

## **Oregon Reproductive Health Program Certification Requirements for Reproductive Health Services Version 1.2**

### **Introduction**

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The Oregon Reproductive Health (RH) Program oversees a statewide network of certified health care providers to ensure access to a suite of reproductive health services (preventive reproductive health care, preconception, and contraception). These services are provided to all individuals regardless of race, color, national origin, immigration status, sex, sexual orientation, gender identity, age, or disability.

This document outlines the minimum requirements service providers must meet in order to be certified by the Oregon Health Authority (OHA) RH Program and receive funding per OAR 333-004-2000 through 333-004-2190.

The Certification Requirements provide the foundation for high-quality services based on national standards of care and align with best practices and recommendations for comprehensive client-centered, culturally-responsive preventive care. The Certification Requirements are based on the following:

- Nationally Recognized Standards (e.g., US Preventive Services Task Force, US Medical Eligibility Criteria)
- Providing Quality Family Planning Services (QFP) – Recommendations from the Centers for Disease Control and Prevention (CDC), and the Office of Population Affairs (OPA)
- National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care

### **Background**

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In 1999, Oregon applied for and received a Medicaid 1115 waiver for family planning which allowed for an expansion of Medicaid coverage to include more people. This program eventually became Oregon ContraceptiveCare or CCare. As a Medicaid program, clients must be either a U.S. citizen or hold eligible immigration status to receive services under CCare.

In 2017, the Oregon Legislature passed the Reproductive Health Equity Act (HB 3391) in response to community partners advocating for the necessity for all women to receive the full array of reproductive health services without cost sharing.

The Reproductive Health Program also receives state general funds to support the provision of high-quality reproductive health services.

### **Section A: Certification Process for Reproductive Health Services**

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#### A.1 Application, Certification, and Renewal Process for Reproductive Health Services

- a. An agency must submit an Application for Certification for Reproductive Health Services and all supporting documents to the RH Program. (Application and instructions are available on the RH Program's website [healthoregon.org/rhcertification](http://healthoregon.org/rhcertification)).
- b. The RH Program will determine if the application is complete and notify the agency of its determination within seven calendar days of receipt of the application.
  1. If the RH Program determines that the application is not complete, the RH Program will notify the agency and the agency will have 30 calendar days to complete their application.
    - A. If the agency does not complete their application within 30 calendar days, their application will be denied.
    - B. The agency may then re-apply or appeal the decision per OAR 333-004-2170.
- c. Once an application is determined to be complete, the RH Program will review the applicable documents and determine if the agency meets the certification requirements.
- d. If the RH Program determines that the certification requirements for reproductive health services are met, the RH Program will inform the agency in writing that the application has been approved and that the agency is certified. This notification will occur no more than 30 calendar days after the RH Program has determined the application to be complete.
- e. Once an application for certification has been approved the RH Program will provide a Medical Services Agreement (MSA) for Reproductive Health Services to be signed by both the Oregon Health Authority and the certified agency.
- f. Certification requirements attested to in the initial application will be verified in an on-site review by the RH Program within one year of approval. (See Section A.2)
- g. If an agency does not meet all requirements in its application for certification for reproductive health services, the RH Program may deny certification.
  1. The RH Program will respond to the agency with a letter of denial providing a clear description of reasons for denial, based on the certification requirements.
  2. An agency may request that the program reconsider the denial of RH Program certification. A request for reconsideration must be submitted in writing to the RH Program within 90 calendar days of the date of the denial letter and must include a detailed explanation of why the applicant believes the Program's decision is an error along with any supporting documentation.
  3. The RH Program shall inform the agency in writing, within 30 calendar days of receipt of the request, whether it has changed its decision.
  4. The agency may appeal this decision per OAR 333-004-2170.
- h. A certified agency must renew its certification annually by completing the RH Program's annual recertification form.

#### A.2 Verification of Certification Requirements for Reproductive Health Services

- a. The RH Program will conduct an on-site verification review to determine compliance with certification requirements of each approved new agency within one year of application approval.

