

# Critical Access Hospital and Rural Health Clinic Conference Focusing on the Quadruple Aim

## Rural Health Clinic Compliance

May 2, 2017

**WIPFLI**<sup>LLP</sup>  
CPAs and Consultants  
HEALTH CARE PRACTICE



## AGENDA

- Section 1557 of the ACA
- Emergency Preparedness
- Provider-Based Status
- Physical Plant and Environment
- Organizational Structure
- Staffing and Staff Responsibilities
- Provision of Services
- Program Evaluation
- Survey Compliance Resources



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## Section 1557 of the Affordable Care Act

## Section 1557 of the Affordable Care Act



### What is Section 1557?

- Section 1557 is the nondiscrimination law in the Affordable Care Act (ACA).
- Section 1557 is important to achieving the ACA's goals of expanding access to health care and coverage, eliminating barriers, and reducing health disparities.
- Section 1557 **prohibits discrimination on the basis of race, color, national origin, sex, age, or disability** in certain health programs and activities.
- Section 1557 builds upon longstanding nondiscrimination laws and provides new civil rights protections.

Content provided by the U.S. Department of Health and Human Services, Office for Civil Rights

## Section 1557 of the Affordable Care Act



### What are some of the notable provisions of Section 1557?

- Section 1557 is the **FIRST** Federal civil rights law to broadly prohibit sex discrimination in health programs and activities.
  - Sex discrimination includes, but is not limited to, discrimination based on an individual's sex, including pregnancy, related medical conditions, termination of pregnancy, gender identity and sex stereotypes.
    - Gender identity means an individual's internal sense of gender, which may be male, female, neither, or a combination of male and female.
    - Sex stereotypes means stereotypical notions of masculinity or femininity.
- Section 1557 applies to the Health Insurance Marketplaces and to all health plans offered by health insurance companies that participate in the Marketplaces.

Content provided by the U.S. Department of Health and Human Services, Office for Civil Rights

## Section 1557 of the Affordable Care Act



### Who must comply with HHS's Section 1557 regulation?

- All health programs and activities that receive Federal financial assistance from HHS.
  - Examples of types of covered entities: hospitals, health clinics, physicians' practices, community health centers, nursing homes, rehabilitation centers, health insurance issuers, State Medicaid agencies, etc.
  - Federal financial assistance includes grants, property, Medicaid, Medicare Parts A, C and D payments, and tax credits and cost-sharing subsidies under Title I of the ACA. (Medicare Part B is not included.)
- All health programs and activities administered by entities created under Title I of the ACA (i.e., State-based and Federally-facilitated Health Insurance Marketplaces).
- All health programs and activities administered by HHS (e.g., Medicare Program, Federally-facilitated Marketplaces).
- Where an entity is principally engaged in health services or health coverage, **ALL** of the entity's operations are considered part of the health program or activity, and must be in compliance with Section 1557 (e.g., a hospital's medical departments, as well as its cafeteria and gift shop).
- The rule does not apply to employment practices such as hiring or firing, except that covered employers are responsible for their employee health benefit programs in certain circumstances.

## Section 1557 of the Affordable Care Act



### Federal Enforcement

- The U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR) enforces Section 1557 as to programs that receive funding from HHS.
- OCR is a neutral, fact-finding agency that receives, investigates and resolves thousands of complaints from the public alleging discrimination in health services and health coverage.
- When OCR finds violations, a covered entity will be required to take corrective actions, which may include revising policies and procedures, and implementing training and monitoring programs. Covered entities may also be required to pay compensatory damages.
- When a covered entity refuses to take corrective actions, OCR may undertake proceedings to suspend or terminate Federal financial assistance from HHS. OCR may also refer the matter to the U.S. Department of Justice for possible enforcement proceedings.
- Section 1557 also provides individuals the right to sue covered entities in court for discrimination if the program or activity receives Federal financial assistance from HHS or is a State-based Marketplace<sup>SM</sup>.

## Section 1557 of the Affordable Care Act

Information for  
Individuals

Filing a  
Complaint

Information for  
Providers

Newsroom

[HHS > Civil Rights Home](#) > [For Individuals](#) > [Section 1557](#) > Translated Resources for Covered Entities

Text Resize **A A A** | Print | Share

Civil Rights for Individuals and  
Advocates

Race, Color, National Origin

Disability

Age Discrimination

Sex Discrimination

Religion

Section 1557

Hill-Burton

### Translated Resources for Covered Entities

#### Translated Resources for Covered Entities

Under Section 1557 of the Affordable Care Act (ACA), covered entities are required to post notices of nondiscrimination and taglines that alert individuals with limited English proficiency (LEP) to the availability of language assistance services. The translated resources below are available for use by covered entities.

