

the aggregation and analysis of patient safety events.

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be "delisted" if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of PSOs.

AHRQ has accepted a notification of proposed voluntary relinquishment from Symbria SAFE, a component entity of Symbria Inc., to voluntarily relinquish its status as a PSO. Accordingly, Symbria SAFE, P0146, was delisted effective at 12:00 Midnight ET (2400) on October 31, 2019.

Symbria SAFE has patient safety work product (PSWP) in its possession. The PSO will meet the requirements of section 3.108(c)(2)(i) of the Patient Safety Rule regarding notification to providers that have reported to the PSO and of section 3.108(c)(2)(ii) regarding disposition of PSWP consistent with section 3.108(b)(3). According to section 3.108(b)(3) of the Patient Safety Rule, the PSO has 90 days from the effective date of delisting and revocation to complete the disposition of PSWP that is currently in the PSO's possession.

More information on PSOs can be obtained through AHRQ's PSO website at <http://www.pso.ahrq.gov>.

**Virginia Mackay-Smith,**  
Associate Director.

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**BILLING CODE 4160-90-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Meeting of the National Advisory Council for Healthcare Research and Quality

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), HHS.

**ACTION:** Notice of public meeting.

**SUMMARY:** This notice announces a meeting of the National Advisory Council for Healthcare Research and Quality.

**DATES:** The meeting will be held on Thursday, November 21, 2019, from 8:30 a.m. to 12:00 p.m.

**ADDRESSES:** The meeting will be held at AHRQ, 5600 Fishers Lane, Rockville, Maryland, 20857.

**FOR FURTHER INFORMATION CONTACT:** Jaime Zimmerman, Designated Management Official, at the Agency for Healthcare Research and Quality, 5600 Fishers Lane, Mail Stop 06E37A, Rockville, Maryland 20857, (301) 427-1456. For press-related information, please contact Bruce Seeman at (301) 427-1998 or [Bruce.Seeman@AHRQ.hhs.gov](mailto:Bruce.Seeman@AHRQ.hhs.gov).

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact the Food and Drug Administration (FDA) Office of Equal Employment Opportunity and Diversity Management on (301) 827-4840, no later than Thursday, November 7, 2019. The agenda, roster, and minutes will be available from Ms. Heather Phelps, Committee Management Officer, Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, Maryland 20857. Ms. Phelps' phone number is (301) 427-1128.

#### SUPPLEMENTARY INFORMATION:

##### I. Purpose

In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App., this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality (the Council). The Council is authorized by Section 941 of the Public Health Service Act, 42 U.S.C. 299c. In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director of AHRQ on matters related to AHRQ's conduct of its mission including providing guidance on (A) priorities for health care research, (B) the field of health care research including training needs and

information dissemination on health care quality and (C) the role of the Agency in light of private sector activity and opportunities for public private partnerships. The Council is composed of members of the public, appointed by the Secretary, and Federal ex-officio members specified in the authorizing legislation.

##### II. Agenda

On Thursday, November 21, 2019, the Council meeting will convene at 8:30 a.m., with the call to order by the Council Chair and approval of previous Council summary notes. The meeting is open to the public and will be available via webcast at [www.webconferences.com/ahrq](http://www.webconferences.com/ahrq). The meeting will begin with an update on AHRQ's budget, programs and initiatives. The agenda will also include a discussion about the challenges and opportunities to leverage AHRQ's CDS Connect to improve care and a conversation about the gaps and opportunities for improving care, with a focus on social determinants of health. The meeting will adjourn at 12:00 p.m. The final agenda will be available on the AHRQ website at [www.AHRQ.gov](http://www.AHRQ.gov) no later than Thursday, November 14, 2019.

Dated: October 30, 2019.

**Virginia L. Mackay-Smith,**  
Associate Director.

[FR Doc. 2019-24081 Filed 11-4-19; 8:45 am]

**BILLING CODE 4160-90-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Reporting of Pregnancy Success Rates From Assisted Reproductive Technology (ART) Programs; Clarifications and Corrections

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces clarifications for and correction to certain data collection fields, terminology, and definitions used for reporting of pregnancy success rates from assisted reproductive technology (ART) programs. This reporting is required by the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA).

**DATES:** These clarifications and corrections will be implemented January 1, 2020.

**FOR FURTHER INFORMATION CONTACT:** Jeani Chang, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, MS-C107-2, Atlanta, Georgia 30341. Phone: (770) 488-6355. Email: ARTinfo@cdc.gov.

