

RHC Policies and Procedures

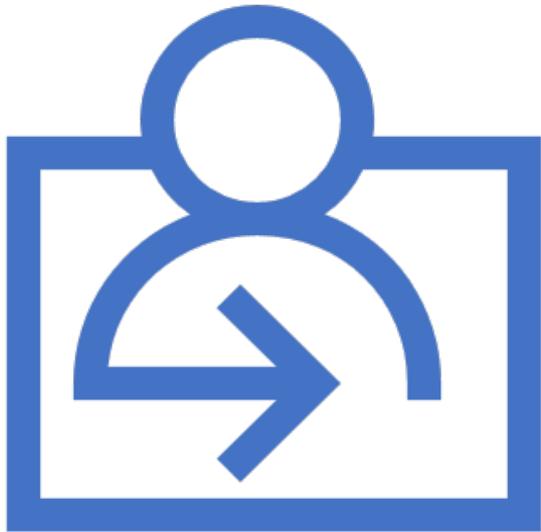
Presented by Patty Harper,
RHIA, CHTS-PW, CHTS-IM, CHC®

2020 RHC Workshop November 4, 2020



Learning Objectives:

1. Understand what RHC regulations require for policy development and periodic policy review.
2. Understand the differences between policies, processes and procedures.
3. Learn how to develop policies that are effective in maintaining RHC compliance.





1.

Understand what RHC regulations require for policy development and periodic policy review.

Let's make it simple: Government control means uniformity, regulation, fees, inspection, and yes, compliance.

--Tom Graves

Healthcare is a regulated industry.

Therefore the framework for compliance already exists.

Don't re-invent the wheel. Use what we already know. And if we don't know, learn and teach!



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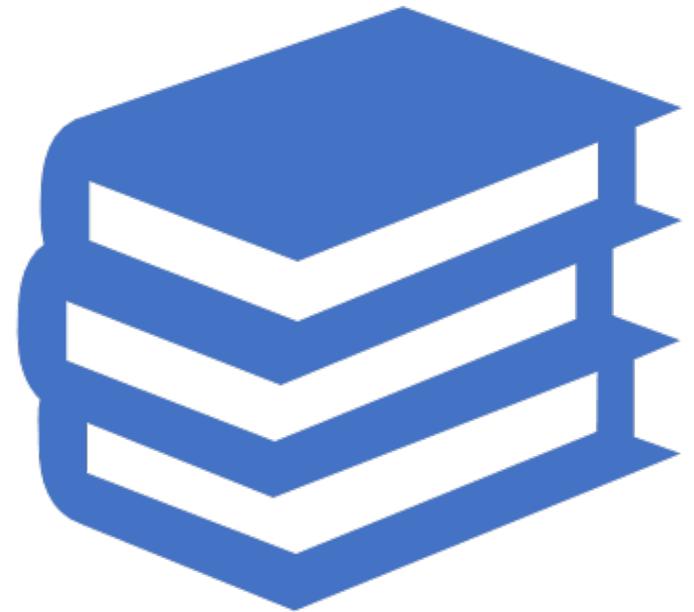
<https://www.ecfr.gov/cgi-bin/ECFR?page=browse>

Federal RHC/FQHC Regulations

**42 CFR §405
Subpart X**

**42 CFR §413.65
Provider Based Status**

**42 CFR §491
Conditions for
certification**



Federal Regulations Medicare Program

42 CFR §405

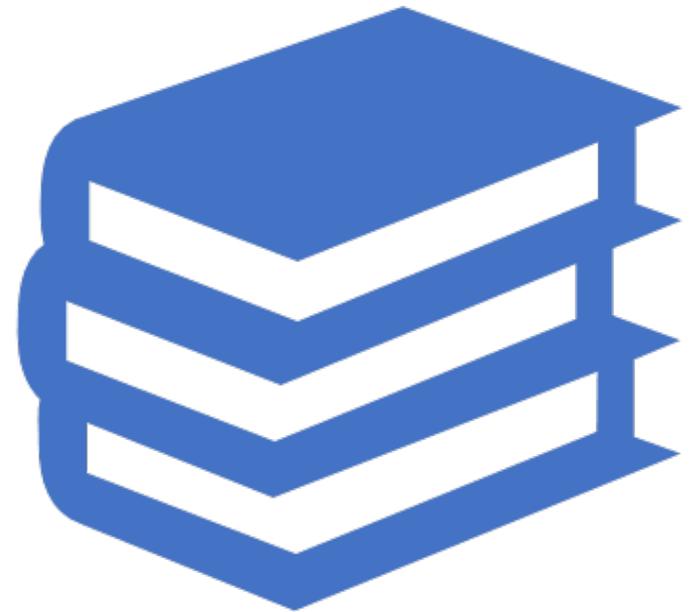
Federal Healthcare for
the Aged and Disabled