#### Sample Resources in English

[Notice of Nondiscrimination - PDF | .docx](#)

[Statement of Nondiscrimination - PDF | .docx](#)

[Tagline - PDF | .docx](#)

## Section 1557 of the Affordable Care Act

[Name of covered entity] complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. [Name of covered entity] does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

[Name of covered entity]:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

- Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact [Name of Civil Rights Coordinator]

If you believe that [Name of covered entity] has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with: [Name and Title of Civil Rights Coordinator], [Mailing Address].

## Section 1557 of the Affordable Care Act

### **Appendix B to Part 92—Sample Tagline Informing Individuals With Limited English Proficiency of Language Assistance Services**

**ATTENTION:** If you speak [insert language], language assistance services, free of charge, are available to you. Call 1-xxx-xxx-xxxx (TTY: 1-xxx-xxx-xxxx).

Content provided by the U.S. Department of Health and Human Services, Office for Civil Rights

## Section 1557 of the Affordable Care Act

- Section 1557 was implemented on October 16, 2016
- If your RHC is not in compliance . . .
  - HHS provides the following resources
    - ~ Educational slides
    - ~ Sample notices and taglines
    - ~ Training guides
    - ~ Estimates of languages spoken

<https://www.hhs.gov/civil-rights/for-individuals/section-1557>



## Emergency Preparedness

42 CFR 491.12

## Emergency Preparedness (42 CFR 491.12)

- CMS released final rule on September 16, 2016
- Implementation date of November 15, 2017
- Remove requirements on emergency preparedness found at § 491.6(c)
- Replaced with new requirements at § 491.12

## Emergency Plan (42 CFR 491.12 (a))

### Emergency Preparedness – November 15, 2017

- “All hazards approach” focuses on the preparedness for a full range of emergencies.
  - Natural disasters
  - Risks of the surrounding area
- Create a risk assessment for each RHC



## Emergency Preparedness (42 CFR 491.12)

Out with the old . . .

- § 491.6(c)
  - The clinic assures the safety of patients in case of non-medical emergencies by:
    - ~ Training staff in handling emergencies,
    - ~ Placing exit signs in appropriate locations, and
    - ~ Taking other appropriate measures that are consistent with the particular conditions of the area in which the clinic is located.

## Emergency Preparedness (42 CFR 491.12)

In with the new . . .

- § 491.12(a) requires the development of an emergency preparedness plan.
- § 491.12(b) requires clinic to develop policies and procedures resulting from the emergency plan.
- § 491.12(c) requires clinic to develop and maintain an emergency preparedness communication plan.
- § 491.12(d) requires clinic to develop and maintain a training and testing program.
- § 491.12(e) allows the clinic to participate in an integrated system-wide emergency preparedness plan.

## Emergency Preparedness (42 CFR 491.12)

- CMS estimates the cost to implement the new emergency preparedness rules at over \$6,000 per RHC.
- These new rules could be caught up in new directives from President Trump.
  - Memorandum on January 20, 2017, that postpones the effective date for 60 days for the purpose of reviewing new regulations prior to becoming effective.
  - Executive Order on January 30, 2017, states that the total incremental cost of all new regulations shall be no greater than zero.
  - It is uncertain if these new rules will be postponed, eliminated, or become effective on the scheduled date.

## Emergency Plan (42 CFR 491.12(a))

### Preparing the Emergency Plan:

- Include the administrator, physician, midlevel, and a registered nurse on the team to assess the risk of the RHC
- Include strategies in the plan for addressing emergencies identified by the risk assessment
- Have a process for cooperation with local, state, and federal emergency preparedness officials
- Document, document, document

## Policies and Procedures (42 CFR 491.12(b))

### Develop Policies and Procedures to Include:

- Evacuation
- Placement of exit signs
- Responsibility of staff
- Shelter for people who remain in the facility
- Preserve medical documentation
- Use of volunteers and other emergency personnel

## Communication Plan (42 CFR 491.12(c))

### Emergency Preparedness Communication Plan

- Comply with federal and state laws
- Update at least annually
- Include contact information
- Include alternative means of communicating with staff and local emergency agencies
- Provide information about patients in the clinic
- Indicate needs and ability to provide assistance

## Communication Plan (42 CFR 491.12(d))

### Training and Testing

- Develop and maintain a training and testing program based on:
  - Risk assessment
  - Emergency plan
  - Communication plan
- Train new and existing staff
- Perform training annually
- Test the emergency plan at least annually

