

ZIKA CONTRACEPTION ACCESS NETWORK

POLICY AND PROCEDURE MANUAL



Please note the original table of contents of the Z-CAN Policy and Procedure Manual is enclosed. We have shared this information for users to see examples of topics to include in a policy and procedure manual. The Overview and Z-CAN Eligibility, and Reporting sections are provided in the sample.

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1 OVERVIEW OF Z-CAN

1.1 Program Summary

Zika virus infection in pregnancy can cause microcephaly and other severe fetal brain defects and has been linked to pregnancy loss and problems in infants, including eye defects, hearing loss, and impaired growth.¹ Pregnancy prevention in women who want to delay or avoid pregnancy is a primary strategy to reduce Zika-related adverse pregnancy and birth outcomes. Approximately 138,000 women in Puerto Rico are at risk of unintended pregnancy. Access to contraception in Puerto Rico is limited by reduced availability of the full range of contraceptive methods, high out-of-pocket costs for patients, insufficient insurance reimbursement, logistical barriers that limit same-day provision, lack of patient education, and a shortage of physicians trained in insertion and removal of long-acting reversible contraception (i.e., intrauterine devices (IUD) and implants).² Ongoing Zika virus transmission in Puerto Rico has created an urgent public health need to remove barriers and increase contraceptive access for women who want to delay or avoid pregnancy. In response, the CDC Foundation, with technical assistance from the Centers for Disease Control and Prevention (CDC), and in partnership with the Puerto Rico Department of Health and other local professional organizations (e.g., Puerto Rico OB/GYN Network (PROGyn)), launched the Zika Contraception Access Network (Z-CAN). To improve access, ZCAN will provide the full range of reversible contraceptive methods to a network of physicians at private medical offices, clinics and community health centers across Puerto Rico. OB/GYNs and other physicians in this network will be trained on provision of all contraceptive methods, including inserting and removing intrauterine devices (IUDs) and contraception implants. All Z-CAN patients will be offered a full range of reversible contraceptive methods using a client-centered counseling approach. Z-CAN patients will receive the contraceptive method of their choice at no cost.

2 Z-CAN ELIGIBILITY

2.1 Z-CAN Patient Eligibility

- All non-pregnant women of reproductive age desiring contraception are eligible to participate in the Z-CAN program regardless of insurance status or ability to pay.
 - Pregnant women who desire post-pregnancy contraception can enroll in Z-CAN at a routine prenatal visit, immediately postpartum (after delivery but prior to hospital discharge) or at their routine postpartum visit (see Section 5: Post-Pregnancy Contraception). All providers should counsel women on preventing Zika infection during pregnancy, including sexual transmission, and on the importance of post-pregnancy contraception.
- Only patients who agree to participate in the Z-CAN program are allowed to receive the Z-CAN contraceptive products.

2.2 Z-CAN Physician Eligibility

- Z-CAN physicians must have a valid medical license and malpractice insurance.
- Z-CAN physicians must complete a mandatory 1-day technical training program conducted by a designated Z-CAN training provider.
- Z-CAN physicians must complete a successful proctoring visit(s)³ before enrolling any Z-CAN patients. To be successfully proctored, a Z-CAN provider must demonstrate he or she can safely insert an IUD according to standard insertion procedures using sterile technique (via direct observation by a Z-CAN proctor). In addition, Z-CAN physicians must demonstrate knowledge of and adhere to the policies and procedures outlined in this document.
- Z-CAN providers and clinics cannot start enrolling any Z-CAN patients until Z-CAN products have been delivered to the clinic in the name of the provider.
- When a Z-CAN physician provides contraceptive services at multiple clinics, a minimum of one staff member (e.g., nurse, medical assistant, health educator) from each clinic must participate in a mandatory 1-day technical Z-CAN training program, and a Z-CAN clinic proctoring visit must be completed before Z-CAN patient visits can begin. A Z-CAN physician who has been successfully proctored and has enrolled patients at one Z-CAN clinic cannot enroll Z-CAN patients in additional clinics until that clinic can become a Z-CAN clinic (see Z-CAN clinic eligibility below).

¹ Rasmussen SA, Jamieson DJ, Honein MA, & Petersen LR. Zika virus and birth defects—reviewing the evidence for causality. *New England Journal of Medicine* 2016;374:1981-1987.

