

# **Assessment of a Preventive Service Program in the Context of a Zika Virus Outbreak in Puerto Rico**

New Information Collection Request

## **Supporting Statement A**

May 8, 2026

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## Abstract

<b>The goal of the project is:</b>	To assess the implementation and associated outcomes of the Zika Contraception Access Network (Z-CAN), an initiative that provided patient-centered services to reproductive-aged women in Puerto Rico who chose to delay or avoid pregnancy while local Zika virus transmission was ongoing. The specific objectives are to assess: (1) prevention strategy adherence among Z-CAN patients at approximately 18 months after receipt of program services; and (2) prevention strategy adherence, patient satisfaction, and unmet need for services among Z-CAN patients at approximately 30 months after receipt of program services.
<b>The intended use of the resulting data:</b>	To monitor program outcomes and determine the program's potential for replication/adaptation during other emergency responses. The information will also be useful to the Puerto Rico Department of Health (PR DOH) and others working to improve services for women to understand ongoing unmet needs for services experienced by women in Puerto Rico.
<b>Methods to be used to collect data:</b>	Online surveys of women who have received services through Z-CAN.
<b>The subpopulation to be studied:</b>	Women aged 18 years or older who received Z-CAN program services.
<b>How the data will be analyzed:</b>	Online survey data will be analyzed using a statistical software package, such as SAS, STATA, or equivalent. Analyses of factors associated with prevention strategy adherence and patient satisfaction will be explored using appropriate analytic methods (e.g., chi-square tests, multivariable logistic regression).

## OVERVIEW PARAGRAPH

This is a request for approval for new information collection request (ICR), “Assessment of a Preventive Service Program in the Context of a Zika Virus Outbreak in Puerto Rico”. This ICR is to supplement an emergency information collection approved by the Office of Management and Budget (OMB) in February 2017 (OMB Control No. 0920-1164; active 2/9/2017 – 5/31/2017). Authorizing legislation for this ICR comes from Section 301 of the Public Health Service Act (42 U.S.C. 241) (**Attachment A**). CDC requests approval to collect data for two years. The purpose of this ICR is to assess a preventive service program launched during the Zika virus outbreak in Puerto Rico to prevent birth defects due to Zika virus infection during pregnancy. The specific objectives are to assess: (1) prevention strategy adherence among Z-CAN patients at approximately 18 months after receipt of program services; and (2) prevention strategy adherence, patient satisfaction, and unmet need for services among Z-CAN patients at approximately 30 months after receipt of program services.

### A. JUSTIFICATION

#### 1. Circumstances Making the Collection of Information Necessary

Zika virus infection during pregnancy has been identified as a cause of microcephaly and other severe brain abnormalities, and has been linked to other problems such as miscarriage, stillbirth, defects of the eye, hearing deficits, limb abnormalities, and impaired growth.<sup>1,2</sup> A primary strategy to prevent these devastating outcomes is to prevent unintended pregnancy among reproductive-aged women at risk of Zika virus infection. During the 2016-2017 Zika virus outbreak, Puerto Rico reported the highest number of Zika virus infections in the United States and its territories, including infections in pregnant women. Additionally, the proportion of unintended pregnancies in Puerto Rico was high (65% vs. 45% in the US overall).<sup>3</sup> To help prevent birth defects due to Zika virus infection during pregnancy, Z-CAN (the Zika Contraception Access Network) was launched to provide patient-centered pregnancy prevention services to women in Puerto Rico who chose to prevent or delay pregnancy while Zika virus transmission was ongoing. The design and implementation of the Z-CAN program, as well as baseline characteristics of the first 21,124 participants served by the program between May 2016 and August 2017, was recently described in a *Lancet Public Health* publication.<sup>4</sup> CDC proposes to monitor program outcomes of interest at approximately 18 and 30 months after receipt of program services, determine the program’s potential for replication/adaptation during other emergency responses, and understand ongoing unmet needs for services experienced by women in Puerto Rico.

