
Oregon Office of Rural Health

38^h Annual Oregon Rural Health Conference

October 29, 2021

Janis McDowell, RN, BSN, MA
Surveyor, CMS Representative
Rural Health Clinics
End Stage Renal Disease Facilities



Agenda

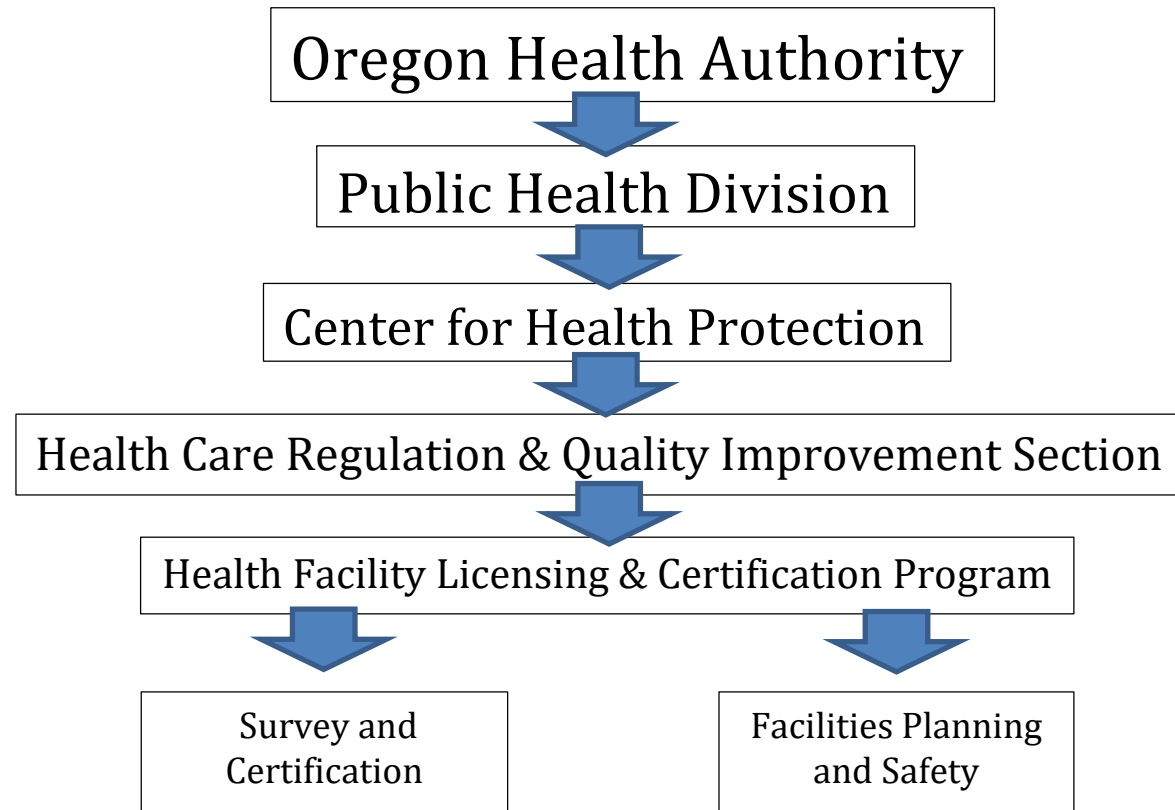
1. Agency Overview
2. Survey Process
3. Covid-19 Resources and Updates
4. Common Citations
5. Emergency Preparedness Rules
6. Additional Role of the SA
7. Questions & Contact Information

Part 1: Oregon Health Authority

OHA Divisions:

1. External Relations
2. Fiscal
3. Agency Operations
4. Health Policy & Analytics
5. Health Systems
6. Office of Equity & Inclusion
7. Oregon State Hospital
8. Public Health
 - Center for Public Health Practice (6 sections)
 - Center for Prevention & Health Promotion (5 sections)
 - **Center for Health Protection (6 sections)**
 - Fiscal & Business Operations; Program Operations; Policy & Partnerships; Science & Evaluation

Overview of OHA



Health Facility Licensing & Certification

Two programs –

- Facilities Planning & Safety
- Survey & Certification
 - Anna L. Davis, JD – Survey & Certification Manager

Survey & Certification Regulated Entities

- Hospitals (CAH, ACU, PSY) including Satellites
- Ambulatory Surgical Centers
- Outpatient Renal Dialysis Facilities (ESRDs)
- Hospice Agencies
- Home Health Agencies
- Rural Health Clinics
- Federal Qualified Health Centers
- Out-Patient Therapy
- Portable X-ray
- In-Home Care Agencies
- Caregiver Registries
- Non-Transplanted Anatomical Research Recovery Organizations
- Freestanding Birth Centers
- Hemodialysis Techs
- Tissue Bank/Organ Procurement Registry
- Special Inpatient Care Facilities
- Extended Stay Centers

Survey & Certification

Team of:

- 14 surveyors specializing in one or more facility types. CMS surveyors are RNs. Surveyors sometimes work in teams.
- FPS Administrative assistants also assist Survey & Certification
- 1 manager

Program Workload:

- **Fixed:** Standard surveys required to satisfy state licensure &/or federal certification requirements
- **Variable:** Federal and state complaint investigations, federal EMTALA reports & immediate jeopardy situations.