42 CFR §420

Program Integrity-
Medicare

42 CFR §455

Program Integrity-
Medicaid

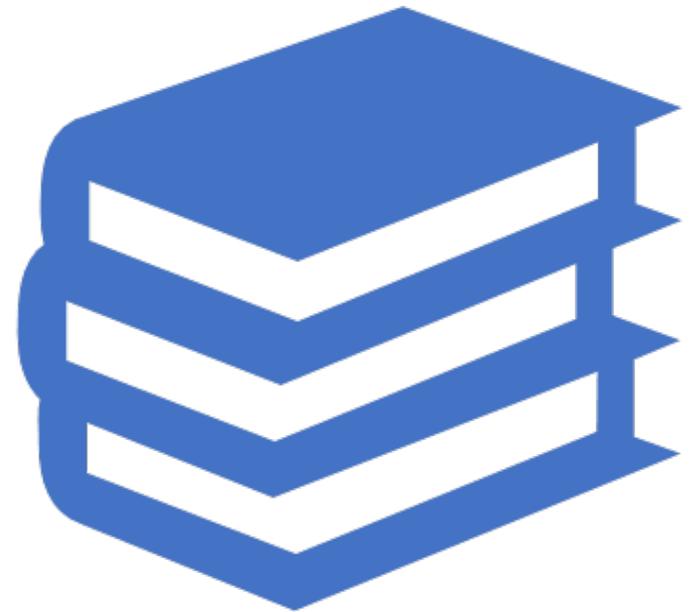


Federal Hospital Regulations

42 CFR §482
Conditions of
Participation

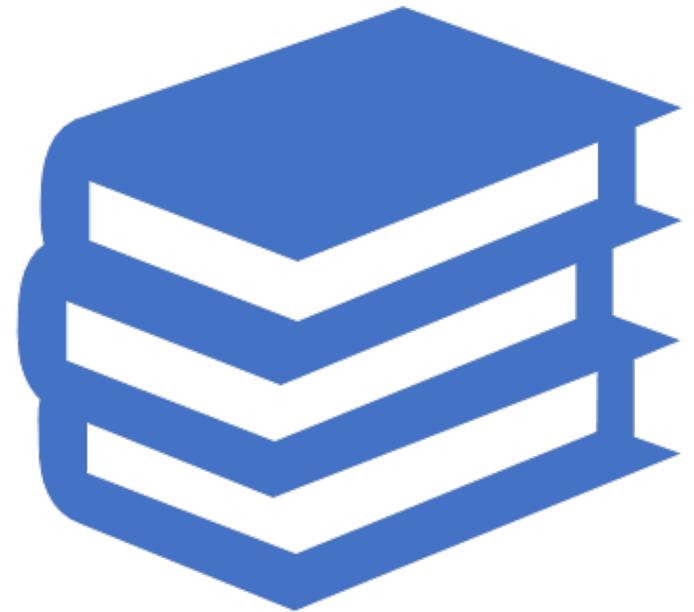
42 CFR §412
Inpatient PPS System

42 CFR §419
Outpatient PPS System



**Federal
Regulations
Critical Access
Hospitals**

**42 CFR §485
Subpart F
Conditions of
Participation**



Specialty & Other Provider Types

42 CFR §485

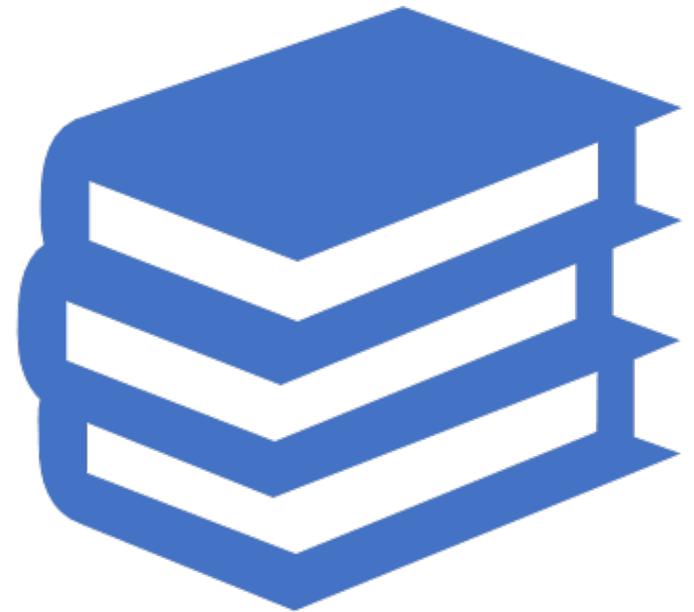
Subpart B: CORFs

**Subpart H: Outpatient
Physical, Occupational,
Speech/Language
Pathology Services**

42 CFR §418: Hospice

**42 CFR §482.56:
Rehabilitation Services**

**42 CFR §484: Home
Health**





Use the regulations as the compliance blueprint.