Z-CAN was launched in April 2016 with funding from the CDC Foundation, in collaboration with the PR DOH (Puerto Rico Department of Health) and other partners. From the inception of Z-CAN, CDC provided technical assistance on many program aspects, including program monitoring. Z-CAN developed a network of 153 physicians at clinics across Puerto Rico trained to provide client-centered contraceptive counseling and same-day access to the full range of FDA-approved, reversible contraceptive methods at no cost to women who chose to delay or

avoid pregnancy during the Zika virus outbreak. This strategy was selected because in April 2016, CDC estimated that approximately 138,000 women in Puerto Rico might have been at risk of unintended pregnancy and not using a highly effective or moderately effective method of reversible contraception.<sup>5</sup> CDC researchers also found that increasing access to contraception in Puerto Rico during a Zika virus outbreak was likely to be cost-saving for the healthcare system overall, reducing Zika virus–related costs by \$65.2 million (\$2.8 million from less Zika virus testing and monitoring and \$62.3 million from avoided costs of Zika virus–associated microcephaly).<sup>6</sup> By March 2017, 138 clinics across Puerto Rico were participating in Z-CAN.

Z-CAN providers were trained, approved for program participation, and began providing services on a rolling basis over several months starting in April 2016. The first patients received services in July 2016 and the majority of Z-CAN providers were approved to provide services by October 2016 (a few were approved to provide services between January-March 2017). Z-CAN program enrollment continued through September 2017. Approximately 28,000 women were enrolled in the Z-CAN program during this period; however, final program participant numbers remain outstanding due to widespread power outages across Puerto Rico after Hurricanes Irma and Maria, which created a backlog of patient enrollment forms from Z-CAN providers.

As part of the Z-CAN program, women who received a long-acting reversible contraceptive (LARC) method (intrauterine device or implant) can have their LARC device removed when desired at no cost from a provider that participated in the Z-CAN program. Longer term assessment of program implementation and associated outcomes is needed to determine the program’s effectiveness in helping women adhere to prevention strategies, identify any adverse consequences, document ongoing unmet need for services, and determine the potential suitability of using a similar strategy in other jurisdictions at high risk of Zika-related birth defects or in other emergency responses.

Emergency approval (OMB No. 0920-1164) was granted in February 2017 to conduct (1) focus groups with women in Puerto Rico aged 18 years or older enrolled and not enrolled in the Z-CAN program; (2) semi-structured, individual interviews with Z-CAN physicians and clinic staff; (3) online surveys of Z-CAN physicians and clinic staff; and (4) online surveys of Z-CAN women 6 months after program enrollment.

- Focus groups with women in Puerto Rico enrolled and not enrolled in the Z-CAN program have been completed and resulted in helpful information to improve program implementation. For example, non-ZCAN women reported having heard about the program but not seeking services because they thought it was “too good to be true.” As a result, communication strategies were refined to address this misperception. Focus group data continue to be analyzed.
- Semi-structured, individual interviews with Z-CAN physicians and clinic staff have also been completed and yielded helpful information related to potential areas for program improvement and sustainability (e.g., general communication with clinics, product distribution, new staff training, and ease of reimbursement). These suggestions were used to implement rapid changes in the program including creation of a program newsletter for communication and expansion of the local program team to help facilitate communications, site visits, new staff trainings, reordering and reimbursement. Interview data continue to be analyzed.

- Online surveys of Z-CAN physicians and clinic staff have been completed. Preliminary findings suggest that in general, while providing Z-CAN services, the majority of Z-CAN physicians were able to ‘very often’ or ‘always’ provide specific contraceptive methods on the same day as a patient requests the method. Overall, the majority of Z-CAN physicians and clinic staff were ‘satisfied’ or ‘very satisfied’ with specific components of the Z-CAN program. Z-CAN physicians were most satisfied with the training and ongoing support they received, and Z-CAN clinic staff were most satisfied with the promotion of Z-CAN and community outreach. Both Z-CAN physicians and clinic staff were least satisfied with the process of reordering contraceptive products. Survey data with Z-CAN physicians and clinic staff continue to be analyzed.
- Online surveys of Z-CAN women 6 months after program enrollment have been completed. Preliminary findings suggest that the majority of Z-CAN patients reported being ‘very satisfied’ with their current contraceptive method. A higher proportion of women currently using an intrauterine device, implant or ring reported being ‘very satisfied’, compared with women currently using the contraceptive shot, birth control pills, or the patch. Survey data with Z-CAN women 6 months after program enrollment continue to be analyzed.