Oregon Rural Health Clinics

Rural Health Clinics (as of September 30, 2021)

Total: 100

- Deemed: 7
- Non-Deemed: 93

Annual Workload

- RHC initial Certification Surveys: varies (2 from October 2020 – September 2021)
- RHC Recertification Surveys: approximately 13 – 14 per year
- RHC/FQHC Complaint Investigations: varies – 2 from October 2020 – September 2021)
- RHC Validation Survey for Deemed facilities (determined by CMS)

Part 2: Survey Process

Pre-Survey Preparation

Develop survey plan and review facility information including:

- Mid-level staffing waivers
- Visiting Nurse Services offered
- Licensure & Ownership
- Services provided
- Prior surveys & complaints
- Review of the facility's location

All surveys, including initial certification, recertification, complaint and revisit, are unannounced

Refer to 42 CFR 1001.1301 – Failure to grant immediate access

Survey Process

RHC Surveys typically are completed in 1 day by 1 surveyor

Entrance Activities – Meet with administration to:

- Explain purpose & scope of survey
- Explain survey process
- Discuss logistics (e.g., survey workspace, photocopies, etc.)
- Provide “needs list” detailing documents to be provided to surveyor

Survey Process

Information Gathering Includes:

- On-site observations
- Patient observation
- Interviews with staff & patients
- Administrative document review of policies & procedures, contracts and program evaluation
- Personnel record review
- Medical record review using representative patient samples
- Emergency Preparedness Review

Exit Conference with Facility Administration

- Survey team shares preliminary findings & next steps
- Note: Survey closure date will be later if survey team asks provider to submit additional information to clarify outstanding questions

Survey Process

10 Business Days Post Survey

Agency Issues Survey Report

- Statement of Deficiencies (SOD), CMS form 2567, documents any deficiencies identified during onsite audit or complaint investigation
- Issued to facility leadership

10 Calendar Days After Facility Receives Report

Facility Submits Plan of Corrections (POC)

- Written response to each deficiency identified during onsite audit or complaint investigation
- POC documents facility's plan to return to compliance

Revisits

Conditions Out Required; Standard Tags Agency's Option

- Surveyors conduct second survey to assess implementation of provider's POC & abatement of cited deficiencies

Part 3: Covid-19 Resources and Updates

On March 8, 2020, Gov. Kate Brown declared a state of emergency to address the spread of COVID-19 in Oregon. The Oregon Health Authority (OHA) serves as the lead agency for the public health response.

The latest guidance, forms, and FAQ for Ambulatory Surgery Centers can be found at our website, www.healthoregon.org/hflc. Additional resources can be found at OHA's Covid-19 Updates page, <http://healthoregon.org/coronavirus>.

Updated Guidance as of June 30, 2021: Personal Protective Equipment, Screening and Visitation in CMS-certified Outpatient Settings

- **PPE** - CDC continues to recommend use of Personal Protective Equipment for healthcare personnel, patients, and visitors in healthcare settings.
- **Screening**- Facilities shall adopt and enforce policies and procedures that require the screening of all individuals before entry.

The Oregon Health Authority (Authority), Public Health Division is temporarily adopting **OAR 333-019-1010** pertaining to vaccination and testing requirements for healthcare providers and healthcare staff to control COVID-19. The temporary rule is effective August 5, 2021, through January 31, 2022. – **FAQs coming soon!**

Part 4: Most Common Citations

10/2018 to 09/2021

RHC Citations are Federal Only

Conditions for Certification are located at 42 CFR
Part 419, Subpart A

Staffing and Staff Responsibilities

- **J 123** – Policies are developed with the advice of a group of professional personnel that includes one or more physician(s) and one or more physician assistant or nurse practitioner. At least one member is not a member of the clinic staff ... These policies are reviewed at least biennially

Most Common Citations

10/2018 to 09/2021

Physical Plant and Environment

- **J 040** – Physical Environment Condition-level tag.
- **J 041** – The clinic is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provisions of direct services.
- **J 042** – Maintenance: The clinic has a preventative maintenance program to ensure that all essential mechanical, electrical and patient-care equipment is maintained in safe operating condition
- **J 043** – Drugs and biologicals are appropriately stored
- **J 044** – The premises are clean and orderly. Includes infection prevention measures

Most Common Citations

10/2018 to 09/2021

Organizational Structure

- **J 101** – Staffing and Staff Responsibilities

Patient Health Records

- **J 152** – Records Systems

Program Evaluation

- **J 160** – Condition out for J 161 and J 162
- **J 161** – The clinic carries out, or arranges for, a biennial evaluation of its total program.