- Would you build a house without a blueprint?
- Would your contractor build the house without ever looking at the plans?
- Federal, State and Local Regulations are the blueprint for any type of facility's compliance.



The Conditions of Participation and Certification require providers and facility types to have a specific organizational structure.

The regulations themselves address which operational aspects should be governed by written policies and procedures.

It makes sense to have policy development parallel the regulations.

RHC Federal Regs & Guidance

42 CFR § 491

<https://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol5/pdf/CFR-2011-title42-vol5-part491.pdf>

CMS Policy Benefit Manual, Chapter 13

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c13.pdf>

CMS Claims Processing Manual, Chapter 9

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c09.pdf>

State Operations Manual, Appendix G

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_g_rhc.pdf

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The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. They are CMS' program issuances, day-to-day operating instructions, policies, and procedures that are based on statutes, regulations, guidelines, models, and directives. The CMS program components, providers, contractors, Medicare Advantage organizations and state survey agencies use the IOMs to administer CMS programs. They are also a good source of Medicare and Medicaid information for the general public.

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100	Introduction
100-01	Medicare General Information, Eligibility and Entitlement Manual
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100-04	Medicare Claims Processing Manual
100-05	Medicare Secondary Payer Manual
100-06	Medicare Financial Management Manual
100-07	State Operations Manual
100-08	Medicare Program Integrity Manual
100-09	Medicare Contractor Beneficiary and Provider Communications Manual

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html>

What does 42 CFR 491 say about RHC Policies?

§491.7 Organizational structure.

(a) *Basic requirements.* (1) The clinic or center is under the medical direction of a physician, and has a health care staff that meets the requirements of §491.8.

(2) The organization's policies and its lines of authority and responsibilities are clearly set forth in writing.

§491.8 Staffing and staff responsibilities.

(2) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's or center's written policies and the services provided to Federal program patients.

§491.9 Provision of services.

(b) *Patient care policies.* (1) The clinic's or center's health care services are furnished in accordance with appropriate written policies which are consistent with applicable State law.

(2) The policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician assistants or nurse practitioners. At least one member is not a member of the clinic or center staff.

(3) The policies include:

(i) A description of the services the clinic or center furnishes directly and those furnished through agreement or arrangement.

(ii) Guidelines for the medical management of health problems which include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the clinic or center.

(iii) Rules for the storage, handling, and administration of drugs and biologicals.

(4) These policies are reviewed at least biennially by the group of professional personnel required under paragraph (b)(2) of this section and reviewed as necessary by the RHC or FQHC.

§491.10 Patient health records.

(a) *Records system.* (1) The clinic or center maintains a clinical record system in accordance with written policies and procedures.

(2) Written policies and procedures govern the use and removal of records from the clinic or center and the conditions for release of information.

§491.11 Program evaluation.

(a) The clinic or center carries out, or arranges for, a biennial evaluation of its total program.

(b) The evaluation includes review of:

(1) The utilization of clinic or center services, including at least the number of patients served and the volume of services;

(2) A representative sample of both active and closed clinical records; and

(3) The clinic's or center's health care policies.

§491.12 Emergency preparedness.

(b) *Policies and procedures.* The RHC or FQHC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

REQUIRED POLICIES	Std		
Corporate Compliance Plan	COM 1.0		ADM 8.0
Standards of Conduct with Non-retaliation statement	COM 3.0		ADM 9.0
Fraud, Waste, and Abuse with Disciplinary & Corrective Action	COM 4.0		ADM 9.0
Leadership Functions with Designation	ADM 5.0	e)	ADM 11.0
Lines of Authority, Categories of Practitioners, & Staffing	ADM 6.0		ADM 12.0
Organizational Chart	ADM 6.0		HR 1.0
Annual Review of Policies / Signed off by Advisory Group	ADM 7.0		QI 1.0
Patient Referral and Transfer of Medical Record with Consent	ADM 7.0		QI 2.0
			EQP 1.0
			EQP 3.0
			INF 1.0
Patient Care Services (clearly stated)			PTS 3.0
Guidelines for Medical Management			PTS 4.0
Consent to Treat			PTS 6.0
Storage of Drugs & Biologicals			DRG 1.0
Lab Practices			DGS 2.0
Work Exposure Plan			REG 2.A
Emergency Preparedness (Non-Medical)			REG 2.D
Refrigerated Medication Management with Power Outage			REG 2.D
Radiology Practices <i>(if applicable)</i>			

Your accreditation organization may require other written policies which demonstrate compliance with other conditions for RHC certification or the RHC standards.