Z-CAN programmatic data, which include data from initial visits, return visits, adverse event forms, and a 2-week patient satisfaction survey provide information on: contraceptive method use before Z-CAN visit, contraceptive method(s) received through Z-CAN, same day receipt of methods, whether methods and related services were provided free of charge, patient satisfaction with services, and receipt of client-centered counseling. As the program implementer, the CDC Foundation funded the collection of Z-CAN programmatic data. As described in the *Lancet Public Health* publication,<sup>4</sup> (**Attachment I**) findings from analyses of programmatic data thus far revealed that whereas only 4% of women enrolled in Z-CAN had used a LARC method before Z-CAN, 68% chose and received a LARC method at their initial visit. Of the women who received a LARC method, 76% had used no method or a least effective method of contraception (i.e., condoms or withdrawal) before their Z-CAN visit. Of the 3,489 women who participated in a 2-week patient satisfaction survey, 93% were very satisfied with the services received, and 93% reported receiving the method that they were most interested in after receiving counseling. The majority (78%) of women rated their care as excellent or very good on every item of an 11-item interpersonal quality of family planning care scale.

CDC now seeks approval to collect data with Z-CAN women at approximately 18 months (shorter, interim online survey) and 30 months (longer, final online survey) after program enrollment. This data will enable longer-term assessment of outcomes of interest, including patient adherence to prevention strategies (e.g., contraception continuation rates), patient satisfaction, and unmet need for services after the program. The information collected is necessary to determine program suitability and sustainability from the patient perspective. Some concerns may only become apparent with longer-term assessment, such as changes in utilization or satisfaction with chosen contraceptive methods, whether women are readily able to access services they are eligible for from a Z-CAN provider during or after the program (i.e., no-cost removal of intrauterine devices and implants), and unmet need for services after the program.

## 2. Purpose and Use of the Information Collection

The purpose of this ICR is to assess a preventive service program launched during the Zika virus outbreak in Puerto Rico to prevent birth defects due to Zika virus infection during pregnancy. The specific objectives are to assess:

1. Prevention strategy adherence (e.g., contraception continuation rates) among Z-CAN patients at approximately 18 months after receipt of program services; and
2. Prevention strategy adherence, patient satisfaction, and unmet need for services among Z-CAN patients at approximately 30 months after receipt of program services.

By extending follow-up with Z-CAN patients to 18 and 30 months post-enrollment, we will be able to assess prevention strategy adherence and patient satisfaction over a longer period. Extending follow-up with Z-CAN patients will also allow us to assess unmet need for services after the program end date, as well as reproductive health outcomes (e.g. unintended pregnancy rates) over time. All of this information is necessary to determine program suitability and sustainability.

As previously mentioned, some concerns may only become apparent with longer-term assessment, such as changes in utilization or satisfaction with chosen contraceptive methods, whether women are readily able to access services they are eligible for from a Z-CAN provider during or after the program (i.e., no-cost removal of intrauterine devices and implants), and unmet need for services after the program. The *practical utility* of the information to be collected as part of this ICR is to determine the program's potential for replication/adaptation in other jurisdictions at high risk of Zika-related birth defects or in other emergency response efforts. The information will also be useful to the PR DOH and others working to improve services for women to understand ongoing unmet needs for services experienced by women in Puerto Rico.

The *negative consequences* of not having the information would be inability to monitor program outcomes over a longer period, inability to determine the program's potential for replication/adaptation in other jurisdictions at high risk of Zika-related birth defects or in other emergency response efforts, and inability to understand ongoing unmet needs for services experienced by women in Puerto Rico after the end of the program.

The data will primarily be used by CDC and the CDC Foundation, in collaboration with the PR DOH and other partners, including Total Solutions, Inc. (TSI) and the University of Puerto Rico (UPR). The data may be used on an ongoing basis (i.e., not limited to a given frequency). Others entities (e.g., jurisdictional departments of health and human services) may also be interested in using the data to inform potential replication/adaptation of the program for their communities.

