ATTACHMENT C7-b.

UPDATES TO REPORTING REQUIREMENTS BY ASSISTED REPRODUCTIVE TECHNOLOGY PROGRAMS

Reporting Requirements by Assisted Reproductive Technology Programs

I. Who Reports

The Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA) requires that each Assisted Reproductive Technology (ART) program shall annually report pregnancy success rates to the Secretary of the Department of Health and Human Services through the CDC. CDC has been collecting data from ART programs starting from ART cycles performed in 1995. Between 1997 and 2003, CDC contracted with the Society for Assisted Reproductive Technology (SART) to annually obtain a copy of their clinic-specific database. Since 2004, CDC has maintained the National ART Surveillance System (NASS), a web-based ART data reporting system.

A practice, program or clinic meets the definition of an ART program if: a) it is a legal entity that practices under State law; b) it can be uniquely recognizable to the consumer; and c) the practice provides ART services to patients who have experienced infertility or are undergoing ART for other reasons. Since many ART programs have more than one physician in the practice and may expand to multiple locations, and since ART cycles may involve multiple practitioners and multiple sites, guidelines in Sections I, 1–5 have been established to delineate ART program criteria, the responsibilities of each ART program's Medical Director, and practice-based reporting.

A. **Criteria to be considered an ART program—**Reporting is practice-based and not physician-based. The criteria preclude one or more individual physicians within a single ART program from reporting their data separately from the remainder of the practice. The criteria also preclude individual physicians who practice independently from pooling their data and reporting together. Any practice that performs at least one ART cycle during the reporting year, as defined in Section III "Data to be

Reported", and meets the following two criteria, is considered to be an ART program and is required to report data through NASS for all ART cycles performed during that reporting year. Each ART program will be assigned a unique NASS ID.

a) An ART program must be a legal business entity (practice name) as defined by its state law.

b) To report as an ART program, the practice must be uniquely recognizable to a consumer apart from another ART program or clinic with whom the practice may share some or all resources or liability, and/or in addition to treating a distinct patient population. Consideration will be given if there are distinguishes features such as: a different legal name under which the practice publically represents itself to the consumer; a distinct, independent practice Web site, consumer directory listing(s), or social media presence; and/or a separate setting or facility for practicing ART.

B. **Reporting responsibilities of the Medical Director**—The Medical Director of the ART program during the time the ART cycles are performed is responsible for verifying and reporting all cycle data for that reporting year. If the Medical Director is not available to verify and approve the reported cycle data under unforeseen circumstances, the Lab Director is to assume the reporting responsibilities as the Medical Director.

a) If there is a change in personnel, including the Medical Director's position, between the time the ART cycle occurred and the time the reporting year data are due, the current Medical Director at the time of final reporting deadline is responsible for ensuring that every ART cycle performed by that practice during the reporting year is reported to CDC.

b) If the current Medical Director is verifying and approving data in NASS for all or a portion of cycles for which a previous Medical Director and/or former corporate entity associated with the ART program was responsible, the current Medical Director must provide proof to CDC

that the previous parties responsible for the cycles agree to this arrangement. (Contact the NASS Help Desk at 1-888-650-0822 to discuss specifics.)

C. **Reporting responsibilities of ART program**

1) **One practice, one site—**An ART program with one or more physicians who share resources and/or liability, but not necessarily patients, at one location.

a) In a practice with several physicians, the Medical Director is required to report every ART cycle performed at the ART program under one NASS ID, even when other practitioners in the ART program may have performed most or all of the work for the cycle(s).

b) An ART program cannot report cycles from another program for which one of their current or former practice physicians are responsible. However, CDC may consider exceptions if the ART programs in question were involved together in reorganization. In these cases, the current Medical Director must provide proof to CDC that the Medical Director and parties responsible for the cycles agree to this arrangement as detailed in Section I.2.b.

2) **One practice, multiple sites—**An ART program with one or more physicians who share resources and/or liability, but not necessarily patients, at multiple locations. Based on the guidelines below, CDC will consider whether an ART program with several locations performing ART should report cycles from one or more locations separately under different NASS IDs or together under one NASS ID. ART program arrangements not addressed here will be deliberated on a case-by-case basis. (Contact the NASS Help Desk at 1-888-650-0822 to discuss specifics.)

a) If the site is located in a different state, has a different Medical Director, or uses a different laboratory than the main ART program at the time the new site is opened, the site must obtain a unique NASS ID and report cycles separately. These criteria are in

effect for new sites in operation as of January 1, 2015. Any site that is in operation prior to January 1, 2015, will not be required to change their current reporting structure.

b) If the site is located within the same state as the main ART program and meets the criteria and definition of an "ART program", programs may report separately under different NASS ID.

c) If reporting together, the Medical Director is required to report all cycles under one NASS ID from each site that performed at least one ART cycle during that reporting year.

d) In all cases, a U.S.-based practice performing cycles in another country may only report the cycles performed in the U.S.

