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 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, Title X Statutes, Regulations, and Legislative Mandates | HHS Office of Population Affairs
2. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs (QFP), rr6304.pdf (cdc.gov)
3. OPA Program Review Tool, December 2019
OPA_Program_Review_Tool_FINAL_1.16.20_corrected.pdf (ndhealth.gov)

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 written guidelines for prevention or treatment of a health condition that gives direction for collection and assessment of data, a plan, client education, consultation, and referral. To reflect safe and realistic care and to avoid legal ramifications, these protocols reflect current evidence-based practice and provides concrete direction and guidance in providing medical services.

These protocols are intended for the **midlevel clinicians and physicians** working in the NDFPP. Midlevel clinicians include nurse practitioners, nurse midwives, physician assistants and clinical nurse specialists. Only those legally authorized for prescriptive practice in the state of North Dakota may initiate, discontinue or alter medications and devices. Other medical/nursing staff in the clinical setting may utilize the information as it applies to their title, job description and practice as set by the ND Board of Nursing. Overview - ND Board of Nursing (ndbon.org)

The Protocol Committee consists of clinicians from the delegate agencies, the ND FPP medical director, contracted mid-level clinician(s) and the state family planning nurse consultant. This committee is responsible for reviewing, revising, or developing protocols for providing medical care to patients. Web sites and hyperlinks in the protocols or references are verified yearly by

the committee members. Any delegate agency midlevel provider or physician is welcome to participate on this committee. All protocols are reviewed and approved by the ND FPP medical director before dissemination to the delegate agencies for clinical use.

The protocols in this manual are predominantly related to the QFP core components (preventing or achieving a pregnancy, STI and HIV testing, pregnancy, infertility and preconception counseling) and conditions that may be encountered in a family planning clinic. The protocol committee recognizes that clinician staff may be able to diagnose and treat other primary care conditions adhering to the current best practice standards.

The protocol manual is divided into four sections. A number comprised of up to three alpha characters (letters) and up to two numeric characters (numbers) identifies each protocol within the sections. The alpha characters identify the section in which the protocol resides, and the numeric characters identify the protocol's numeric position within that section (e.g. CON-12). Each protocol in the manual is broken into the following components:

- **Definition**
- **Subjective** data encompasses comments, information and complaints from the client, information that has no other substantiation and is not perceptible to the observer.
- **Objective** data encompasses information derived from physical examination, laboratory findings, or from prior clinical records. This information is perceptible to the senses of the observer.
- **Laboratory** includes lab work that should or may be done to affirm a definitive assessment.
- **Assessment** refers to the diagnosis or statement of the problem or the condition.
- **Plan** includes recommendations for medications, procedures or interventions to be carried out based on the assessment.
- **Client Education** includes recommendations for client information and counseling to ensure compliance with the treatment plan. This includes cautions regarding medications and possible complications of infections and treatments. This section also contains recommendations for when a client should return to the clinic for follow-up or routine care.
- **Consult/Refer to Physician** includes the conditions or situations in which the provider assesses the need for consultation with or a referral to a physician or other health provider.
- The notation "should include" in the Subjective and Objective Data categories means the findings should be present for the assessment to be made. The notation "may include" indicates that any of the following findings may or may not be present. The notation "must

exclude" indicates that the findings must not be present. If they are present, the assessment and treatment do not apply.

The Women's Health Care Clinic Medical Protocols (Torrance, CA) were utilized as the foundation for the majority protocols in the manual. Updates for this manual were discontinued in 2017, therefore, references from that source were removed in April 2018.

All references are cited in APA format and/or by website link at the end of each protocol.

The Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use (July 2016) is sited in the Contraceptives section of the manual and should be kept as a part of the North Dakota Protocol Manual. Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use. (cdc.gov)

The protocols in this manual are subject to change as new evidence-based practice is recommended by nationally accredited organizations. The ND FPP, in accordance with the MMWR Providing Quality Family Planning Services: rr6304.pdf (cdc.gov) recommendations, uses the following hierarchy for guideline review and updates:

1. CDC guidelines (tailor recommendations for higher risk individuals)
    a. Program Requirements for Title X Funded Family Planning Projects 2021 Title X Final Rule | HHS Office of Population Affairs
    b. Providing Quality Family Planning Services (April 2014) rr6304.pdf (cdc.gov)
    c. Sexually Transmitted Disease Treatment Guidelines Table of Contents - STI Treatment Guidelines (cdc.gov)
    d. U. S. Selected Practice Recommendations for Contraceptive Use (July 2016) CDC - Summary - US SPR - Reproductive Health
    e. U. S. Medical Eligibility Criteria for Contraceptive Use (July 2016) US Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2016 | CDC
2. USPSTF (focus is average risk individuals)
3. Recommendations from other major medical professions (e.g., ACOG, AAFP, AAP, NPWH, ASCCP)

Protocols will be reviewed by the protocol committee and updated annually, as directed by the Title X guidelines. New, reviewed, or revised protocols will bear the month and year of revision. The medical protocol manual is also available online. Individual delegate agencies are responsible to keep their protocol manual current or use the online version.

A protocol review form is posted on the online on the ND FPP website. Signature on this form indicates annual review of the protocol manual by all midlevel and physicians working within the delegate agency, and by staff participating in the medical services to the clients.

a. 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 give individuals the chance to make suggestions to improve, change, or add information to any existing protocol, or make suggestions for 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;
- reduces the risk of accidental destruction of records earlier than intended;
- facilitate operations by promoting efficiency in retrieving records; and
- frees up valuable storage space with destruction of 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
- Move outdated Protocols and related documents to the Protocol archive. Related documents may include: Title pages, outdated protocols, referenced materials, authorizing signature page, memos.
- ND FPP will add a discontinued date to indicate when the document is retired.

NFPRHA---Contraception-Clinical-Protocols-List---.pdf (nationalfamilyplanning.org)
HHS.nd.gov

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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