## 3. Use of Improved Information Technology and Burden Reduction

This ICR consists of online surveys with patients. All data collection tools (i.e., online surveys) have been designed to collect the minimum amount of information necessary to meet the study objectives.

The online surveys with Z-CAN patients will be self-administered electronically on personal devices (e.g., computers, smart phones). Use of online surveys has several advantages. They are less expensive to deploy, reduce the need for data entry thereby eliminating transcription errors, allow respondents to respond at a time that is most convenient to them, and reduce respondent burden by allowing respondents to automatically skip questions that are not applicable based on an answer to a previous question. All skip patterns will be verified prior to launching the surveys.

#### **4. Efforts to Identify Duplication and Use of Similar Information**

CDC is not aware of any systematic collection of the information described in this ICR. Although CDC received emergency OMB approval for the ICR “**Emergency Zika Package IV: Assessment of Contraceptive Use and Needs, Puerto Rico, 2016**” (CAPRZ, OMB Control No. 0920-1114), that data collection effort largely occurred prior to the launch of the Z-CAN program; it was designed to collect population-representative estimates of contraceptive use among women of reproductive age and was not designed to capture information specifically about Z-CAN patients or their experiences. Also, that data collection effort was cross-sectional and did not assess data specific to the experiences of Z-CAN patients over time, such as adherence to prevention strategies or receipt of services in concert with program protocols. Results from that data collection effort found that 85% of women surveyed were at risk for unintended pregnancy, and among those, 45% were using no contraception or a less effective contraceptive method, translating to an estimated 300,000 women in Puerto Rico who were at risk for unintended pregnancy and were not using effective contraception at the height of the Zika virus outbreak. These findings demonstrate the need for the Z-CAN program during the outbreak.

Since the initiation of the Z-CAN program, CDC received OMB approval for the ICR “**Zika Reproductive Health Call-Back Survey (ZRHCS), Puerto Rico 2017**” (OMB Control No. 0920-1212). This data collection, like the one discussed above, was not designed to capture Z-CAN participants and was also cross sectional. Data from this collection will address change in contraceptive use over time, on the population level, and will also be used to compare contraceptive patterns among Z-CAN women and the general population of reproductive age women in Puerto Rico.

Both of these population-based data collections (CAPRZ and ZRHCS) will complement the data intended to be collected with the current ICR by providing information on changes in contraceptive use in the population as a whole during the time of Z-CAN program implementation, but these prior data collections do not provide information on Z-CAN program use, prevention strategy adherence and satisfaction, or unmet needs for services over time.

In addition to the information collections above, CDC received emergency OMB approval for the ICR “**Formative Assessment Regarding Contraception Use in the U.S. Virgin Islands**

**(USVI) in the Context of Zika” (OMB Control No. 0920-1148)** to assess barriers and facilitators specific to USVI.

Finally, CDC also received emergency OMB approval for several ICRs that involved data collection with pregnant or immediately postpartum women including:

- “Formative Evaluation of Zika Prevention Kits for Pregnant Women in Puerto Rico” (OMB Control No. 0920-1071)
- “Assessment of Interventions Intended to Protect Pregnant Women in Puerto Rico from Zika Virus Infections” (OMB Control No. 9020-1118),
- “Emergency Zika Package: Zika Postpartum Emergency Response Survey, Puerto Rico, 2016” (OMB Control No. 0920-1127), and Zika Postpartum Emergency Response Survey (ZPER), Puerto Rico, 2017 (OMB Control No. 0920-1199).

None of these ICRs collected information that could be used to assess Z-CAN, as they target assessment of different population and needs (Zika avoidance in women who are already pregnant, contraceptive barriers in the U.S. Virgin Islands).