3) **Multiple ART programs involved in one cycle—**Different ART programs responsible for ovarian stimulation, oocyte retrieval, and/or embryo transfer. The following guidelines should be used:

a) The requirement to report cycles lies with the ART program that accepts responsibility for the embryo culture. The ART programs involved must have a method in place to ensure that these cycles can be prospectively reported by the ART program required to report them. In addition, all canceled cycles must be reported by the ART program accepting responsibility for the embryo culture.

b) An ART program that agrees to accept patients from another program after a treatment cycle has been initiated is required to report the cycle as their own if the patient's oocytes/ embryos are cultured in the laboratory associated with the ART program accepting the patient. In this case, the requirement for prospective reporting will not be enforced.

c) The requirement to report cycles involving previously cryopreserved oocytes/embryos are to be reported by the ART program that accepts responsibility for thawing the oocytes/embryos.

4) **Multiple ART programs sharing one ART laboratory—** Reporting is practice-based and not laboratory-based. Independent ART programs that share an embryology laboratory or use another program's laboratory must report their cycles independently under their own unique NASS IDs.

II. Description of Reporting Process

A. Reporting Activities_

Each year CDC sends announcement letters to all qualifying ART programs 90 days before the submission deadline for ART cycles. The anticipated deadline for reporting data to CDC is December 15th of the year, one year subsequent to the reporting year in question. (For example, the anticipated deadline to report data on cycles initiated between January 1, 2012 and December 31, 2012 is December 15, 2013.) An ART clinic is considered to be non-compliant with the federal reporting requirements of the FCSRCA if the clinic was in operation at any time during the reporting year and performed any ART cycles and (a) failed to submit ART cycle data to CDC by the reporting deadline, or (b) the clinic success rates table was not verified by signature of the medical director of the clinic by the same deadline. These clinics will be listed as non-reporting clinics in the ART annual report and on the CDC website. If the clinic was in operation any time during the reporting year but did not perform any ART cycle, this clinic will not be included in the ART annual report (neither as reporting nor as non-reporting clinic).

ART programs that are submitting data to CDC via the NASS or through an approved alternative (i.e., SART-member clinics may report their data to NASS through SART) will be considered to be in compliance with federal reporting requirements of the FCSRCA. Regardless of the method chosen for

submitting data to NASS, each clinic must complete the annual submission steps as detailed in the NASS Annual Submission Guide posted on the NASS website (www.artreporting.org). A NASS account can be set up by calling the NASS Help Desk at 1-888-650-0822 or by sending an e-mail to NASS@Westat.com. NASS accounts established previously can be used for data submission by the same clinic, although user passwords may need to be re-established if they have expired since last using NASS. ART programs should also notify the NASS Help Desk of any changes in clinic location, ownership, or key staff (i.e., Practice, Medical, or Laboratory Director) and provide NASS with a list of all practicing physicians in the program.

Cycle-specific data for the following patients must be included in the reporting database: (1) all patients undergoing ART, (2) all patients undergoing ovarian stimulation or monitoring with the intent of undergoing ART but who did not proceed to oocyte retrieval or transfer of embryos for any reason; this includes women whose cycles are canceled for any reason, (3) all patients providing donor oocytes, and (4) all patients undergoing monitoring and/or embryo (or oocyte) thawing with the intention of transferring cryopreserved embryos. All cycle data must be reported prospectively, i.e., reporting of initial cycle intent and selected patient details is required within four days of cycle initiation. Currently, each ART patient is assigned a unique, clinic-specific NASS ID that is system-generated when the clinic first enters the patient in NASS. The clinic is responsible for linking this ID to the patient's medical records and future ART cycles across reporting years. Each ART cycle for each patient is also assigned a unique cycle code. In the reporting system, the patient is identified by the clinic code, the patient code, and the cycle code assigned by NASS. The patient's name and social security number are not included in the reporting database. Therefore, each clinic must maintain personal identifiers in the clinic database on site in order to link every cycle reported to CDC to a specific patient.

B. Updating of Reporting Requirements

The field of ART is a rapidly developing medical science. These reporting requirements, including data collection instruments, variables, and definitions will be periodically reviewed and updated as new knowledge concerning ART methods and techniques becomes available. During such a review, professional and consumer groups and individuals will be consulted to confirm the validity of the new or revised data collection tools. Clinics will be notified in writing at least 90 days in advance of January 1st of the reporting year of all changes to the reporting requirements.