**SUPPLEMENTARY INFORMATION:** On August 26, 2015, HHS/CDC published a notice in the **Federal Register** (80 FR 51811) announcing the overall reporting requirements of the National ART Surveillance System (NASS). The notice described who shall report to HHS/CDC; the process for reporting by each ART program; the data to be reported; and the contents of the published reports. This current notice, published November 5, 2019, includes clarifications for some variables and definitions to improve quality of data. Corrections were made to align with current terminology. These clarifications and corrections will be helpful by clarifying reporting requirements in certain unique situations and updating terminology to align with current practice. This notice includes the current guidance and definitions that will be implemented starting January 1, 2020.

### Clarifications and Corrections

#### Section II. When and How To Report

##### Section A. Reporting Activities

*Current:* All cycle data must be reported prospectively, *i.e.*, reporting of initial cycle intent and select patient details is required within four days of cycle initiation.

*Clarification (to improve the quality of data by clarifying prospective reporting requirements for natural cycles and frozen cycles; effective January 1, 2020):* All cycle data must be reported prospectively, *i.e.*, reporting of initial cycle intent and select patient details is required: (a) At least one day prior to oocyte retrieval for all natural cycles using fresh embryos created from fresh eggs; (b) at least one day prior to thaw for all frozen oocyte or frozen embryo cycles; and (c) within four days of cycle initiation for all other cycles.

##### Section B. Cycle Information

*Current:* Intended banking type (Embryo banking, autologous oocyte banking, donor oocyte banking).

*Clarification (to differentiate oocyte source for banking cycles; effective January 1, 2020):* Intended banking type

(Embryo banking from autologous oocytes, embryo banking from donor oocytes, autologous oocyte, donor oocyte).

##### Section C. Patient History

*Current:* Number of Prior ART cycles (Fresh & Frozen).

*Clarification (to clarify question applicability; effective January 1, 2020):* Number of Prior ART cycles started with the intent to transfer oocytes or embryos.

##### Section F. Stimulation and Retrieval

*Current:* Date of retrieval.

*Clarification (to clarify the definition for different treatment protocols; effective January 1, 2020):* In general, each retrieval should be reported as its own cycle. This includes egg retrievals for fertility preservation cycles (*e.g.*, for cancer patients). In the case of continuous stimulation or dual stimulation to maximize the number of eggs retrieved in the shortest possible time, the cycle start date for the subsequent retrieval will be the day that stimulation medication was restarted after the trigger was administered for the previous egg retrieval; if the stimulation medication was never stopped, stimulation start will be the day after the previous egg retrieval.

If a patient is having a second egg retrieval due to a “failed trigger” (*i.e.*, patient medication administration error or poor response to the trigger that results in unexpectedly low number of eggs), the second trigger and retrieval date would be used for reporting as part of the first cycle. In this case, the interval between the first and second retrieval should not exceed 2 days. If the interval exceeds 2 days, each retrieval should be entered as its own cycle.

##### Section G. Laboratory Information

*Current:*

Indication for ICSI (Prior failed fertilization, Poor fertilization, PGD or PGS, Abnormal semen parameters, Low oocyte yield, Laboratory routine, Frozen cycle, Rescue ICSI, Other)

PGD (Pre-implantation genetic diagnosis) or screening (PGS)

Reasons for PGD or PGS

Technique used for PGD or PGS

*Correction (to update the terminology for preimplantation genetic testing; effective January 1, 2020):*

Indication for ICSI (Prior failed fertilization, Poor fertilization, PGT, Abnormal semen parameters, Low oocyte yield, Laboratory routine, Frozen cycle, Rescue ICSI, Other)

PGT (Pre-implantation genetic testing)

Reasons for PGT

Technique used for PGT

##### Section H. Transfer Information

*Current:* Endometrial Thickness Prior to Embryo Transfer.

*Clarification (to clarify the timing of measurement; effective January 1, 2020):* Most Recent Endometrial Thickness.

##### Section J. Definitions

*Current:* Cycle start date (cycle initiation date)—

(1) For fresh embryo (both donor and nondonor): The first day that medication to stimulate follicular development is given in a stimulated cycle or the first day of menses in an unstimulated cycle. For example:

a. The first day of gonadotropins in a gonadotropin only cycle or in a long suppression GnRH agonist-gonadotropin cycle;

b. The first day of GnRH agonist in a GnRH agonist flare-gonadotropin cycle;

c. The first day of clomiphene or letrozole in a clomiphene/gonadotropin cycle or a clomiphene only cycle;

d. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.

(2) For fresh embryo donor cycles:

a. The first day exogenous sex steroids are given to patient to prepare the endometrium;

b. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.

(3) For frozen embryo cycles (both donor and non-donor):

a. The first day exogenous sex steroids are given to prepare the endometrium;

b. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.

(4) For oocyte/embryo banking cycles:

a. The first day of gonadotropins in a gonadotropin only cycle or in a long suppression GnRH agonist-gonadotropin cycle;

b. The first day of GnRH agonist in a GnRH agonist flare-gonadotropin cycle;

c. The first day of clomiphene or letrozole in a clomiphene/gonadotropin cycle or a clomiphene only cycle;

d. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.