2.

Understand the differences between policies, processes and procedures.

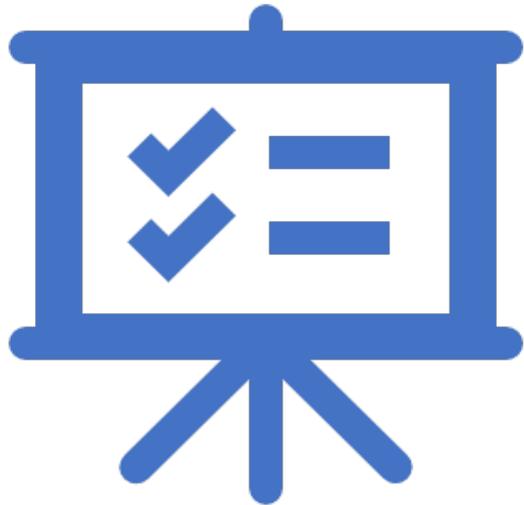
A true professional not only follows but loves the processes, policies and principles set by his profession.” — Amit Kalantri

Policies are broad statements of compliance which are static unless there is a regulatory change. Less is More.

Processes are more defined in nature, dynamic, and are usually created internally or in conjunction with other guidance. Provide Clarity. Can Be addendums to Policies.

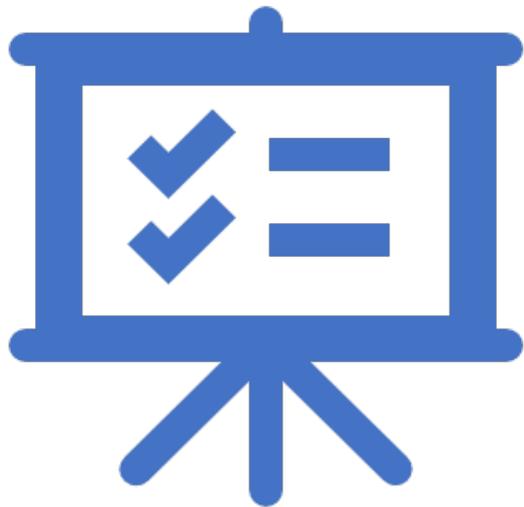
Procedures are specific steps in performing a task. These are dynamic, promote efficiencies in workflow and ensure quality performance. Used for training and internal guidance. Promotes standardization of tasks.

Tips for Policy Development



- Don't make policy writing more difficult than it needs to be.
- Use broad language that established compliance without locking you into a rigid process or procedure that might change.
- Organize policies topically or in the order of the survey tags or standards. Have a standard format.
- Policies should not be used to manage people but to ensure compliance.

Tips for Policy Development



- Focus on straightforward regulatory compliance when developing policies.
- Know what the conditions of certification are. Speak to those.
- Less is sometimes more
- Processes and Procedures can often be addressed in supplemental documents, training manuals, and work task instructions.



Organizational Structure and Ownership

J Tag References: J-0060,
J-0061, J-0062, J-0081,
J-0084, J-0086
§ References: 491.7, 491.8,
491.9

Policy Type: Administrative

Policy Number:
110.00

Adopted or Revised Date: 9/27/2019

Policy Declaration: This is the Organizational Structure and Ownership Policy of the clinic. The clinic is identified as Crossroads Clinic.

Policy Purpose: The purpose of this policy is to disclose in a written document the organizational structure of the Clinic which is Rural Health Clinic (RHC). Furthermore, the policy is designed to give detailed information about the governance, management and staffing of the clinic.



3.

Learn how to
develop
policies that
are effective in
maintaining
RHC
compliance.

“The aim of the wise is not to secure pleasure, but to avoid pain.”
— Aristotle

Healthcare is a reactive industry by nature.

Taking time to be strategic and proactive is **difficult** but **necessary**.

Changing our mindset about compliance is the first step.