Part 5: Emergency Preparedness

Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers

- (1) **Overview:** One additional Condition of Participation (CoP) / Condition for Coverage (CfC) that is required to participate in Medicare.
- (2) **Purpose:** To establish national emergency preparedness requirements that ensure adequate planning for natural and manmade disasters, including emerging infectious disease outbreaks, and coordination with federal, state, tribal, regional and local emergency preparedness systems.
- (3) **Application:** All 17 provider and supplier types:
- Hospitals;
 - Critical Access Hospitals (CAHs)
 - Religious Nonmedical Health Care Institutions (RNHCIs);
 - Ambulatory Surgical Centers (ASCs);
 - Hospices;
 - Home Health Agencies (HHAs)
 - Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)
 - End-Stage Renal Disease (ESRD) Facilities
 - Psychiatric Residential Treatment Facilities (PRTFs);
 - All-Inclusive Care for the Elderly (PACE);
 - Transplant Centers;
 - Long-Term Care (LTC) Facilities;
 - Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID);
 - Comprehensive Outpatient Rehabilitation Facilities (CORFs)
 - Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services
 - Community Mental Health Centers (CMHCs)
 - Organ Procurement Organizations (OPOs)

Emergency Preparedness

(4) Enforcement Date: started on November 15, 2017

(5) Substantive Requirements: Each provider/supplier has dedicated EP regulations incorporated into its CoPs / CfC requirements.

- Some vary by provider/supplier

(6) Emergency Preparedness Program Shared Elements:

- Risk Assessment and Planning – Develop emergency plan on documented facility-based and community-based risk assessments, using an all-hazards approach, focus on capacities and capabilities, update every 2 years
- Policies and Procedures – Develop P&Ps based on emergency plan, risk assessment, and communication plan, update every 2 years
- Communication Plan – Develop communications plan that meets state and federal standards and coordinates care within facility, across providers, with state/local public health departments and emergency management systems, update every 2 years
- Training and Testing – Develop training & testing programs, P&Ps, conduct drills & exercises, document analysis of drills and exercises

(7) Resources: CMS website downloads; SOM Appendix Z

Emergency Preparedness

Most Common Citations

- **E0037 – EP Training Requirements:** Develop training programs that cover emergency preparedness policies and procedures
 - Initial training to all new and existing staff, individuals providing services under arrangement and volunteers
 - Provide emergency preparedness training at least every 2 years
 - Maintain documentation of all emergency preparedness training
- **E0039 – EP Testing Requirements:** Must conduct exercises to test the emergency plan annually
 - Participate in a full-scale exercise that is community-based every 2 years (if a community-based exercise is unavailable, conduct an individual facility-based functional exercise)
 - Conduct an additional exercise every 2 years, opposite the year the full-scale or functional exercise
 - Analyze the response to and maintain documentation of all drills, tabletop exercises and emergency events

Emergency Preparedness

Most Common Citations

- **E0001– Establishment of the Emergency Program:** The facility must establish and maintain a comprehensive EP program
- **E0004 – Develop EP Plan:** The facility must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years
- **E0006 – Plan based on All-Hazards Risk Assessment:** Emergency plan must be based on, and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach. Must include strategies for addressing emergency events identified by the risk assessment.
 - Emerging infectious diseases need to be included as part of the all-hazards approach