*Clarification (to clarify the definition for different types of cycles; effective January 1, 2020):* Cycle start date (cycle initiation date)—

(1) For cycles using fresh embryos created from fresh nondonor eggs: The first day that medication to stimulate follicular development is given in a stimulated cycle or the first day of menses in an unstimulated cycle. For example:

a. The first day of gonadotropins in a gonadotropin only cycle or in a long

suppression GnRH agonist-gonadotropin cycle;

b. The first day of GnRH agonist in a GnRH agonist flare-gonadotropin cycle;

c. The first day of clomiphene or letrozole in a clomiphene/gonadotropin cycle or a clomiphene only cycle;

d. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.

(2) For cycles using fresh embryos created from fresh donor eggs:

a. The first day exogenous sex steroids are given to patient to prepare the endometrium;

b. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.

(3) For cycles using frozen eggs or frozen embryos (both donor and non-donor):

a. The first day exogenous sex steroids are given to prepare the endometrium;

b. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.

(4) For oocyte/embryo banking cycles:

a. The first day of gonadotropins in a gonadotropin only cycle or in a long suppression GnRH agonist-gonadotropin cycle;

b. The first day of GnRH agonist in a GnRH agonist flare-gonadotropin cycle;

c. The first day of clomiphene or letrozole in a clomiphene/gonadotropin cycle or a clomiphene only cycle;

d. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.

*Current: Preimplantation genetic diagnosis (PGD)*—Characterization of a cell or cells from preimplanted embryos from IVF cycles to determine the presence or absence of a specific genetic defect.

*Preimplantation genetic screening (PGS)*—Characterization of a cell or cells from preimplanted embryos from IVF cycles to identify genetic abnormalities.

*Correction (to update the terminology; effective January 1, 2020):*

*Preimplantation genetic testing (PGT)*—Testing performed to analyze DNA from oocytes or embryos for determining genetic abnormalities, including aneuploidies (PGT-A), monogenic/single gene defects (PGT-M), and chromosomal structural rearrangements (PGT-SR).

Dated: October 30, 2019.

**Sandra Cashman,**

*Executive Secretary, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Scholarships for Disadvantaged Students, OMB No. 0915-0149—Revision

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR have been provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this Notice has closed.

**DATES:** Comments on this ICR should be received no later than December 5, 2019.

**ADDRESSES:** Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to (202) 395-5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-1984.

#### SUPPLEMENTARY INFORMATION:

*Information Collection Request Title:* Scholarships for Disadvantaged Students Program OMB No. 0915-0149—Revision.

*Abstract:* HRSA seeks to update the Scholarships for Disadvantaged Students (SDS) program-specific form to collect 3 years of student data instead of 1 year of student data from SDS program applicants. This will assist the agency in making funding decisions for SDS program awards. The form will reflect programmatic changes to the SDS program, made after consideration of the comments received in response to the request for public comment, published at 84 FR 23571, which will be finalized in the forthcoming SDS Policy Change **Federal Register** Notice.

*Need and Proposed Use of the Information:* The purpose of the SDS

Program is to make grant awards to eligible schools to provide scholarships to full-time, financially needy students from disadvantaged backgrounds enrolled in health professions programs. To qualify for participation in the SDS program, a school must be carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including students who are members of racial and ethnic minority groups (section 737(d)(1)(B) of the Public Health Service (PHS) Act). To meet this requirement, a school must show that at least 20 percent of the school's full-time enrolled students and graduates are from a disadvantaged background. HRSA previously required schools to demonstrate this percentage by submitting 1 year of data; a school must now provide this data for the most recent 3 year period.<sup>1</sup> The proposed revisions to the SDS program-specific form will require applicants to provide the percentage of full-time enrolled students and graduates from a disadvantaged background over a 3-year period, consistent with this policy change.

An additional change to the SDS program is that a 3 year average, instead of a 1 year average, will be used to calculate priority points, which are provided to eligible schools based on the proportion of graduating students going into primary care, the proportion of underrepresented minority students, and the proportion of graduates working in medically underserved communities (section 737(c) of the PHS Act). The proposed revisions to the SDS program-specific form will require applicants to provide a 3 year average for these percentages, consistent with this policy change, as opposed to the 1 year of data previously required.

*Likely Respondents:* Institutions that apply for SDS program awards.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train

<sup>1</sup> The SDS program will allow an exception for newly established schools; that is, schools that have not been in existence long enough to have three years of enrollment and graduation data. However, these schools will be required to demonstrate that at least 20 percent of the school's full-time students are students from disadvantaged backgrounds, with at least two years of student enrollment, and at least one year of graduation data.