Administration (7)	Environmental (16)
<p><u>Regulatory Compliance</u></p> <p>Policy: 100 T V E</p> <p>Evidence (4)</p> <ul style="list-style-type: none"> • Crossroads_100-A_855A • Crossroads_100-B_State License • Crossroads_100-C_CLIA Certificate • Crossroads_100-D_Occupancy License 	<p><u>Physical Plant Safety: General</u></p> <p>Policy: 200 T V E</p> <p>Evidence (3)</p> <ul style="list-style-type: none"> • Crossroads_200-A_Physical Plant Licenses, Inspections, Permits • Crossroads_200-B_Floor Plan Exits • Crossroads_200-C_Insurance Information
<p><u>Formal Corporate or Organization Compliance Plan</u></p> <p>Policy: 105 T V E</p> <p>Evidence (3)</p> <ul style="list-style-type: none"> • Crossroads_105-A_Compliance Plan • Crossroads_105-B_Standards of Conduct • Crossroads_105-C_Standards of Conduct Notice 	<p><u>Preventive and Required Maintenance</u></p> <p>Policy: 210 T V E</p> <p>Evidence (2)</p> <ul style="list-style-type: none"> • Crossroads_210-A_Bio-Med Service Contract • Crossroads_210-B_BioMed Sticker Example_06252019
<p><u>Organizational Structure and Ownership</u></p> <p>Policy: 110 T V E</p> <p>Evidence (1)</p> <ul style="list-style-type: none"> • Crossroads_110-A_Ownership Statement 	<p><u>Building Sanitation and Cleanliness</u></p> <p>Policy: 215 T V E</p> <p>Evidence (1)</p> <ul style="list-style-type: none"> • Crossroads_215-A_Sanitation
<p><u>Organizational Chart Structure</u></p> <p>Policy: 120 T V E</p> <p>Evidence (4)</p> <ul style="list-style-type: none"> • Crossroads_120-A_Organizational Structure • Crossroads_120-B_Org Chart • Crossroads_120-C_Current Board 	<p><u>Storage, Handling & Administration of Drugs, Biologicals, and Pharmaceutic...</u></p> <p>Policy: 220 T V E</p> <p>Evidence (3)</p> <ul style="list-style-type: none"> • Crossroads_220-A_Temperature Logs • Crossroads_220-B_Sample Medications Log • Crossroads_220-C_Safe Injection Poster_06252019

- Systematically Organize Policies
- Number Policies
- Have Standard Format
- Show Effective Dates

What will Prove Your Compliance with a Regulation?



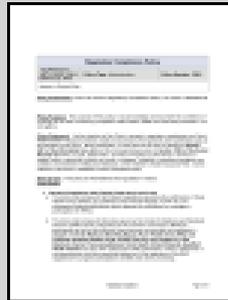
- Identify Which “Evidence” Documents demonstrate Compliance
- Organize these documents for easy retrieval.

Identify
Supporting
Evidence
Documents and
Correlate Them
to Related
Policies

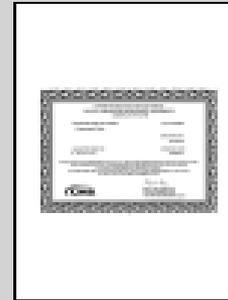
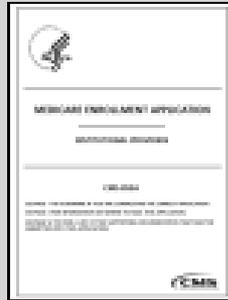
CMS Tag

J- 0011; J-0012; J-0013

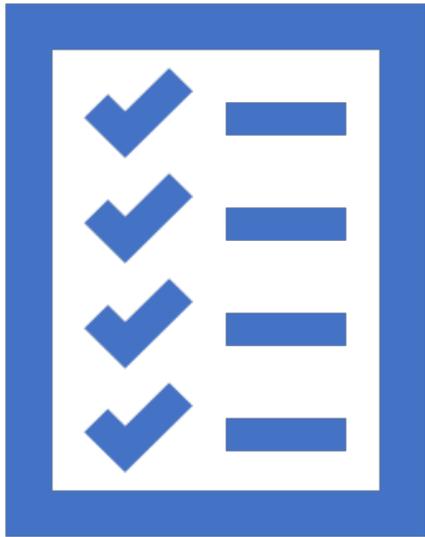
Policy



Evidence (4)



Examples of Evidence Documents



- Licenses
- Certificates
- Inspection Reports
- Correspondence to/from CMS/Medicare Contractor
- Correspondence to/from state agencies
- Other Agency Correspondence
- Quality, QAPI, and Risk Documents and Forms
- Samples of Notices and Disclosures
- Proof of Education and Training