Emergency Preparedness

Most Common Citations

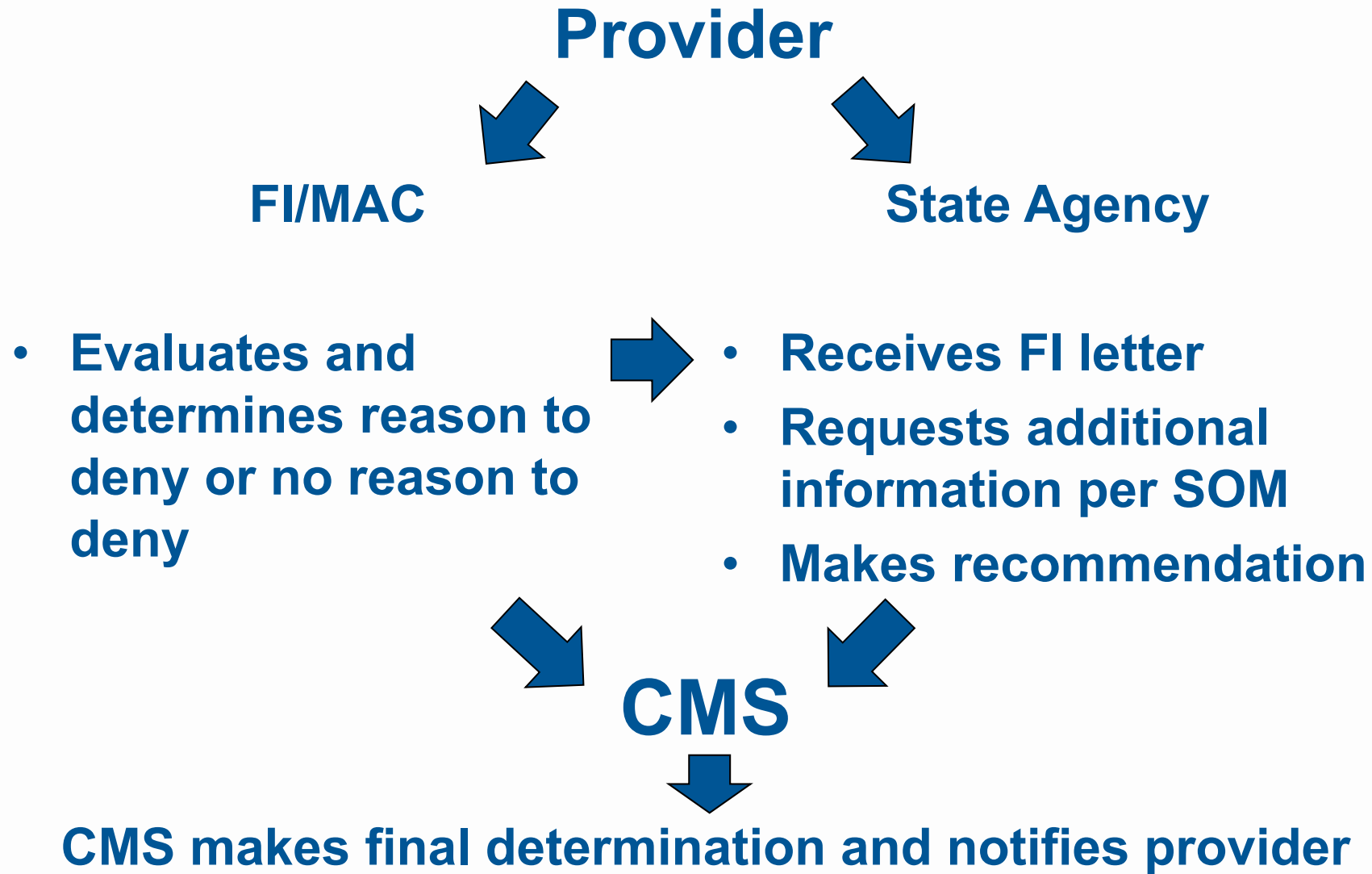
- **E0042 – Integrated Health Systems:** If a clinic is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated EP Plan, the clinic may choose to participate in the system's coordinated EP program.
- If a clinic elects to participate in a unified plan, then:
 - The clinic must actively participate in the development of the unified plan
 - The plan must be developed to take into consideration the clinic's unique circumstances, patient populations and services offered
 - Each clinic must be capable of actively using, and is in compliance, of the plan

Emergency Preparedness Most Common Citations

- **E0042 – Integrated Health Systems (continued):**
 - The clinic must have documentation of both the community-based and individual facility-based risk assessments using an all-hazards approach
 - The clinic must be actively involved in the annual review of the program requirements and any program updates
 - Each clinic must maintain individual training records of staff and records all training exercises

Part 6: Additional Tasks of the SA

- **Administrative**
 - **Name changes**
 - **Administrator changes**
 - **Voluntary terminations**
 - **Address changes**
 - **Addition of services**
 - **Changes of Ownership**
 - **Initial licensure**
 - **Initial certifications**
 - **Waivers**



Part 7: Questions & Contact Information

Program Information:

General Inquiries

mailbox.hcllc@state.or.us

(971) 673-0540

www.healthoregon.org/hflc

Additional Resources:

Janis McDowell, RN, BSN, MA

RHC/ESRD Surveyor

janis.s.mcdowell@state.or.us

(971) 533-4054

Anna L. Davis, JD

Survey & Certification Manager

anna.l.davis@state.or.us

(971) 673-2950

Oregon
Health
Authority