI for the purposes of marketing any of their products or services without the express written authorization of the patient or to disclose the PHI to any other entity for the purposes of marketing their products or the products.

HIPAA SECURITY

OVERVIEW

The Privacy Rule sets the standards for how PHI should be controlled; the Security Rule sets the standards that establish how to protect ePHI. The HIPAA Security Rule adopted standards for the security of electronic protected health information (ePHI) that is collected, maintained, used and/or transmitted by electronic medium.

SECURITY OBJECTIVES:

Security safeguards will vary from practice to practice because HIPAA allows flexibility in approach and establishes that security safeguards be “reasonable and appropriate” to an individual practice and protect three principles: Confidentiality, Integrity, and Availability.

SAFEGUARDS

Safeguards are categorized as administrative, physical and technical, and must be in written form to protect against "any reasonably anticipated threats or hazards to safeguard the confidentiality (privacy), integrity, and availability of electronic PHI. The three basic safeguards, which are presented later in procedural form, are:

A. Administrative Safeguards are administrative actions, policies, and procedures to manage the program and the conduct of the employees.

B. Physical Safeguards are the physical measures, policies, and procedures to protect our electronic information systems from natural disaster and unauthorized intrusion, and

C. Technical Safeguards are the policies and procedures, the technology and media used to protect the electronic PHI and control access to it.
BREACH NOTIFICATION RULE

HIPAA adopted the Breach Notification Rule in February of 2009 in response to requirements established of the Health Information Technology for Economic and Clinical Health (HITECH) Act. The Breach Notification Rule requires covered entities to investigate and report provide notification to affected individuals and to the Secretary of Health and Human Services following the discovery of a breach of unsecured PHI. It also requires that procedures be implemented and staff be trained to guard against, as well as respond to, breaches of unsecured PHI.

BREACH DISCOVERY/INVESTIGATIONS:

When a questionable disclosure of confidentiality is discovered, it is necessary to investigate to determine whether or not a breach has occurred. The Omnibus Rule established that if PHI is accessed, released, and/or inappropriately disclosed and was not “secure”, a breach had occurred. Therefore, if the information was “secure” – as defined by and within HIPAA, the disclosure might have been inappropriate, but it is not considered a “Breach”.

UNSECURED PROTECTED HEALTH INFORMATION

HIPAA defines unsecured PHI as: “Protected Health Information (PHI) that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology specified by the Secretary in guidance.”

As established by HIPAA, PHI is considered to be rendered unusable, unreadable, or indecipherable to unauthorized individuals if electronic PHI has been encrypted as specified by the HIPAA Security Rule, the media on which the PHI is stored or recorded have been shredded or destroyed [and] cannot be read or otherwise reconstructed, or the electronic media have been cleared, purged, or destroyed.

BREACH NOTIFICATION

When a breach is discovered, the doctor must provide appropriate notification to affected patients as soon as possible and, when necessary, to the Secretary of Health and Human Services.

NOTIFICATION TO PATIENTS

HIPAA has two specific notification methods:

“Actual” Notification is direct written communication to the individuals whose PHI has been breached, posted by first-class mail to the last known address of the individual(s) affected by the breach. Electronic notification, such as notification by e-mail, may be used if the individual(s) affected have previously agreed to such communication.

“Alternative Notification” is notification that is used if initial contact information is out-of-date.

NOTIFICATION TO MEDIA

Notification to the media is required following the discovery of a breach in which the Protected Health Information is that of more than 500 residents.

NOTIFICATION TO THE SECRETARY OF HHS

Notification to the Secretary of Health and Human Services is required - not more than sixty (60) days from the date of discovery - in all breach incidents whether a single incident or one of more than 500 individuals.
All notifications of **fewer than 500** affected individuals will be submitted to the Secretary **no later than sixty (60) days after the end of each calendar year.**

**RECORDS KEEPING**

Documentation of all breaches must be maintained for a minimum of **six (6) years.**

**NOTIFICATION BY A BUSINESS ASSOCIATE**

A **Business Associate must notify the practice** when it discovers a breach of PHI. The notification(s) to the affected individuals must be made **without unreasonable delay, but in no case later than sixty (60) days** from the date that the Business Associate discovered, should have discovered the breach.

**HIPAA’S OMNIBUS RULE UPDATE**

**OMNIBUS RULE OVERVIEW**

The Omnibus Rule was written to “**help protect patient privacy and safeguard patients’ health information in and ever expanding digital age**”. It clarified breach notification requirements and expanded the obligations of Business Associates to protect patient PHI.

The Omnibus Rule also reemphasized the requirements of the covered entities to conduct annual program assessments, rewrite Business Associate Agreements; update Privacy and Security written programs and Statements of Privacy Practice and Acknowledgement of Receipt forms to meet the Omnibus Rule standards.

The Omnibus Bill also reiterated that all breaches of patient protected information will be investigated regardless of the size or number of patient records involved.
Thank you for attending!

18300 Cascade Avenue South, Suite 130
Seattle, Washington 98188

For additional information or services, please contact HARRISBIOMEDICAL at

www.harrisbiomedical.net
206-575-4610 | 866-548-2468
206-575-8177 [fax]