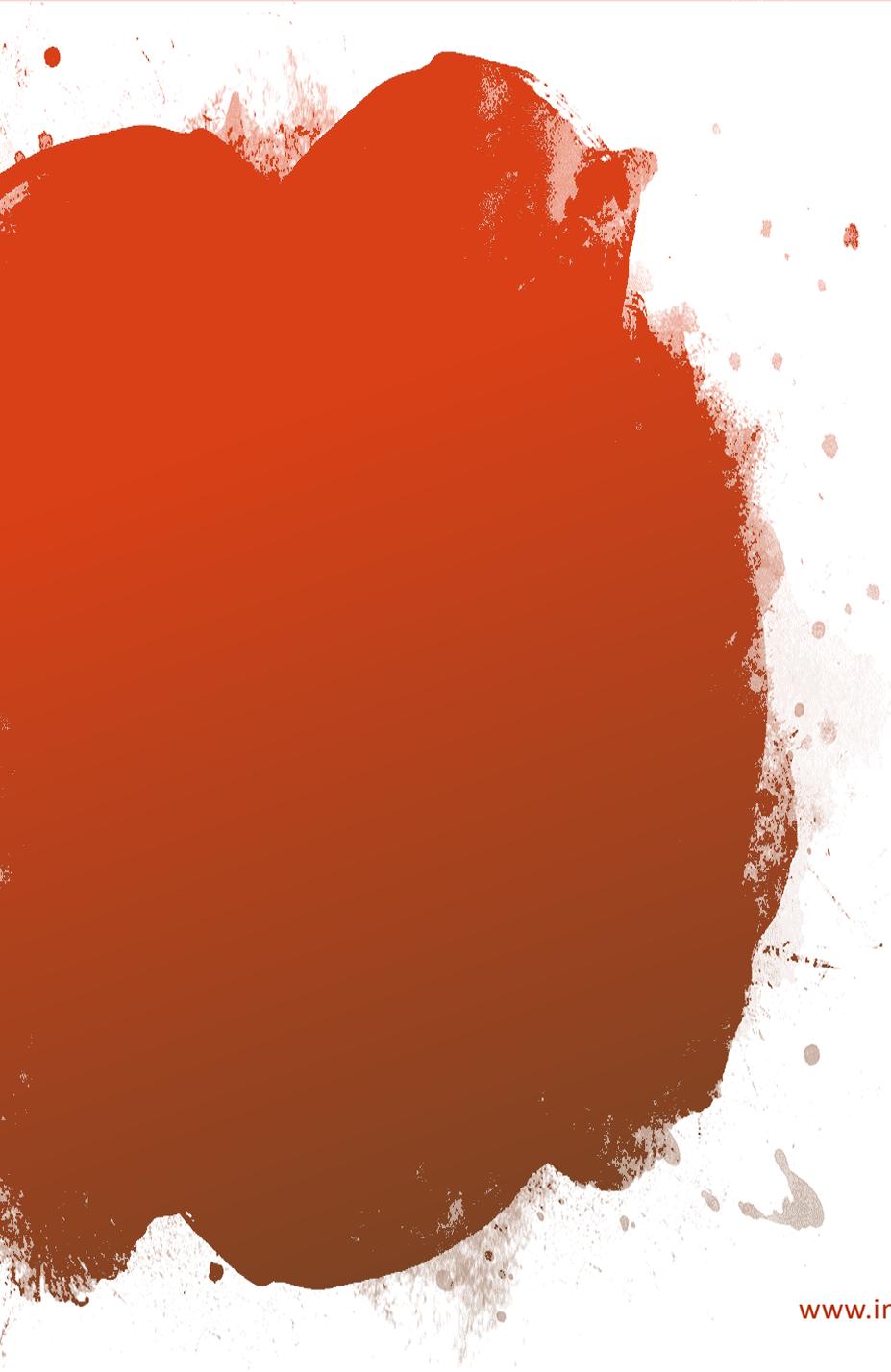
“What can be asserted without evidence can also be dismissed without evidence.”

— Christopher Hitchens

Proof of compliance especially during a survey can be difficult if supporting “evidence” documents are not easy to retrieve.

Correlate supporting evidence to policy numbers or to survey tags or standards.

Refer to the SOM Appendices or the AO guidance to determine what might be needed.



Implement a Training and Review Program

The most influential people strive for genuine buy-in and commitment - they don't rely on compliance techniques that only secure short-term persuasion.—Mark Goulston

Create Buy-in by engaging all staff.

Have a training schedule: on hire, whenever there is a change, and periodically thereafter. Facilitate training and engagement.

Document or track training.

Obtain feedback from staff.

Training Program Basics



- ✓ Upon Hire
- ✓ Periodically
- ✓ At Least Annually or
When there is a
Change

- Training on Corporate Compliance
 - Fraud and Abuse
 - Non-Discrimination
 - Non-Retaliation
- Standard of Conduct
- Privacy & Security
- HIPAA as related to job function
- Employee Handbook
- Policies and Procedures
- Emergency Preparedness
- Safety, Use of PPE, Location of Emergency Items
- Job Description/Expectation
- In-service on use of equipment



Build in a Failproof Tickler System

“Wasted strokes, like missed deadlines, are preventable and costly.”

