



CLINIC OPERATIONS COMPLIANCE MANUAL

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TCC Healthcare

CLINIC OPERATIONS COMPLIANCE MANUAL

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Introduction

Purpose

The purpose of this document is to communicate TCC Health Clinic (TCC or “the clinic”) policies and procedures, including those policies and procedures that cover clinic staffing, clinic operations, and the clinic’s HIPAA information privacy and security compliance requirements. The policies and procedures contained here are collectively referred to throughout this document as the “TCC operations compliance manual” or “the manual”.

TCC must maintain detailed operational policies and procedures, including defining certain outcomes and deliverables as described here, in response to this document. The clinic has many operational processes in place and TCC management is placing an increased emphasis on detailed written policy and procedure documents to support our HIPAA compliance program and to fully inform all clinic staff about proper conduct in the workplace and when working with patients and their information. In addition, because the HHS rules that implement the requirements of HIPAA are evolving regulatory requirements, the clinic must review its operations, policies, procedures, and any deliverables that relate to them, on an ongoing basis to ensure continued compliance with HIPAA.

Scope

The policies and procedures in this manual apply to all TCC Health Clinic patient care and office administration staff, including physicians. All members of TCC’s workforce who have access to PHI must comply with this manual in its entirety. Those members of the TCC workforce who do not have routine access to PHI are still expected to understand the

clinic's policies and procedures related to HIPAA compliance and they must fully comply with all other TCC staff and clinic operations policies and procedures.

For purposes of this manual, TCC's workforce includes individuals who would be considered part of the workforce under HIPAA such as employees, volunteers, trainees, and other persons whose work performance is under the direct control of TCC, whether or not they are paid by TCC. The term "employee" includes all of these types of workers.

This manual is the official source for compliance information on the subjects identified in its table of contents. In many cases, there may be additional procedures that address specific tasks and duties, such as back-office procedures for billing and accounting; however, those procedures must not conflict with the compliance requirements identified here.

Each policy and procedure section here contains more detailed information as to the scope of that specific material when such information goes beyond the overall scope of the manual.

Background

The clinic has created this manual to promote knowledge and accountability for all of the TCC workforce involved in the clinic's operations. The inclusion of general operations policies and procedures here is intended to simplify our overall compliance program and help ensure patient care safety and quality beyond just our HIPAA compliance obligations. That being said, HIPAA is the most significant set of rules that govern healthcare operations in the U.S., including for TCC Health Clinic, and you will find that the HIPAA-related information in this manual represents the large majority of its content.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations and rules identify the clinic's responsibilities as a HIPAA-regulated healthcare provider, define the rights of patients for access to and control of

their information, and restrict the clinic's ability to use and disclose protected health information.

Protected health information (PHI) means information that is created or received by the clinic and relates to the past, present, or future physical or mental health or condition of a patient; the provision of health care to a patient; or the past, present, or future payment for the provision of health care to a patient; and that identifies the patient or for which there is a reasonable basis to believe the information can be used to identify the patient. PHI includes information of persons living or deceased.

Manual Organization & Design

Main Subject Areas

This manual is designed to address requirements of all TCC Health Clinic normal operations. In the interest of simplicity for staff and for maintaining updates to the clinic's policies and procedures, we have opted to create a single, unified document that contains all the TCC policies and procedures that govern the work done in the clinic.

Related policies and procedures are grouped together here in the following main sections:

- Staff Policies & Procedures
- Clinic Operations Policies & Procedures
- Responsibilities as a HIPAA Covered Entity
- PHI Use & Disclosure Policies & Procedures
- Procedures for Complying with Patient Rights Under HIPAA

You may find that certain information is addressed in multiple sections. Such coverage is designed to capture all the requirements in their proper context. The information that is found in the clinic operations area is provided mainly to help answer operational

questions quickly, whereas the same subject in the HIPAA section is intended to communicate, fully, all the information you need to make a decision about how to function and ensure that you remain in full compliance with TCC's HIPAA compliance program.

Individual Policy & Procedure Data Table

At the start of each individual policy and procedure's content, you will find a simple table below the title of the policy and procedure. This table is designed to help visually mark the beginning of a new subject and to track key information about the specific policy:

- **Policy Number** – We use a simple policy numbering scheme that consists of the initials of the main subject area followed by a two-digit sequence number (e.g., UD01 is the first of the clinic's *PHI Use & Disclosure Policies & Procedures*. TCC staff do not routinely use or need to know these numbers.
- **Policy Effective Date** – The manual cover includes the original effective date for the whole manual. The effective date entry in this table helps recognize that a given policy might be an addition within the manual and to make clear when it was added at the clinic. Most of the policies and procedures in the manual will have the same effective date as the manual, June 8, 2008.
- **Persons Affected** – In addition to the description of the overall scope of this manual and of each policy and procedure area, this entry helps further specify whether individual policies or procedures apply to a more specific part of the TCC workforce. Most of the policies and procedures will have the same general statement that they apply to all TCC staff.
- **Regulatory Reference** – The regulatory reference entry is used for the overall management of the clinic's policies and procedures by the clinic's management and compliance staff to help us quickly identify content that may be subject to

change due to regulatory changes. Other TCC staff are not expected to learn this information.