- b. After the initial on-site verification review, the RH Program will conduct regular on-site compliance reviews for all agencies every three years, based on a schedule developed by the RH Program.
- c. RH Program staff will work with the agency to schedule the on-site verification review at a mutually agreed upon time. The agency will be notified, in writing, a minimum of 30 calendar days before its scheduled on-site verification review.
- d. The onsite review includes, but is not limited to:
  - 1. Review of enrollment forms, consent forms, and all other forms used in providing reproductive health services;
  - 2. Review of documents, policies, procedures and protocols;
  - 3. Chart audit;
  - 4. On-site clinical observation; and
  - 5. On-site observation of patient environment and physical environment.
- e. An exit report will be provided at the completion of the review.
  - 1. Preliminary findings will be presented to the Reproductive Health Coordinator (RHC), designated under Section B.6., the administrator, and other staff interested in attending.
  - 2. If no certification deficiencies are identified during the review, the RH Program shall indicate as such in the exit report.
  - 3. If certification deficiencies are identified, the agency will be provided an opportunity to dispute any findings identified during the review at this time.
  - 4. A timeframe will be determined in which all compliance findings must be addressed.
  - 5. The RH Program may conduct an on-site follow-up visit to ensure compliance findings have been resolved.
- f. A copy of all the review materials and a final written exit report will be provided to the RHC within 14 calendar days after the exit review.
- g. The RH Program will perform regular billing, enrollment, medical chart audits, and other quality assurance reviews.
- h. The RH Program may conduct a review of the agency without notice of any or all certification requirements for compliance and perform a verification on-site review if the RH Program is made aware of issues of compliance or complaints from any source.
- i. At any time, the agency may request an administrative review of compliance, which includes an on-site visit. The review will be considered a “no-penalty” review with the exception of gross violation or negligence that may result in agency decertification.
- j. The agency must notify the RH Program within seven calendar days of any change that brings the agency out of compliance with the certification requirements.

### A.3 Process for Ensuring Compliance

- a. If certification deficiencies are found during any RH Program or agency-initiated review, the agency must:

1. Submit a plan for corrective action and date for meeting compliance within a 30, 60 or 90 calendar day period, depending on the finding and compliance feasibility; and
  2. Come into compliance by the specified date or the RH Program will issue a letter of non-compliance with notification of suspension or decertification.
- b. Compliance verification may be determined through submission of documentation or through an additional on-site review.
  - c. An agency with its certification status suspended may have its suspension lifted once the RH Program determines that compliance with certification requirements for reproductive health services has been achieved satisfactorily.
  - d. If compliance findings are not met within the designated 30, 60 or 90 calendar day timeframe, the agency may ask for an extension, providing justification.
  - e. If the agency fails to address all compliance findings within 180 calendar days of the date of the initial non-compliance notification, the RH Program may seek to suspend or terminate the agency's certification.
  - f. An agency that has been decertified may reapply with an amended application and additional documentation at any time.

## **Section B: Administrative Requirements for Reproductive Health Services**

### **B.1 Administrative Policies**

- a. Agencies must follow written administrative policies approved by the RH Program. A complete set of sample policies is available on the RH Program's website ([healthoregon.org/rh](http://healthoregon.org/rh)).
- b. An agency must adopt or adapt current RH Program administrative policies.
- c. Agencies must update administrative policies within six months of notification of any revisions to the sample policies by the RH Program.
- d. Administrative policies must be approved and signed by agency's authorizing official (AO).
- e. For agencies that do not currently have administrative policies approved by the RH Program, signed policies must be submitted for approval by the RH Program prior to certification.
- f. Agencies must review its administrative policies annually.

### **B.2 Informed Consent**

- a. The informed consent process, provided verbally and supplemented with written materials by the agency, must be presented in a language and style the client understands.
- b. An agency must inform clients that:
  1. Services are provided on a voluntary basis.
  2. They cannot be coerced to accept services or to use any particular method of birth control.

3. Receipt of reproductive health services is not a prerequisite to receipt of other services provided by the agency.
- c. Staff must be informed by the agency that they shall not coerce clients to receive services
- d. An agency must have clients sign an informed consent form annually.

#### B.3 Confidentiality

- a. Agencies must follow the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, HIPAA Security Rule, and Health Information Technology for Economic and Clinical Health (HITECH) Act.
- b. Services must be provided in a manner that respects the client's privacy and dignity.
- c. Clients must be assured of the confidentiality of services and their medical and legal records.
- d. Services must remain confidential during billing and collecting payments, when requested by clients.