— Lorii Myers

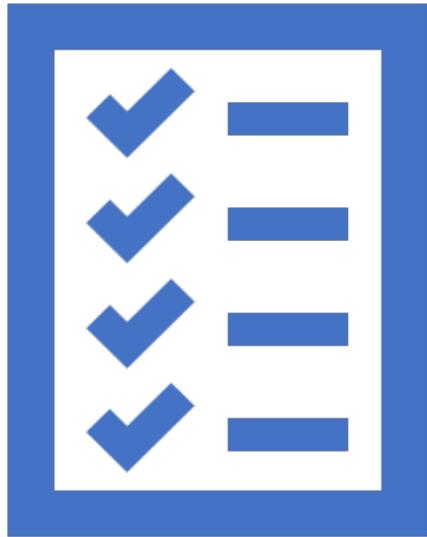
Some policy or document management systems have a built-in tickler function.

Spreadsheets, calendars or tickler organizers can all work. Create a format that works for you and your facility.

Set reminders far enough in advance to allow for processing time, approval time, or scheduling.

Build-in accountability so that more than one person is aware of a deadline.

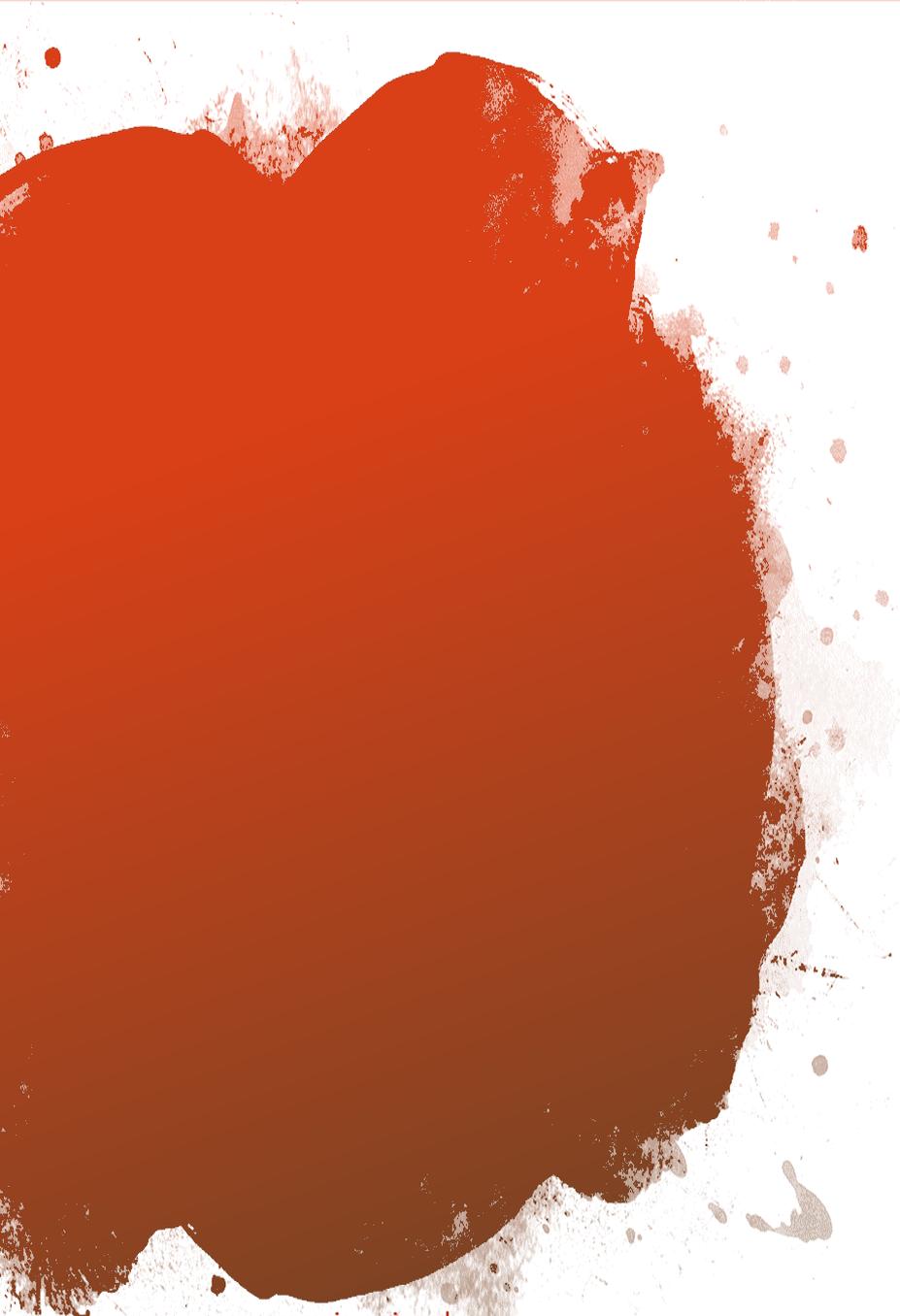
Examples of Tickler Dates



- Licenses Renewals
- Inspections
- Required Employee Training
 - Periodic
 - Annual Education Fair
- Policy Review Dates
- Program Evaluation Dates
- Performance Evaluations
- Updated Employee Forms
- Emergency Preparedness Testing/Training
- Employee Health
- ***Anything that a policy specifically states will require review or retraining.***