Programmatic data collected by the CDC-Foundation does exist, but is distinct from and will provide important contextual data for interpreting the information to be collected under the current request. This programmatic data includes demographic information at the time of initial program visit (age, education, employment status, marital status, type of insurance) and information on visits that occurred during program implementation (date, contraceptive method received, method removal). Data from the proposed online surveys with Z-CAN patients will be linked to the programmatic data for analyses to assess prevention strategy adherence and patient satisfaction over time.

No other similar data collections have been conducted or are underway, as confirmed via literature searches of electronic databases and discussions with stakeholders and federal partners.

## **5. Impact on Small Businesses or Other Small Entities**

We do not expect respondents to represent small businesses or other small entities.

## **6. Consequences of Collecting the Information Less Frequently**

Z-CAN patients will be asked to respond to online surveys at approximately 18 and 30 months after their initial Z-CAN visit. Since women’s satisfaction with their contraceptive method and continued use of that method may vary over time,<sup>7-10</sup> it is important to assess these outcomes, as well as unmet need for services and reproductive health outcomes over a longer period including after the end of Z-CAN. Some concerns may only become apparent with longer-term assessment, such as changes in utilization or satisfaction with chosen contraceptive methods, whether women are readily able to access services they are eligible for from a Z-CAN provider during or after the program (i.e., no-cost removal of intrauterine devices and implants), and ongoing unmet needs for services after the program. Collecting this information from Z-CAN patients less frequently will preclude this assessment.

## **7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

The activities outlined in this package fully comply with all guidelines of 5 CFR 1320.5.

## **8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

- A. A 60-day Notice was published in the Federal Register on March 30, 2018, vol. 83, No. 62, pp. 13752-13754 with the title “Assessment of a Preventive Service Program in the Context of a Zika Virus Outbreak in Puerto Rico” (**Attachment B-1**). CDC received one non-substantive comment (**Attachment B-2**).
- B. Local collaborators, including Puerto Rico Obstetrics and Gynecology (PROGyn), a medical non-profit organization, and UPR, have been involved in discussions since early September 2016 regarding the design of the overarching program monitoring and assessment strategy to ensure cultural appropriateness and community relevance in all aspects of data collection, including recruitment efforts, instruments, and consent processes. There are no unresolved problems with outside collaborators.

## **9. Explanation of Any Payment or Gift to Respondents**

Women who receive services through the Z-CAN program will receive invitations to complete online surveys at approximately 18 and 30 months after program enrollment. Z-CAN patients participating in the surveys will be provided with a gift card valued at \$5 for each of the surveys completed, as a token of appreciation. This is the amount women received for completing the 6 month survey, as approved in our emergency clearance. Providing tokens of appreciation are needed to ensure adequate participation from hard to reach populations. Inability to recruit adequate participation would result in reduced sample sizes, which would compromise our ability to use the information collected from respondents, and would also result in participation bias by reducing participation among hard to reach women. The token of appreciation amount was determined through discussions with local collaborators with expertise in conducting data collection activities with the study population. Removing the token of appreciation would incur significant costs for extended recruitment and timeline delays, which could threaten our ability to assess the effectiveness of the Z-CAN program.

## **10. Protection of the Privacy and Confidentiality of Information Provided by Respondents**

The Chief Privacy Officer for CDC has determined that the Privacy Act does apply to this data collection (**Attachment C**). CDC will not be given information in identifiable form (IFF) such as name, e-mail or phone number. However, each participant will have a unique identifier that will be used to identify and retrieve records across various project components. The System of Records Notice (SORN) being used for this data collection is: 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems (<https://www.cdc.gov/SORNnotice/09-20-0136.htm>). Given the applicability of the Privacy Act, all appropriate security controls and rules of behavior will be incorporated to protect the confidentiality of information obtained. All individuals involved in any data collection activity will be trained concerning procedures and

practices to ensure privacy of data. The sections below describe the protections in place to preserve privacy and confidentiality.

Z-CAN patients were assigned a unique identification number by the Z-CAN program (i.e., Z-CAN identification number). The Z-CAN program office maintains a list of all Z-CAN patients who completed the 2-week patient satisfaction survey that occurred after the initial Z-CAN visit (as part of Z-CAN programmatic monitoring activities and not as part of this ICR) and their contact information. CDC has engaged a contract company to carry out the new collection. The Z-CAN program office will provide the data collection contractor a file containing the Z-CAN identification numbers, names, and emails of those to be surveyed. A password-protected electronic file will be used to transmit the information to the contractor. The password to unlock the file will be provided to the contractor via telephone and not in written form (technical control). Z-CAN identification numbers will be used to track responses.