#### B.4 Linguistic and Cultural Responsiveness

- a. Agencies must have a comprehensive strategy to provide culturally and linguistically appropriate services.
- b. All services, support, and other assistance must be provided in a manner that is responsive to the beliefs, interpersonal styles, attitudes, languages, and behaviors of the client receiving services, and in a manner that has the greatest likelihood of ensuring maximum program participation.
- c. The agency must make interpretation services available to all clients needing or requesting such assistance at no cost to the client. Qualified or certified interpretation services are strongly recommended when available.
  1. The agency must notify clients in need of interpretation services of the availability of such services in accordance with the Civil Rights Act of 1964 and sections 1557, 1331 and 1001 of the Affordable Care Act (ACA).
  2. All persons providing interpretation services must adhere to confidentiality guidelines.
  3. Family and friends shall not be used to provide interpretation services, unless requested by the client.
  4. Individuals under age 18 shall never be used as interpreters for clinic encounters for clients with limited English proficiency or who otherwise need this level of assistance.
  5. When possible, the agency shall employ bilingual staff, personnel, or volunteers skilled or certified in the provision of medical and clinical interpretation that meets the needs of clients with limited English proficiency or who otherwise need this level of assistance during all clinic encounters.
- d. The agency shall make easily understandable print materials available to clients and post signage in the languages of groups represented or commonly encountered in the service area.

- e. Culturally and linguistically appropriate health educational materials must be available for clients needing them.
  - 1. All print, electronic, and audiovisual materials shall be appropriate in terms of the client's language and literacy level. A client's need for alternate formats must be accommodated.
- f. A patient bill of rights shall be posted in a public area of the clinic. See the RH Program's website for a sample patient bill of rights ([healthoregon.org/rh](http://healthoregon.org/rh)).

#### B.5 Federal Requirements Regarding Abortion Services.

- a. An agency may not use federal funds for abortion services.
- b. For agencies that provide abortion services, the agency must have clear policies that require the separation of federal funds (CCare) from other funds used for abortion services.

#### B.6 Designation of Reproductive Health Coordinator (RHC)

- a. The agency must designate an individual as the RHC to be the key point of contact in accordance with OAR 333-004-2070(4)(f). The RHC is responsible for:
  - 1. Having an understanding of all aspects of the RH Program and how it is operationalized within all clinic sites, including client enrollment, clinical services, and billing and data submission;
  - 2. Ensuring program compliance at all clinic sites;
  - 3. Responding to requests for information from the RH Program in a timely manner; and
  - 4. Attending the annual Reproductive Health Coordinators' Meeting, and other required trainings and meetings provided by the RH Program.

#### B.7 Required Training

- a. Orientation to the RH Program is provided to all new agencies by state Program staff within three months of becoming a certified provider of reproductive health services.
- b. The designated RHC at each agency is responsible for coordinating subsequent staff orientation and training.
- c. At minimum, the agency/RHC is responsible for providing annual training to staff on the following:
  - 1. Encouraging family involvement,
  - 2. Relationship safety – counseling on resisting sexual coercion,
  - 3. HIPAA compliance,
  - 4. Mandatory reporting,
  - 5. Cultural responsiveness,
  - 6. Blood borne pathogen prevention, and
  - 7. Emergency management – medical emergencies.

#### B.8 Review of Informational and Educational Material

- a. All educational material provided to clients who receive reproductive health services must be reviewed by an Information and Education (I&E) committee to determine that material is:
  - 1. Factually correct;
  - 2. Suitable for the population or community receiving the information;
  - 3. Culturally and linguistically appropriate; and
  - 4. Provided at clients' level of understanding.
- b. There must be documentation of the materials review, including the review outcome.
- c. An agency may maintain and use its own I&E committee, or use the RH Program's statewide I&E committee.

#### B.9 Community Participation, Education, and Project Promotion

- a. Collaborate with Local Public Health Authorities (LPHAs), community partners, and other RH service providers to:
  - 1. Identify ways community members will be involved in developing, assessing and/or evaluating the reproductive health services.
  - 2. Periodically assess the needs of the community with regards to awareness of and need for access to reproductive health services.
  - 3. Develop and implement a community education and service promotion plan to:
    - A. Enhance the community's understanding of the RH Program; and
    - B. Make known the availability of services.

#### B.10 Compliance with Federal, State, and Local Laws and Regulations

- a. Agencies must maintain the appropriate level of Clinical Laboratory Improvement Amendments (CLIA) certification.
- b. Agencies must meet the following pharmacy requirements:
  - 1. Apply for and maintain Community Health Center License from Oregon Board of Pharmacy if agency utilizes RNs for dispensing.
  - 2. Register and maintain 340B and Apexus Prime Vendor certification, if eligible. Reimbursement for supplies at acquisition cost will be based on 340B drug program pricing or actual acquisition cost.
- c. Agencies must comply with all relevant National Voter Registration Act (NVRA) rules. (OAR 165-005-0060 through 165-005-0070).