ART programs are ultimately responsible for ensuring that their data are mapped accurately into the required NASS format if using third-party electronic medical records or reporting systems to submit their ART data through NASS to CDC. ART programs must ensure their clinic data can be correctly transmitted to NASS for pre-import NASS quality control reviews and imported into NASS in time for the required NASS annual submission steps by the CDC deadline. CDC will continue to inform clinics of all necessary requirements for importing data from other electronic medical record systems into NASS and for checking imported data to ensure that it retains the accuracy and compatibility of the data entry system from which it was extracted.

Each ART program should be aware that the Paperwork Reduction Act is applicable to this data collection. Under the Paperwork Reduction Act of 1995, a Federal agency shall not conduct or sponsor a collection of information from ten or more persons other than Federal employees, unless the agency has obtained approval from the Office of Management and Budget (OMB) for the collection of information. A person is not required to respond to a collection of information unless it displays a currently valid OMB control number. CDC has obtained OMB approval to collect this data under OMB control No. 0920–0556.

C. External Validation of Clinic Data

As part of the annual routine activities of this surveillance program, all ART programs are subject to external validation of their reporting activities, which will include review by appropriate professionals from outside the clinic staff. This review may include but is not limited to examination of medical and laboratory records and comparison with data reported in NASS.

Each year, CDC selects a random sample of 5–10% of all reporting ART programs, after taking into consideration some clinic characteristics, for an on-site validation visit. If major data discrepancies were identified during data validation, CDC may re-select these ART programs for data validation during the following reporting year(s) to make sure that data errors were corrected. If the data errors have not been corrected after two validation visits, CDC will include a warning statement about possible issues with the accuracy of ART success rates. The purpose of validation is to evaluate the overall accuracy of data reported in NASS. To do so, data submitted to NASS are compared with data recorded in the patient medical records, which allows for the calculation of discrepancy rates. The CDC validation process is not an assessment of clinical practice or overall record keeping; however, the results of the validation may be helpful to ART programs. All potential data discrepancies identified during the on-site visit will be discussed with staff of the ART program. Aggregate findings for validated data fields from all ART programs participating in validation will be reported in CDC's annual *ART National Summary Report*.

Each clinic is responsible for maintaining appropriate medical and laboratory records that contain information reported in NASS. This information must be able to link each patient, cycle, oocyte retrieved, transfers, and pregnancy outcomes for the purpose of external validation.

III. Data to be Reported (see attachments C5 and C6)

IV. Published Reports and Data Usage

Since the inception of the National ART Surveillance System, ART data have been used to provide consumers, providers, researchers and the general public with a comprehensive picture of the national ART-related data as well as standardized clinic-specific success rates. In addition, multiple publications in peer-reviewed journals present results of analyses of ART surveillance data to inform the field and clinical practice.

A. Annual ART Reports

The annual reports consist of two components:

1. Fertility Clinic Success Rates Report—this report has 3 major sections:
    a) Commonly asked questions—provides background information and an explanation of the data reporting process.
    b) Fertility clinic tables—displays tabulated results of success rates for all reported ART procedures at individual U.S. fertility clinics.
    c) Appendices—contains a glossary of technical and medical terms used in the report, the names, addresses, and telephone numbers of all reporting clinics and non-reporting clinics, and a list of national consumer organizations offering support to people experiencing infertility.
2. National Summary Report—this report uses pooled data presented as graphs and charts to provide an in-depth picture of the type, number, and outcomes of ART cycles performed in the United States.

As resources allow, additional information may also be published.

B. Data Usage

The CDC retains a copy of each reporting ART program's annual data files. In addition to the annual ART reports, the NASS database is used to evaluate emerging ART research questions and to monitor safety and efficacy issues related to ART treatment for improving maternal and child health outcomes. The NASS does not collect information on long-term outcomes of ART; this information can be obtained by linking ART surveillance data, while protecting patient's confidentiality, with other surveillance systems and registries, such as vital records, hospital discharge data, birth defects registries, cancer registries, and other surveillance systems and registries. These linkages provide a unique opportunity to establish state-based public health surveillance of ART and to study short- and long-term outcomes of ART.

C. Confidentiality and Data Access

ART surveillance data are protected under Assurance of Confidentiality, Section 308(d) of the Public Health Service Act (42 U.S.C. 242m). Starting from 2013, researchers are able to analyze ART surveillance data using the National Center for Health Statistics (NCHS)'s Research Data Centers (RDC) at http://www.cdc.gov/art/AccessData.html under authorization of Sections 304 and 306 of the Public Health Service Act, 42 USC242(k). Researchers requesting access to the linked NASS data files are subject to all RDC procedures and protocols.