Each participant will be asked to provide consent electronically prior to beginning the online survey, which will be described as “patient satisfaction surveys.” The Z-CAN program will not be mentioned by name in the invitation link. This description is vague enough to prevent someone who may have access to the invitation (who is not the intended participant) from immediately knowing the purpose of the survey. This is an added layer of privacy protection for Z-CAN patients.

Data will be collected via a secure, web-based survey platform (i.e., HIPAA-compliant version of Survey Monkey). All Survey Monkey information systems and infrastructure are hosted in world-class data centers. These data centers include all the necessary physical security controls (e.g., 24×7 monitoring, cameras, visitor logs, entry requirements). Survey Monkey has dedicated cages to separate equipment from other tenants. In addition, these data centers are SOC 2 accredited. Survey Monkey is also equipped with security features to help protect the data, including automatic logoff after 30 minutes of inactivity and logging of account access and modifications to survey data, including account logins/failures, account password and username requests, survey response exports, sharing, and deletions; and transferring surveys to other accounts. The platform also implements administrative, physical, and technical safeguards to protect the confidentiality and integrity of the data, such as regular risk assessments of systems, backup data plans, disaster recovery plans, and regular system monitoring, updating, and patching.

- The contractor will download the survey data at scheduled intervals and strip names, emails, and phone numbers from the dataset before saving as a secure password-protected file on a secured server. The datasets will contain the Z-CAN identification numbers of respondents for tracking and linking purposes. Survey data will be transmitted to CDC by the contractor at scheduled intervals via Secure Access Management Services (SAMS), CDC’s largest electronic authentication provider for external partners supporting the secure exchange of electronic files between CDC and partner organizations. Transmitted data will not contain any information in identifiable form; instead, only de-identified data will be provided. The data collection contractor will work closely with CDC’s National Center for Chronic Disease Prevention and Health Promotion’s Office of Informatics and Information Resources to ensure that technical and security standards, processes, and procedures are followed (administrative control).

At CDC, password protection will impose user name and password log-in requirements to prevent unauthorized access. Each user name will be assigned limited access rights to files and directories at varying levels to control file sharing. Computer facilities at all sites are protected from potential fire or water damage. Further, CDC is in compliance with applicable federal law requiring the protection of federal computer networks from cybersecurity risks like hacking, internet attacks, and other security weakness; computer network experts working for, or on behalf, of the government, may intercept and review information sent through government networks for cyber threats if the information is sent through the government network triggers a cyber threat indicator.

Data will be analyzed and reported by CDC in aggregate to prevent identification of individuals. Information that could potentially be used to indirectly identify an individual will be suppressed in reports; for example, aggregated data will not be stratified into subcategories that might allow for identification of individuals.

## **11. Institutional Review Board (IRB) and Justification for Sensitive Questions**

### *IRB Approval*

The protocol has been reviewed and approved by the IRB of the CDC (**Attachment D-1**) and the UPR (**Attachment D-2**). Both IRBs determined the study to be not greater than minimal risk to subjects.

### *Justification for Sensitive Questions*

Some topics covered in the data collection activities may be sensitive for some participants (e.g., contraception, occurrence of pregnancy). However, these questions are essential to meeting the goals of the information collection. During the informed consent process, participants will be notified of the types of the questions that will be asked and also notified that they may decline to discuss any of the topics or decline to answer any question without penalty. Steps to protect the privacy of information provided by respondents is included in Section 10.