#### B.11 Access to Care

- a. All services must be provided in a manner that protects the dignity of the client.
- b. All services must be provided to clients without regard to client's income, insurance status, or ability to pay for services.
- c. All services must be provided to clients without regard to race, color, national origin, immigration status, sex, sexual orientation, gender identity, age, or disability in accordance with applicable laws, including Title VI of the Civil Rights Act of 1964, section 1557 of the ACA, the Americans with Disabilities Act (ADA) of 1990, section 504 of the Rehabilitation Act of 1973, and Oregon Revised Statutes chapter 659A.

- d. The agency's clinic facility(s) must be compliant with ADA requirements.
- e. Clients must be offered information about where to access free or low-cost primary care services.
- f. Clients in need of full-benefit health insurance coverage, private or public, must be given information about how to obtain health insurance enrollment assistance.

#### B.12 Quality Assurance / Quality Improvement Process

- a. Agencies must have a documented process to address quality assurance and quality improvement efforts within their clinic(s), per the RH Program's administrative policy.

## **Section C: Clinical Requirements for Reproductive Health Services**

### C.1 Collaborative Agreements and Partnerships

- a. The agency must maintain current collaborative agreements or partnerships with relevant agencies to facilitate client access to clinics, such as: Women, Infant, and Children (WIC), Oregon Health Plan (OHP) enrollment assisters, and transportation providers.
- b. The agency must maintain current collaborative agreements or partnerships with relevant providers of other health care services, including:
  1. Emergency care,
  2. HIV/AIDS care,
  3. Treatment agencies,
  4. Infertility specialists,
  5. Primary care, and
  6. Diagnostic services.

### C.2 Clinical Protocols

- a. Agencies must follow written clinical protocols for services that are in accordance with QFP, US Medical Eligibility Criteria for Contraceptive Use (US MEC), US Selected Practice Recommendations for Contraceptive Use (US SPR), US Preventive Services Task Force (USPSTF) and other national standards of care. Agencies must cite and follow national standards.
- b. An agency must adopt or adapt current RH Program clinical protocols located on the RH Program's website ([healthoregon.org/rh](http://healthoregon.org/rh)).
- c. Agencies must update clinical protocols within 6 months of notification of any revisions by the RH Program.
- d. Clinical protocols must be approved and signed by agency's Medical Director or Health Officer responsible for the clinic site(s).
- e. For agencies that do not currently have clinical protocols approved by the RH Program, signed protocols must be submitted for approval by the RH Program with the application for certification.
- f. Agency must review its clinical protocols annually.

### C.3 Clinical and Preventive Services

- a. Clinical services must operate under the direction of a physician, preferably with experience in reproductive health.
- b. The agency must provide comprehensive medical, informational, educational, social and referral services related to reproductive health services for clients seeking such services.
- c. Appointments for established clients must be available within a reasonable time period, generally less than two weeks. New clients who cannot be seen within this time period must be given the option to be referred to other qualified provider agencies in the area.
- d. Core services must be offered to clients, as appropriate. Core services are defined as:
  1. A broad range of contraceptives as defined by the RH Program;
  2. Pregnancy testing and options counseling;
  3. Counseling and education to assist with achieving or preventing pregnancy;
  4. Basic infertility;
  5. STI screening and treatment;
  6. Preconception health; and
  7. Breast and cervical cancer screening.
- e. Clients in need of additional medical or psychosocial services beyond the scope of the agency must be provided information about available local resources.

### C.4 Pharmacy / Contraceptive Drugs, Devices, and Supplies

- a. The agency must have a broad range of acceptable and effective approved contraceptive methods and services, including emergency contraception, available to the client on-site during the clinic visit.
- b. Clients must be able to get their first choice of contraceptive method unless there are specific contraindications.
  1. Approval from the RH Program must be obtained when unable to provide a long-acting reversible contraceptive (LARC) method(s), and a referral system for the method must be in place.
  2. Agencies must have a referral system in place for the provision of vasectomy and female sterilization services.
- c. Birth control methods must be dispensed on-site following Oregon Board of Pharmacy rules (OAR 855-043-0700 through 855-043-0750).
  1. RNs may dispense three and no more than six months of a birth control method under a standing order.
  2. A client's ongoing use of a birth control method must be under a current written prescription.
- d. The agency must follow written policies and procedures for drug management, including security, acquisition, storage, dispensing and drug delivery, disposal, and record keeping.
- e. The agency must establish procedures to ensure training and continued competencies in the dispensing of drugs by RNs.