² Tepper NK, Goldberg HI, Bernal MI, et al. Estimating Contraceptive Needs and Increasing Access to Contraception in Response to the Zika Virus Disease Outbreak — Puerto Rico, 2016. *MMWR Morb Mortal Wkly Rep* 2016;65:311–314.

³ Multiple proctoring visits may be required.

2.3 Z-CAN Clinic Eligibility

- Z-CAN clinics must have at least one trained Z-CAN staff member.
- Z-CAN clinics must undergo a site visit to ensure that they meet site criteria before they can begin enrolling Z-CAN patients, including having a designated locked cabinet where Z-CAN products will be kept separate from other clinic products, having refrigerated space to store vaginal rings, and documentation that the staff is aware of the policies and procedures associated with providing ZCAN products.
- Z-CAN clinics must adhere to the procedures outlined in this manual and complete all reporting requirements outlined in this manual.
- Z-CAN clinics must adhere to the agreements laid out in the signed Subcontractor Agreement (MOA#: Z-CAN) with the CDC Foundation.
- Z-CAN contraceptive supplies cannot be transferred from one clinic to another.
- Z-CAN contraceptive supplies cannot be shared among providers in the same clinic even if the other providers are Z-CAN trained.
- Z-CAN clinics and providers cannot charge Z-CAN patients for the contraceptive method(s) provided through Z-CAN.
- Other than certain community health center clinics that have unique arrangements, Z-CAN clinics cannot charge patients or third-party insurance for any Z-CAN services. (See Section 8: Billing.) Community health centers cannot charge insurance for contraceptive methods and must follow the billing procedures for insertion and removal costs as outlined in their individual contracts.
- Z-CAN clinics are responsible for ensuring that Z-CAN patients or their insurance providers are not billed for contraceptives administered as a part of the Z-CAN program.
- Z-CAN clinics must provide all patients who receive Z-CAN services with a clinic phone number that they can call for questions or concerns.
- Z-CAN clinics must be able to abide by the policies and procedures for managing

3 PATIENT VISITS

4 ADVERSE EVENTS

5 POST-PREGNANCY CONTRACEPTION

6 REPORTING

6.1 Protecting Patient Privacy and Confidentiality

- **DO NOT** include personally identifiable patient information such as name, medical record number, phone number, e-mail address, mailing address, or date of birth on patient encounter forms that are submitted to the Z-CAN program.
 - These include:
 1. INITIAL VISIT Patient Encounter Form
 2. RETURN VISIT Patient Encounter Form
 3. Adverse Event Form
- **DO NOT** submit IUD/Implant Consent Forms and Procedure Notes to the Z-CAN program. These forms contain the patient's name and medical record number. These documents and any other documents containing a patient signature or additional medical information are for your clinic's internal records only and should never be submitted to the Z-CAN program.

6.2 Submitting Z-CAN Forms

- **At least once per week**, Z-CAN clinic staff are required to submit INITIAL VISIT Patient Encounter Forms and RETURN VISIT Patient Encounter Forms for patients seen at the clinic during the past week. These forms should be submitted within 7 days of each patient visit. (**Exception:** if a patient experiences an adverse event, these forms must be submitted with the Adverse Event Form within 24 hours.)

- **At least once per week**, Z-CAN clinic staff are required to **FAX** new entries on the **Master Z-CAN Patient ID List** to XXX-XXX-XXXX (secure fax) to provide contact information for the patient satisfaction survey.
- Within 24 hours of seeing a patient or being notified by a patient of an adverse event, submit the **Adverse Event Form** and the corresponding **INITIAL VISIT Patient Encounter Form** or **RETURN VISIT Patient Encounter Form** to the Z-CAN Program. **If reporting a Severe Adverse Event, you must also call the Medical Director at XXX-XXX-XXXX within 24 hours.**
- On a monthly basis, or when your clinic has reached its PAR level, Z-CAN clinic staff must complete the **Contraception and Supply Order Form** and e-mail it to XXXXXXXX. If this form is not received on a monthly basis, clinics may not get the next shipment of supplies in time to meet clinic needs.
 - During the first month of your clinic's participation in Z-CAN, the shipment of contraceptive methods and supplies may be more frequent.

7 CONTRACEPTIVE SUPPLIES – INVENTORY MANAGEMENT, ORDERING AND LOGGING

8 BILLING

9 QUALITY ASSURANCE

10 REMOVAL OF IUDS AND IMPLANTS