## **12. Estimates of Annualized Burden Hours and Costs**

### **A. Estimated Annualized Burden Hours**

Online surveys will be conducted with approximately 1,920 Z-CAN patients aged 18 years or older to assess prevention strategy adherence (e.g., contraception continuation rates), patient satisfaction, and unmet need for services at approximately 18 and 30 months following their enrollment in Z-CAN. Potential participants will be the first 3,200 Z-CAN patients who completed the 2-week patient satisfaction survey conducted by the CDC Foundation as part of regular program improvement activities. We expect approximately 60% of these patients will consent to participate in the 18 month survey (for a total sample of 1,920, annualized sample 960; **Attachment H-1**). Although approximately 50% of patients consented to participate in the 6-month survey, disruptions in data collection occurred because of Hurricanes Irma and Maria,

and we are hopeful that with additional follow-up efforts, a higher response rate will be obtained. Participation at 30 months is anticipated to be 55% (for a total sample of 1760, annualized sample 880, divided among 660 participants completing version A of the 30-month survey [**Attachment H-2**] and 220 completing version B of the survey [**Attachment H-3**])

At the time of their initial Z-CAN visit, Z-CAN patients were only notified about potential follow-up surveys through 12 months post-enrollment. Therefore, to ensure that we do not contact women no longer wishing to participate in follow-up surveys, a thank you message will be sent approximately 1-2 months before the 18-month survey with information describing further follow-up contact planned and how patients can opt out of being contacted about these additional follow-up activities. Also, approximately 1-2 weeks before the invitations to participate in the 18-month and 30-month surveys are distributed, a pre-notification will be sent. Additionally, to help improve follow-up, short interim contact messages may be sent to women in between survey time points to maintain contact with women and request updated contact information, if any. The interim contacts, including the thank you message, survey pre-notification, and short interim messages will be sent via email or text message; these communications are included in **Attachment E** (English and Spanish).

The invitation to participate in the 18-month and 30-month surveys will also be sent via email or text message and will include an electronic link to the survey; the invitation is included in **Attachment F** (English and Spanish). Women must provide informed consent electronically to participate in the 18- and 30-month online surveys (**Attachment G**; English and Spanish).

The survey content will vary for the 18-month survey (**Attachment H-1**; English and Spanish) and the 30-month survey. The 18-month survey will be a shorter, interim survey (estimated 7 minutes on average to complete) and the 30-month survey will be a longer, final survey (estimated 10 minutes on average to complete). Since it is possible that Z-CAN patients may respond to the 30-month survey who did not participate in the 18-month survey, there are two different versions of the 30-month survey – one for Z-CAN patients who responded to the 18-month survey (version A) (**Attachment H-2**; English and Spanish) and one for Z-CAN patients who did not respond to the 18-month survey (version B) (**Attachment H-3**; English and Spanish). The content for the 30-month survey version B will be identical to the content for the 30-month survey version A, except that women will be asked about outcomes of interest over a different time period (since initial Z-CAN visit rather than within the past 12 months).

The 18-month survey will be launched, on an ongoing basis, beginning immediately after OMB approval for those participants who had already enrolled  $\geq 18$  months prior and continuing through January 2019. The 30-month survey will be launched, on an ongoing basis beginning April 2019 and continuing through January 2020.

Although instruments listed (**Attachments H-1, H-2 and H-3**) include both English and Spanish to facilitate review of the package, only the Spanish versions will be used for actual survey implementation. Screen shots of the surveys are provided in **Attachment H-4** (18-month survey), **Attachment H-5** (30-month survey version A), and **Attachment H-6** (30-month survey version B).

The total number of annualized burden hours in this ICR is estimated to be 259.

<b>Type of Respondents</b>	<b>Form Name</b>	<b>No. of Respondents</b>	<b>No. of Responses per Respondent</b>	<b>Average Burden per Response (in hours)</b>	<b>Total Annualized Burden (in hours)</b>
Z-CAN patients aged 18 years or older	Online surveys (18-month follow-up) <b>(Attachment H-4)</b>	960	1	7/60	112
Z-CAN patients aged 18 years or older who completed the 18 mo survey	Online surveys (30-month follow-up) <b>(Attachment H-5)</b>	660	1	10/60	110
Z-CAN patients aged 18 years or older who did not complete the 18 mo survey	Online surveys (30-month follow-up) <b>(Attachment H-6)</b>	220	1	10/60	37
<b>Total</b>					<b>259</b>

### ***B. Estimated Annualized Burden Costs***

For women aged 18 years or older and able to conceive included in this ICR, we do not know what the wage rate category will be for the selected participants. Therefore, we used the minimum wage rate for Puerto Rico (\$7.25 per hour) (available at <https://www.dol.gov/whd/minwage/america.htm#PuertoRico>).