TICKLER LIST

Date	Subject	Evidence
10/5/2019	200-C Replace Declaration Sheet on insurance coverage	200-C Property Insurance All 06132019
10/18/2019	290-A Verify exercises are within one-year	290-A Emergency Preparedness Plan All 06132019
11/1/2019	215-A Review all cleaning contracts	215-A Sanitation and Cleaning Contracts All 06132019
11/8/2019	380-A Review the PHI Release Authorization form	380-A Authorization to Release Health Information All 06132019
11/29/2019	410-A Verify current Employment Application	410-A Employment Application All 06132019
12/1/2019	500-A Replace the Clinic's Annual Evaluation	500-A Annual Program Evaluation All 06132019
12/10/2019	290-C Verify current Training Evidence	290-C Emergency Preparedness Training All 06132019
12/10/2019	400-B Replace Employment Poster	400-B Labor Law OSHA Posters All 06132019
12/15/2019	110-A Review Ownership and Disclosure	110-A Ownership and Disclosure Statement All 06132019
1/2/2020	220-A Replace sample temperature logs with current temperature logs	220-A Temp Logs for Refrigerated and Frozen Medications All 06132019
1/6/2020	100-D Renew state license. A check will be required, Don't delay.	100-D State Licensing LA 06132019
1/10/2020	410-C Update Employee Training Records	410-C Employee Training All 06132019
1/15/2020	130-C Ensure OCR Notice and Taglines are correct	130-C OCR Language Translation Links All 06132019
2/1/2020	100-A Review 855A to make sure the persons on the 855A are still in the same roles	100-A CMS 855A Application All 06132019
2/4/2020	290-B Update Emergency Preparedness Risk Assessment	290-B Emergency Preparedness Risk Assessment All 06132019
2/5/2020	390-A Update HIPAA Risk Assessment	390-A IT Related Documents All 06132019
3/1/2020	600-B Review / Replace Consent Forms	600-B Consent Forms All 06132019
4/1/2020	220-C Verify Medication Safety Poster in on the wall in the Nursing Station	220-C-Medication Safety Poster All 06132019
4/10/2020	200-A Verify current inspections	200-A Physical Plant Licenses, Inspections, and Permits All 06132019



Monitor Regulatory Changes

Redesign your
blueprint as
needed

“To be relevant, you need to be purposeful”
— Sunday Adelaja

Don't assume that the written policies you inherited are up-to-date or complete. Even corporate level policies can fail to meet compliance especially when rural health providers are scarce within the system.

Don't wait for a survey deficiency to reveal a gap in compliance.

Revise and Simplify—making sure that the policies and training are following the regulatory blueprint.

Monitoring Changes in Regulations

Sign up for newsletters, announcements, newsfeeds and mailing lists.

Set up email folders for these activities

Allocate time weekly to review updates and clean up the folder.

Attend state, regional and national meetings

Develop relationships with other stakeholders outside your organization.

Networking

7 Steps to creating a culture of compliance

Create a Paradigm Shift

Design A Compliance Blueprint

**Develop Written Policies and
Procedures Based on your Blueprint**

**Identify Supporting Evidence
Documents**

**Implement a Training and Review
Program**

Build-in a Failproof Tickler System

Monitor Regulatory Changes



Questions or More Discussion?

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Patty Harper, RHIA, CHTS-PW, CHTS-IM, CHC®

InQuiseek Consulting

Pharper@inquiseek.com

318-243-2687

Patty Harper is CEO of InQuiseek Consulting. She has over 22 years of healthcare experience in the areas of healthcare finance & reimbursement, health information management, compliance, and practice management. She began her healthcare career as a hospital controller and reimbursement analyst. Patty holds a B.S. in Health Information Administration (cum laude) from Louisiana Tech University. She is credentialed through AHIMA as a RHIA, CHTS-IM, and CHTS-PW. Patty successfully completed AHIMA's ICD-10 Academy and was recognized as an ICD-10 Trainer for several years. She is also Certified in Healthcare Compliance (CHC®) through the Compliance Certification Board. Patty is a frequent speaker and contributor for national, state and regional and rural healthcare associations on these and other reimbursement-related topics. She has held memberships regional, state and national organizations throughout her healthcare career including NARHC, NRHA, AHIMA, MGMA, and HFMA. Patty currently serves on the Board of NARHC and LRHA.