## Communication Plan (42 CFR 491.12(e))

### Integrated Healthcare Systems

- Two options:
  - Develop an emergency preparedness plan as an entire health system
  - Develop a plan independently as an RHC



## Provider-Based Status

## Provider-Based Requirements

- The elective status as a Rural Health Clinic provider type for Medicare and Medicaid purposes requires that a specific set of criteria be met as a condition of RHC participation.
- The provider-based element of PB-RHC status overlays numerous additional requirements as an integral component of an existing Medicare provider, generally a hospital.
- A PB-RHC must meet the requirements of provider-based status as well as maintain compliance with the Rural Health Clinic conditions of participation to obtain its favorable reimbursement for Medicare and Medicaid.

## Provider-Based Requirements

### Requirements and Obligations 42 CFR 413.65 (excerpts)

- Clinic operation under the ownership and control of the main provider:
  - 100% owned by the provider, same governing body, common bylaws and operating decisions of the governing body, final responsibility, and administrative decisions

## Provider-Based Requirements

### Requirements and Obligations (continued):

- Administration and supervision:
  - Direct supervision, accountability, integration (HR, billing, payroll)
- Clinical services:
  - Clinical privileges, chief medical officer, quality assurance and utilization review, medical records integration (unified retrieval systems)

## Provider-Based Requirements

### Requirements and Obligations (continued):

- Financial integration:
  - Shared income and expenses, cost center on the MC Cost Report
  - Costs included in the main provider's trial balance
- Public awareness:
  - Signage (use hospital's name, not parent name or system)
  - Common registration forms
  - Common billing statements
- Other requirements (e.g., management contracts, EMTALA, etc.)

## Provider-Based Requirements

### Example

413.65(e)(2)(iii)

The following administrative functions of the facility or organization are integrated with those of the provider where the facility or organization is based: billing services, records, human resources, payroll, employee benefit package, salary structure, and purchasing services.

Either the same employees or group of employees handle these administrative functions for the facility or organization and the main provider, or the administrative functions for both the facility or organization and the entity are . . . contracted.

## Filing the Attestation Statement

- ✓ Filed with the Medicare Contractor (MAC).
- ✓ Not a required filing, so no standard CMS forms.
- ✓ Sample forms provided by MAC (website download).
- ✓ Final approval by CMS regional office.
- ✓ Subject to interpretation.

## Filing the Attestation Statement

### Attestation Example

Wisconsin Physicians Service (WPS)

[http://www.wpsmedicare.com/j8macparta/departments/audit\\_reimbursement/\\_files/wps\\_attest\\_form.pdf](http://www.wpsmedicare.com/j8macparta/departments/audit_reimbursement/_files/wps_attest_form.pdf)

- Must not be submitted until after CMS 855 approval.
- Do not submit until after RHC Tie-In notice (RHC provider number is required).
- Include supporting documentation.
- 20-page Attestation document.

## Filing the Attestation Statement

### Attestation Example (continued)

Selected excerpts

“Provide pictures of provider-based signage clearly identifying the provider-based entity as part of the main provider (e.g., a photo of the sign, website, yellow pages, patient forms, etc.). Advertisements that only show the facility to be part of or affiliated with the main provider's healthcare system are not acceptable.”



## Filing the Attestation Statement

### Attestation Example (continued)

Selected excerpts

“Submit list of all clinical staff (i.e., physicians, nurses, physical therapists, radiology technicians, etc.) working at the facility or organization showing job titles and name of employer. Also include whether professional staff have clinical privileges at the main provider.”



## Filing the Attestation Statement

### Reporting Changes to the Attestation

42 CFR 413.65(c) *Reporting of material changes in relationships*

A main provider that has had one or more facilities or organizations considered provider-based also may report to CMS any material change in the relationship between it and any provider-based facility or organization, such as a change in ownership of the facility or organization or entry into a new or different management contract that would affect the provider-based status of the facility or organization.



## Physical Plant and Environment

42 CFR 491.6

## Physical Plant and Environment (42 CFR 491.6)

### Physical Plant Safety

- To insure the safety of patients, personnel, and the public, the physical plant should be maintained consistent with appropriate state and local building, fire, and safety codes. Reports prepared by state and local personnel responsible for ensuring that the appropriate codes are met should be available for review.
- Determine whether the clinic has safe access and is free from hazards that may affect the safety of patients, personnel, and the public.



## Physical Plant and Environment (42 CFR 491.6)

### Preventive Maintenance

- A program of preventive maintenance should be followed by the clinic. This includes inspection of all clinic equipment at least yearly, or as the type, use, and condition of equipment dictates; the safe storage of drugs and biologicals (see 42 CFR 491.6(b)(2)); and inspection of the facility to ensure that services are rendered in a clean and orderly environment. Inspection schedules and reports should be available for review by the surveyor.