Rule

Immediately following the intro table described above, you will find the rule statement. The rule statement is the shortest summary of the policy requirement at the highest level. This section is usually a simple one- or two-sentence statement that says what must happen and when.

Explanation

Following the rule statement, the explanation section provides information about how the rule came to be and to describe key terms that must be understood in order to understand the rule and the resulting policy and procedure information. This part of each individual policy and procedure serves a similar role to the *Background* section in the *Introduction* to the whole manual.

Purpose

Within the explanation, the purpose subheading describes the intent behind the policy and procedure, in terms of compliance with the rule statement.

Definitions

Definitions of terms that may not be commonly understood in the general clinic operations may be found under this subheading. Keep in mind that you may see terms appear in more than one individual policy and procedure, and the definition of the term in each may vary and is specific to the context of the individual subject to which it relates.

Policy

The information in the policy section identifies all the necessary specifics of what must be accomplished and when things should start and or finish in order for the rule to be met.

Policy content also provides information on what must not be done, penalties for policy failures, and clarifications about deadlines that are dependent on other factors.

The language used policy statements content intentionally avoids defining who must do these things and how they must be done.

Procedure

Procedure section content identifies who should do the work necessary to fulfill a policy and provides step-by-step instructions to assist those workers with completion of that work.

Control Mechanisms

Control mechanisms are specifically identified tools for determining progress and evaluating performance. They may include administrative tools (such as observations or audits by management), physical tools (such as locked shred bins), or technical controls (such as the ability to lock a computer when it is unattended). Control mechanisms may involve combinations of these types of tools.

The content of each control mechanism section in the clinic's policies and procedures lists examples of control mechanisms that can facilitate monitoring for compliance of that particular policy and procedure. Compliance monitoring policies and procedures are the responsibilities of TCC's management and Privacy Officer and are not included in this manual. The listed control mechanisms are meant to let all staff know about the kinds of things we may monitor to make sure our policies and procedures are being followed and our compliance program is working.

End of Manual Content

After all of the individual policies and procedures content, the manual provides an appendix of additional information and a detailed history of the manual.

Additional Information

This single appendix identifies sources of supplemental information and provides links to other resources that connect to the clinic's compliance program, including forms related to the individual patient rights policies and procedures, templates for communications, training logs, etc.

Document History Table

The document history table that closes out the manual provides a high-level, but complete history of the manual's creation and evolution into its current form and content.

Disposal of Papers Containing Sensitive Information

Policy Number: CO08	Policy Effective Date: 8.27.2010
Persons Affected: All TCC Health Clinic workforce members, including temporary workers and contract staff working on behalf of the clinic in the clinic facility	
Regulatory Reference: HIPAA 164.530(c)(1) and other state and federal regulations governing physical data protection	

Rule

Papers containing sensitive information must be disposed of in a manner designed to prevent unauthorized access to the sensitive information once the papers are no longer needed.

Explanation

Purpose

The purpose of this document is to make sure that everyone understands the limits on what may be placed in unsecured recycle bins, and describe acceptable procedures for complying with this rule.

This document is not, however, intended to help decide what should be disposed of versus what should be retained in physical files. For determining whether a particular piece of paper should be filed or disposed of, please consult the *Recordkeeping* policy and procedure and the HIPAA compliance sections later in the manual.

Definition of Sensitive Information

The term "sensitive information" is one that is broad and often depends on other circumstances. Depending on the context, you may find that a piece of information is

sensitive in some situations and not in others. But there are certain types of information that should always be considered sensitive at the clinic:

Personally-identifying information (PII) - Information that identifies a specific individual or that can be used by combining it with other data to identify an individual.

Some common types are full name, SSN, driver's license number, credit card number, birthdate, birthplace, and genetic information. Some less obvious types may include age (even without birthdate), job position, workplace, gender or race.

Though individual elements might not be PII, when combined they can become PII. One study showed that nearly 90% of the U.S. population could be personally identified by combining gender, ZIP Code, and full date of birth. So, for example: Though there might be at least 1,000 females in every American town of 2,000 people, it is very likely that there is only one female in Richland, MO born on May 25, 1949.

Protected health information (PHI) - In short, any health-related PII; or any information about an individual's health condition, health care, or payment for health care that identifies or could be used to identify the individual.

Such health information is considered PHI when it includes any one of several PII elements such as those described above and several others specifically listed in HIPAA.

Because the TCC Health Clinic is a HIPAA covered entity, the presumption is that information we collect and use is PHI unless specifically proven to be another sensitive category or non-sensitive information.

Confidential business information - Information about business operations, including policies and procedures, checklists, form letters, financial reports, training materials, etc., whether it has any individual PII or PHI included or not.

As you can see, a majority of the information TCC works with would be considered one of these types of sensitive information. As a result, a majority of the papers we use in doing

our work are likely to contain sensitive information that should be disposed of in a secure manner to avoid data breaches in violation of federal and state laws.