### C.5 Laboratory

- a. Testing must be available on-site following CLIA rules and regulations.
- b. The agency must have the ability to collect specimens and samples. Samples may be sent off-site to a CLIA-certified laboratory.
- c. Written policies and procedures for laboratory testing following CLIA regulations must be maintained. Staff proficiency testing must be included in the policies.
- d. Written policies and procedures for Infection Control following CDC recommendations must be maintained.

### C.6 Medical Emergencies

- a. The agency must maintain a current plan for medical emergencies.

### C.7 Education and Counseling Services

- a. Education and counseling services must be provided using a client-centered approach that helps the client clarify their needs and wants, promotes personal choice and risk reduction, and takes into account diverse cultural and socioeconomic factors of the client and psychosocial aspects of reproductive health.
- b. Clients should be offered client-centered counseling and education on the following:
  1. Contraceptives
  2. STI risk reduction
    - A. Assessment
    - B. Prevention methods
  3. Encouraging parental/family involvement in seeking reproductive health services
  4. Resisting sexual coercion
    - A. Relationship safety
    - B. Intimate partner violence
    - C. Human trafficking
  5. Preconception
    - A. Pregnancy intention
  6. Abstinence
  7. Infertility
- c. Pregnant women must be offered information and counseling regarding each of the following options in a neutral, factual and non-directive manner:
  1. Prenatal care and delivery
  2. Infant care, foster care, or adoption
  3. Abortion
- d. A written brochure with pregnancy options information and referrals to agencies that provide services in a factual and non-directive manner must be offered and provided upon request.
- e. Agency staff must make referrals for clients for additional counseling, as needed.

## **Section D: Fiscal and Billing Requirements for Reproductive Health Services**

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#### D.1 Compliance with Federal, State, and Local Requirements

- a. The agency must comply with the applicable audit requirements and responsibilities set forth in the Office of Management and Budget Circular A-133 entitled “Audits of States, Local Governments and Non-profit Organizations”.
- b. The agency must follow the written fiscal policy in accordance with RH Program-approved administrative policies. A sample fiscal policy is located on the RH Program’s website ([healthoregon.org/rh](http://healthoregon.org/rh)).
- c. For agencies that don’t currently have fiscal policies approved by the RH Program, signed policies must be submitted for approval by the RH Program with their application for certification.
- d. Provider agencies are required to submit revenue and expenditure reports using forms provided by the OHA.

#### D.2 Billing Requirements

- a. The agency must submit claims to the RH Program claims processing vendor (currently Ahlers and Associates).
- b. The agency has a legal obligation to seek third party reimbursement, if applicable. The agency:
  1. Must be enrolled with and bill the (OHP);
  2. Must be credentialed with and bill private insurance companies; and
  3. Must provide assurance of confidentiality, when indicated.
- c. Agencies may not request a deposit from the client in advance of services covered by RH Program.

#### D.3 Payment

- a. Reimbursement from the RH Program for services provided to eligible clients under OAR 333-004-2020 must be accepted as payment in full with no charge to the client.
- b. Clients can be billed for services that are outside of the RH Program scope of services as defined in OAR 333-004-2040.
- c. The agency must notify clients prior to the visit that they may be billed for services not covered by the RH Program.
- d. No one shall be denied reproductive health services if unable to pay.
- e. An agency may accept voluntary donations.

### **Section E: Data Collection and Reporting Requirements for Reproductive Health Services**

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#### E.1 Collection of Client Enrollment and Encounter Data

- a. The agency must assure that all required client enrollment data is collected using the RH Program Enrollment Form and enters such data into the web-based RH Program Eligibility Database.

- b. The agency must assure that all required visit/encounter data variables as indicated on the RH Program Clinic Visit Record (CVR) are being collected and the agency must submit data and billing information to the RH Program data collection vendor (currently Ahlers and Associates).
- c. The agency must assure that all RH Program required data are collected and submitted for all clients receiving reproductive health services regardless of source of pay.

#### E.2 Annual Request for Information

- a. Agencies must submit annual updates on agency, clinic, and staff contact information to the RH Program.

#### E.3 Additional Reporting

- a. Agencies must submit additional data required by federal funders, as needed.