## Organizational Structure

42 CFR 491.7

## Organizational Structure (42 CFR 491.7)

### Basic Requirements

- Ascertain that the clinic is under the medical direction of a physician(s), has a staff that meets the requirements of § 491.8, and has adequate written material covering organization policies, including lines of authority and responsibilities.



## Organizational Structure (42 CFR 491.7)

### Written Policies

- Written policies should consist of both administrative and patient care policies. Patient care policies are discussed under 42 CFR 491.9(b). In addition to including lines of authority and responsibilities, administrative policies may cover topics such as personnel, fiscal, purchasing, and maintenance of building and equipment. Topics covered by written policies may have been influenced by requirements of the founders of the clinic, as well as agencies that have participated in supporting the clinic's operation.



## Organizational Structure (42 CFR 491.7)

### Disclosure of Names and Addresses

- The clinic discloses names and addresses of the owner, person responsible for directing the clinic's operation, and physician(s) responsible for medical direction.
- Any change in ownership or physician(s) responsible for the clinic's medical direction requires prompt notice to the RO. Neither of these changes requires resurvey or recertification if the change can otherwise be adequately verified. Notice of any change in the physician(s) responsible for providing the clinic's medical direction should include evidence that the physician(s) is licensed to practice in the state.



## Staffing and Staff Responsibilities

42 CFR 491.8

## Staffing and Staff Responsibilities (42 CFR 491.8)

### Staffing

- The clinic or center has a health care staff that includes one or more physicians. Rural health clinic staffs must also include one or more PAs or NPs.
- A physician, NP, PA, nurse-midwife, clinical social worker, or clinical psychologist is available to furnish patient care services at all times the clinic or center operates. In addition, for rural health clinics, a NP or a PA is available to furnish patient care services at least 50% of the time the clinic operates.



## Staffing and Staff Responsibilities (42 CFR 491.8)

### Physician's assistant and the nurse practitioner responsibilities:

- Participate in the development, execution, and periodic review of the written policies governing the services the clinic furnishes;
- Provide services in accordance with those policies;
- Arrange for, or refer patients to, needed services that cannot be provided at the clinic;
- Ensure that adequate patient health records are maintained and transferred as required when patients are referred; and
- Participate with a physician in a periodic review of the patient's health records.



## Staffing and Staff Responsibilities (42 CFR 491.8)

### Physician responsibilities (DO/MD):

- Provides medical director for the clinic's activities and consultation for and medical supervision of the health care staff.
- In conjunction with the PA and/or NP member(s), the physician participates in developing, executing, and periodically reviewing the clinic's written policies and the services provided to federal program patients.
- Periodically reviews the clinic's or center's patient records, provides medical orders, and provides medical care services to the patients of the clinic or center.





## Provision of Services

42 CFR 491.9

## Provision of Services (42 CFR 491.9)

### Providing Rural Health Clinic Services

- The law describes an RHC as a facility primarily engaged in providing RHC services as defined in this subpart. Under this definition, a facility may provide services in addition to RHC services, usually related health care services such as the “other ambulatory services” covered by Medicaid state plans. Certification as an RHC applies to the facility as a whole and the total operating schedule of the facility (the hours it is open) is considered when determining if the facility is primarily engaged in providing RHC services.



## Provision of Services (42 CFR 491.9)

### Providing Rural Health Clinic Services

- If on-site observation of services provided and discussion with the staff indicate that the majority of the services provided by the clinic are primary medical care (treatment of acute or chronic medical problems which usually bring a patient to a physician's office), then the clinic may satisfy the "primarily engaged" requirement providing that RHC services are offered at least 51% of the total operating schedule.



## Provision of Services (42 CFR 491.9)

### Patient Care Policies Requirements

- Review the clinic's policies and ascertain who developed them . . . it is necessary to ascertain that the current physician member(s) and the NP, certified nurse-midwife, and/or PA member(s) of the staff have an in-depth knowledge of the policies and have had the opportunity to discuss them, adopt them as is, or make any agreed-to written changes in them.



## Provision of Services (42 CFR 491.9)

### Patient Care Policies Requirements

- In some cases, the clinic may involve health care professionals from a hospital with which the clinic has an agreement for patient referral. In any event, at least one member of the group of professionals may not be a member of the clinic's staff. Professionals who are not directly related to health care delivery (attorneys, community planners, etc.) are potentially useful.