If you have any question as to whether a particular paper you want to dispose of should be treated as containing sensitive information, please just dispose of the paper in an approved, secure shred bin.

Policy

Papers containing sensitive information of any kind must be placed into locked shred bins or shredded when the papers are no longer needed.

Papers containing sensitive information must not be left in the blue bins at individual desks or in the large break-room recycling bins. These bins are strictly for segregating recyclable paper from trash waste.

Sensitive information also must not be placed into any unlocked larger bin. Doing so could result in a data breach that exposes TCC to legal risk and/or potential regulatory penalties, as well as result in individual penalties for anyone disposing of the sensitive information in an unprotected manner.

Procedures

Routine Daily Procedures

As you will see below, all papers from our facilities ultimately end up being removed and shredded by our disposal service; however, from the moment a piece of paper is no longer needed, the person working with that piece of paper needs to dispose of it in a secure manner.

To simplify operations and take the burden of decision-making off of individual TCC staff members, each employee must place all of his or her own paper waste into the now-locked larger bins. This approach relieves clinic employees from the risk and

personal stress of needing to decide whether any specific sheet of paper contains sensitive information or not.

This simplification is justified because all of our paper waste, whether it contains sensitive information or not, goes through the same destruction process once it is removed from our premises. In addition, our operations make it very likely that most of the papers we handle will contain some kind of sensitive information.

Below are two alternative procedures that comply with this policy:

- Immediate disposal - When papers with which you are currently working are no longer needed, take them to the nearest shredder or place them in the nearest locked disposal bin:
 - Immediately when you are finished working the them (if doing so is not disruptive to your work), or
 - As needed when you leave your work area for your next scheduled appointment or break or when you leave for the day.
- Secure temporary storage and periodic disposal - As an alternative to immediate shredding or secure disposal, you may accumulate such papers for a limited time (such as the current workweek) at your desk or in your office, provided that the papers are always locked away and not accessible to the general office workforce or patients when you are not present. This alternative does not include using the blue bins for your temporary storage, unless you can secure the blue bin when you are not present. Then, periodically, empty your temporary storage bin into a locked large disposal bin.

If you have any questions or concerns, please know that you may address those confidentially with the clinic's Privacy Officer.

Document Disposal Service Procedures

There are no individual or departmental procedure requirements with regard to our overall document disposal services relationship. The clinic's Privacy Officer is responsible for any changes to the vendor relationship and procedures. The following information is simply being provided so that clinic personnel will have an understanding of how our document disposal service works.

The way our full paper waste disposal process works is that we have blue recycle bins at our desks and on-site large bins to accumulate paper until our disposal service comes. Each night, blue bin contents are dumped by our cleaning crew into unsecured large bins. As such, those unlocked large bins do not provide adequate protection for sensitive information until it is destroyed.

Prior to this policy and procedure, we had certain bins that were locked. To accommodate our need to secure sensitive information until it is disposed of, beginning with the effective date of this policy and procedure, we are locking nearly all of our remaining large paper bins.

Our disposal service comes on Fridays or on demand as our operations require. When they come, they gather the existing bins, empty them into their secure disposal truck, and return the empty bins to us. The service then takes the bin contents from here to their site where the papers are shredded. TCC has inspected the service's operations and will continue to periodically do site visits to ensure that the service has appropriate safeguards in place to protect the bin contents through the process of shredding the papers.

Important Note: Please contact our Privacy Officer if you find any issues with the bins' availability, their locks, or any of them not being emptied regularly.

Control Mechanisms

In order to ensure that the clinic stays in compliance with its own policies and procedures as well as applicable law, the Privacy Officer, TCC management, or clinic business manager will order or complete compliance audits. In response to complaints by patients, regulators, or TCC personnel, the Privacy Officer, TCC management, or clinic business manager will conduct compliance investigations.

As a part of such compliance audits or investigations, we may take actions or require that department heads and individual staff to take actions and report findings to ensure that controls such as the following are being used to maintain confidence that clinic personnel are complying with this policy:

- Random checks of blue bin content
- Inspection of locks on and content of large paper disposal bins
- Observation of the document disposal service
- Inspection of disposal service facilities
- Review of document disposal service agreements and contracts

Document Change History

Version	Date	Action Taken	Action Taken By	Role
1.0	6.8.2008	Initial document creation	Glenn Mills	Writer
1.0	6.8.2008	Approved	Ryan Holmes	Approver
1.1	11.15.2009	Corrected for formatting & small errors	Glenn Mills	Writer
1.1	11.18.2009	Approved	Ryan Holmes	Approver
2.0	8.2.2013	Full review & revision to meet HIPAA Omnibus Rule requirements	Glenn Mills Ana Attorney	Writer Legal Reviewer
2.0	8.15.2013	Approved	Ryan Holmes	Approver
3.0	4.3.2018	Full HIPAA review & integration of clinic ops policies & procedures	Glenn Mills T. Writer	Writers & Editors
3.0	4.17.2018	Approved	Ryan Holmes	Approver