The estimated annual response burden cost to participants for this ICR will be \$1,877.75.

<b>Type of Respondent</b>	<b>Form Name</b>	<b>Total Annualized Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Annualized Respondent Costs</b>
Z-CAN patients aged 18 years or older	Online surveys (18-month follow-up) <b>(Attachment H-4)</b>	112	\$7.25	\$812.00
Z-CAN patients aged 18 years or older who completed the 18 month survey	Online surveys (30-month follow-up) <b>(Attachment H-5)</b>	110	\$7.25	\$797.50
Z-CAN patients aged 18 years or	Online surveys (30-month follow-up)	37	\$7.25	\$268.25

Type of Respondent	Form Name	Total Annualized Burden Hours	Hourly Wage Rate	Annualized Respondent Costs
older who did not complete the 18 month survey	(Attachment H-6)			
<b>TOTAL</b>				\$ 1,877.75

### 13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no anticipated costs to respondents other than their time to participate.

### 14. Annualized Cost to the Federal Government

The total estimated cost to the federal government is \$706,784.27. This amount is based on the contractor's costs for carrying out the data collection activities and reporting and CDC personnel time for obtaining CDC approvals, providing project oversight, and participating in analysis and dissemination of the results. The table summarizes expenses to the federal government. Salary estimates were obtained from the US Office of Personnel Management salary scale and were based on Step 1 employees for the Atlanta locality (available at <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/ATL.pdf>). This project will be executed as part of Contract No. 200-2017-93464.

Expense Type	Expense Explanation	Annual Costs (dollars)
Contract	Contract No. 200-2017-93464 (Total Solutions, Inc.)	\$550,184.67
	<b>Subtotal, Contract Costs</b>	<b>\$550,184.67</b>
CDC Personnel	Behavioral Scientist GS-14, 30% of FTE	\$32,484.30
	Health Scientist GS-14, 30% of FTE	\$32,484.30
	Health Scientist GS-13, 50% of FTE	\$45,815.50
	Statistician GS-13, 50% of FTE	\$45,815.50
	<b>Subtotal, CDC Personnel</b>	<b>\$156,599.60</b>
	<b>TOTAL COST TO THE GOVERNMENT</b>	<b>\$706,784.27</b>

### 15. Explanation for Program Changes or Adjustments

No program changes or adjustments apply at this time.

### 16. Plans for Tabulation and Publication and Project Time Schedule

Data analysis will be conducted using a statistical software package (e.g., SAS, STATA, SUDAAN). Descriptive statistics will be examined, and appropriate analytic tests (e.g., chi-

square tests, multivariable logistic regression) will be applied to examine research questions (e.g., factors associated with Z-CAN patient contraceptive continuation rates at 18 and 30 months).

Below are key activities and target dates for this ICR:

Activity	Time Schedule
Web-based survey platform is built	Currently under development
Assemble contact information of potential respondents	Currently underway
Send web-based link for Z-CAN patient 18-month survey, on rolling basis, to Z-CAN patients based on Z-CAN enrollment date	Immediately upon OMB approval (target: no later than September 30, 2018) through January 2019
Send web-based link for Z-CAN patient 30-month survey, on rolling basis, to Z-CAN patients based on Z-CAN enrollment date	Beginning April 2019 through January 2020
Data are converted to analytic dataset and sent to the CDC	Periodically during data collection for preliminary analyses
Survey data are analyzed	Periodically during data collection for preliminary analyses; final data to be analyzed within 2-3 months after data collection
Manuscripts are developed and submitted for publication	3-5 months after end of data collection

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

The OMB expiration date will be displayed on necessary materials and documents.

**18. Exceptions to Certification for Paperwork Reduction Act Submission**

There are no exceptions to the certification.

## References (Attachment I)

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