## Provision of Services (42 CFR 491.9)

### Patient Care Policies Requirements

- The requirements concerning written policies address four areas:
  - 1) Description of Services
    - Directly and through arrangement
    - For example, taking complete medical histories, performing complete physical examinations, assessments of health status, routine lab tests, diagnosis and treatment for common acute and chronic health problems and medical conditions, immunization programs, family planning, complete dental care, emergency medical care.

## Provision of Services (42 CFR 491.9)

### Patient Care Policies Requirements

- The requirements concerning written policies address four areas:
  - 2) Guidelines for Medical Management
    - For example, protocols, medical directives, criteria for diagnosing and treating conditions.

## Provision of Services (42 CFR 491.9)

### Patient Care Policies Requirements

- The requirements concerning written policies address four areas:
  - 3) Drugs and Biologicals
    - Storage of drugs and biologicals
    - Dealing with outdated drugs
    - Prescribing and dispensing

## Provision of Services (42 CFR 491.9)

### Patient Care Policies Requirements

- The requirements concerning written policies address four areas:
  - 4) Review of Policies
    - The group of professional personnel is responsible for an annual review of patient care policies.

## Provision of Services (42 CFR 491.9)

### Direct Services

- The purpose of the Rural Health Clinic Services Act is primarily to make available outpatient or ambulatory care of the nature typically provided in a physician's office or outpatient clinic and the like. The regulations specify the services that must be made available by the clinic, including specified types of diagnostic examination, laboratory services, and emergency treatments.
- The clinic provides medical emergency procedures as a first response to common life-threatening injuries and acute illness and has available the drugs and biologicals commonly used in lifesaving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids.

## Provision of Services (42 CFR 491.9)

### Direct Services

- Ability to perform (furnish) six basic lab tests:
  - Chemical examinations of urine
  - Hemoglobin or hematocrit
  - Blood sugar
  - Examination of stool specimens
  - Pregnancy tests
  - Primary culturing for transmittal to a certified laboratory



## Program Evaluation 42 CFR 491.11

## Program Evaluation (42 CFR 491.11)

- An evaluation of a clinic's total operation including the overall organization, administration, policies and procedures covering personnel, fiscal, and patient care areas must be done at least annually. This evaluation may be done by the clinic, the group of professional personnel required under 42 CFR 491.9(b)(2), or through arrangement with other appropriate professionals.



## Program Evaluation (42 CFR 491.11)

### The evaluation includes review of:

- The utilization of clinic or center services, including at least the number of patients served and the volume of services.
- A representative sample of both active and closed clinical records.
- The clinic's or center's health care policies.

## Program Evaluation (42 CFR 491.11)

The purpose of the evaluation is to determine whether:

- The utilization of services was appropriate.
- The established policies were followed.
- Any changes are needed.

**The clinic or center staff considers the findings of the evaluation and takes corrective action if necessary.**

## Program Evaluation (42 CFR 491.11)

- If the facility has been in operation for at least a year at the time of the initial survey and has not had an evaluation of its total program, report this as a deficiency. It is incorrect to consider this requirement as not applicable (N/A) in this case.
- A facility operating less than a year or in the start-up phase may not have done a program evaluation. However, the clinic should have a written plan that specifies who is to do the evaluation, when and how it is to be done, and what will be covered in the evaluation.



## Survey Compliance Resources

## Resources

### Resources

- Rural Health Clinic Survey Report (CMS 30)  
[http://formuniverse.com/Forms/CatalogView/Healthcare/Centers%20for%20Medicare%20and%20Medicaid%20Services%20\(CMS\)/Reports/CMS30.pdf](http://formuniverse.com/Forms/CatalogView/Healthcare/Centers%20for%20Medicare%20and%20Medicaid%20Services%20(CMS)/Reports/CMS30.pdf)
- State Operations Manual (SOM Appendix G)
  - [http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_g\\_rhc.pdf](http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_g_rhc.pdf)
- 42 CFR 491
  - <http://www.gpo.gov/fdsys/granule/CFR-2011-title42-vol5/CFR-2011-title42-vol5-part491>

# Questions?

# Thank you!

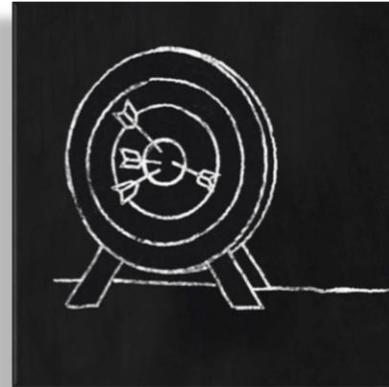
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