# North Dakota Family Planning Program (ND FPP)
# Medical Protocol Manual Introduction

The Title X Family Planning Program is administered by the Office of Population Affairs (OPA), Office of the Assistant Secretary for Health (OASH), within the U.S. Department of Health and Human Services (HHS).

This protocol manual was initially developed to meet the specifications and stipulations of the Office of Population Affairs (OPA), Program Requirements for Title X Funded Family Planning Projects, Version 1.0 (April 2014). As stated in these guidelines: *"All grantees should assure services provided within their projects operate within written clinical protocols that are in accordance with nationally recognized standards of care, approved by the grantee, and signed by the physician responsible for the service site."*

Links to the Title X statute and implementing regulations, other statutory provisions that are applicable to the Title X program, regulations related to sterilization, and additional resources to maximize the quality of services offered by Title X projects are provided below.

1. Title X program requirements, https://opa.hhs.gov/grant-programs/title-x-service-grants/title-x-statutes-regulations-and-legislative-mandates
2. Providing Quality Family Planning Services in the United States: Recommendations of the U.S. Office of Population Affairs (QFP) (Revised 2024) https://www.ajpmonline.org/article/S0749-3797(24)00310-6/fulltext
3. OPA Program Review Tool, September 2022, https://opa.hhs.gov/grant-programs/title-x-service-grants/about-title-x- service-grants/title-x-program-expectations#review-tool

The Title X regulations specify that Title X projects must provide services in a manner that "ensures equitable and quality service delivery consistent with nationally recognized standards of care" (42 CFR § 59.5(a)(3)). *Providing Quality Family Planning Services in the United States: Recommendations of the U.S. Office of Populations Affairs (Revised 2024)* is an update to the QFP recommendations originally published by OPA and the Centers for Disease Control and Prevention (CDC) in 2014, and it is a nationally recognized standard of care for providing quality sexual and reproductive health (SRH) services for people of reproductive age.

All services listed in QFP are offered to female and male clients, including adolescents, as specified in clinical protocols. All clinical services are provided in accordance with client confidentiality and privacy policies.

Protocols are structured guidelines for preventing or treating health conditions. They provide clear direction for data collection and assessment, treatment planning, client education, consultation, and referral. To ensure safe, realistic care and minimize legal risks, these protocols align with current evidence-based practices, offering clear direction and guidance for delivering medical services.

These protocols are designed for midlevel clinicians and physicians working in the North Dakota Family Planning Program (ND FPP). Midlevel clinicians include nurse practitioners, nurse midwives, physician

assistants, and clinical nurse specialists. Only those legally authorized for prescriptive practice in North Dakota may initiate, modify, or discontinue medications and devices. Other medical and nursing staff may reference this information as it applies to their role, job description, and scope of practice as defined by the North Dakota Board of Nursing, https://www.ndbon.org/

The Protocol Committee is composed of clinicians from subrecipient agencies, the ND FPP contracted midlevel clinician, and the state family planning nurse consultant. This committee is responsible for reviewing, revising, and developing protocols to guide patient care.

Committee members verify the websites and hyperlinks in protocols and references annually. Any midlevel provider or physician from a subrecipient agency is welcome to participate in the committee. All protocols must be reviewed and approved by the committee before being distributed to subrecipients for clinical use.

The protocols in this manual primarily focus on the core components of QFP, including pregnancy prevention or achievement, STI and HIV testing, pregnancy, infertility, and preconception counseling, as well as conditions commonly encountered in a family planning clinic. The Protocol Committee acknowledges that clinical staff may also diagnose and treat other health conditions in accordance with current best practice standards.

- The protocol manual is organized into four sections, with each protocol identified by a unique code consisting of up to three letters (alpha characters) and up to two numbers (numeric characters). The letters indicate the section in which the protocol belongs, while the numbers specify its position within that section (e.g., CON-12). Each protocol in the manual is divided into the following components:
- **Definition**: Provides a clear description of the condition or situation addressed by the protocol.
- **Subjective Data**: Includes comments, information, and complaints from the client, as well as information that lacks other substantiation and is not perceptible to the observer.
- **Objective Data**: Consists of information gathered from physical examinations, laboratory results, or prior clinical records. This data is perceptible to the senses of the observer.
- **Laboratory**: Details lab work that should or may be conducted to support a definitive assessment.
- **Assessment**: Provides the diagnosis or a statement of the problem or condition.
- **Plan**: Outlines recommendations for medications, procedures, or interventions based on the assessment.
- **Client Education**: Offers guidance for client information and counseling to ensure adherence to the treatment plan, including cautions regarding medications, potential complications, and infections. This section also recommends when the client should return to the clinic for follow-up or routine care.
- **Consult/Refer to Physician**: Specifies the conditions or situations in which the provider should consider consulting with or referring the client to a physician or other healthcare provider.

The notation "should include" in the Subjective and Objective Data categories means that the listed findings should be present for the assessment to be made. The notation "may include" indicates that

any of the following findings are optional and may or may not be present. The notation "must exclude" means that the listed findings must not be present; if they are, the assessment and treatment outlined do not apply.

The Protocol Committee makes every effort to cite references in APA format and/or provide website links at the end of each protocol.

The protocols in this manual are subject to change as new evidence-based practices are recommended by nationally accredited organizations. The ND FPP follows the hierarchy below for guideline review and updates:

1. CDC Guidelines (tailored recommendations for higher-risk individuals)
    - Program Requirements for Title X Funded Family Planning Projects
    - Providing Quality Family Planning Services
    - Sexually Transmitted Disease Treatment Guidelines
    - U.S. Selected Practice Recommendations for Contraceptive Use
    - U.S. Medical Eligibility Criteria for Contraceptive Use

2. USPSTF Recommendations (focused on average-risk individuals)

3. Recommendations from other major medical organizations (e.g., ACOG, AAFP, AAP, NPWH, ASCCP)

Protocols will be reviewed by the Protocol Committee and updated annually, in accordance with Title X guidelines. New, reviewed, or revised protocols will be labeled with the month and year of revision. The medical protocol manual is also available online. Individual subrecipients are responsible for keeping their protocol manual current or for using the online version.

A protocol review form is posted online on the ND FPP website. Signing this form confirms that all midlevel providers, physicians, and staff involved in medical services to clients within the subrecipient agency have reviewed the protocol manual annually.

A protocol update form is available to all agencies and can be submitted at any time to any member of the Protocol Committee. The purpose of the form is to provide individuals with the opportunity to suggest improvements, changes, or additions to any existing protocol or propose new protocols.

**Archiving of Protocols:**

It is the policy of ND FPP to preserve and maintain records as required by law and to destroy them when appropriate. Archiving outdated protocols ensures:

- Compliance with current federal and state laws and regulations.
- Reduction of the risk of accidental destruction of records before the intended time.
- Facilitation of operations by promoting efficiency in retrieving records.
- Maximization of storage space by eliminating outdated documents.

ND FPP will maintain an electronic repository to store state protocols that are no longer in effect. All reviews and edits will be recorded and tracked in the state H: drive. Outdated protocols and related documents will be moved to the protocol archive. Related documents may include title pages, outdated protocols, referenced materials, authorizing signature pages, and memos. ND FPP will add a discontinued date to indicate when the document is retired.

If you have any questions about the manual or suggestions for changes that will make it more useful or usable, please contact:

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