

SAFETY CERTIFICATION IN
OUTPATIENT PRACTICE EXCELLENCE (“SCOPE”) FOR WOMEN’S HEALTH
PARTICIPATION AGREEMENT

This Safety Certification in Outpatient Practice Excellence (“SCOPE”) Participation Agreement is entered into by and between The American Congress of Obstetricians and Gynecologists, with an address at 409 12th Street SW, Washington, DC 20024, (“ACOG”) and [*name of the legal entity that owns the practice*]

_____, with its principal place of business at _____ (the “Client”) (each a “Party” and collectively the “Parties”). This Agreement sets forth the scope of services that ACOG shall perform on behalf of the Client and includes the terms required for a valid Business Associate Agreement under the federal privacy regulations (the “Privacy Rule”) and the federal security regulations (the “Security Rule”) promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), codified at 45 C.F.R. parts 160 and 164. For good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

I. Background

A. SCOPE is a program of the American Congress of Obstetricians and Gynecologists. SCOPE is designed to assess the implementation and use of patient safety concepts and techniques within a physician office in which obstetrics and/or gynecology services are provided. Physician offices that successfully complete the SCOPE process are awarded certification that is valid for three years.

B. The Client operates an obstetrics and gynecology medical practice with an office located at _____ (the Office). The Client wishes for ACOG to conduct an SCOPE review of the Office.

II. The SCOPE Process

A. The SCOPE process will begin with the Client completing an application questionnaire and submitting information and documents as requested by ACOG.

B. ACOG will analyze the Client’s application and determine whether all necessary information has been submitted. If information is missing, ACOG shall inform the Client of what is needed to complete the application.

C. Once the Client has submitted all required information, ACOG shall select a Reviewer who will review the Office for the purpose of validating all information reported by the Client on the application.

D. ACOG shall notify the Office of whether the review will include a site visit. If applicable, ACOG shall coordinate with the Office to arrange for a site visit.

E. After completion of the review, ACOG shall provide the Client with a written assessment of the Office's implementation and use of patient safety concepts and techniques. The written assessment will be based upon current American College of Obstetricians and Gynecologists' (the College) guidelines, other ACOG and College publications, and the considered opinion of the Reviewer in consultation with ACOG and College staff.

F. At the time of the written assessment, ACOG shall notify the Client regarding whether the Office satisfied the criteria for SCOPE certification. If the Office satisfies the criteria for SCOPE certification, ACOG shall provide the Client with a certificate and instructions for maintaining and publicizing its certification, including usage guidelines for displaying the SCOPE Certification Mark (see IX).

G. The review, and the work of the Reviewer, shall be complete when the written assessment is delivered to the Client. The opinions of the Reviewer shall be expressed solely through the final written assessment. The Reviewer shall not explain, interpret, or discuss the written assessment with the Client. The Client shall not contact the Reviewer after receiving the written assessment. Instead, the Client shall direct any questions regarding the assessment to the Director of the SCOPE program within thirty (30) days of receiving the assessment.

III. Fee

In consideration for the services to be provided under this Agreement, the Client shall pay to ACOG a total fee of \$ _____ (the "Fee"). Client shall pay a non-refundable deposit of 25% of the Fee upon signing this Agreement. Client shall pay the balance of the Fee when Client submits its application.

IV. Responsibilities of the Client

A. The Client agrees that it shall provide complete and accurate information to ACOG and the Reviewer. The Client shall not withhold information relevant to the SCOPE process, regardless of whether such information is requested by ACOG or the Reviewer. The Client agrees that its obligations shall continue, and that it shall have an ongoing duty to inform ACOG of any relevant information, until ACOG delivers the written assessment to the Client.

B. The Client agrees that it shall not request or seek to compel ACOG or the Reviewer to testify regarding the review and/or the assessment in connection with any hearing or proceeding. In the event that ACOG, its employees or members, and/or the Reviewer (collectively, the "ACOG Witnesses") are required by law to appear in connection with any legal proceeding arising from, or in any way relating to, the review, the Client shall reimburse each of the ACOG Witnesses for their reasonable travel expenses

and shall provide a reasonable per diem payment for time spent preparing for and attending the proceeding.

C. The Client agrees that it shall not provide any Protected Health Information to ACOG or the Reviewer, except during the site visit portion of the review, if applicable. Under no circumstances shall the Client provide to the Reviewer any medical records of any patient who has threatened or initiated litigation against the Office, Client, or any individual who provides health care in the Office.

D. In order to identify any potential conflicts of interest, ACOG shall provide the Client with the name and curriculum vitae of the Reviewer in advance of the review, and the Client shall inquire with persons who will be subject to the review regarding any prior knowledge of the Reviewer. The Client shall make the name and credentials of the Reviewer available to all physicians, nurses, other health care providers, and office staff in the Office and shall provide them with an opportunity to object to the identity of the Reviewer. This requirement can be satisfied by posting a notice of the upcoming review in an appropriate place, listing the name of the Reviewer, and advising where and until what dates his or her credentials can be reviewed.

E. After satisfying the requirements of Paragraph IV(D), the Client shall execute the Acknowledgement, attached as Exhibit A, stating that it has notified the physicians, nurses, other clinicians, and office staff of the Office of the upcoming SCOPE review and has made available the name and credentials of the Reviewer. The Client shall indicate on the Acknowledgement whether any person raised any objection to the Reviewer. The Client shall return the executed Acknowledgement to ACOG within two weeks of the date that it receives the name and curriculum vitae of the Reviewer.

F. During the Term of this Agreement, the Client shall promptly inform ACOG of any new information or material changes to the Office, its policies, procedures, or personnel, that, if such information had been available to ACOG at the time of the review, might have adversely affected the Office's certification status, including but not limited to (i) sale of the practice, (ii) significant staff turn-over. The Client shall promptly cooperate with any request for additional information by ACOG.

V. REPRESENTATIONS AND WARRANTIES

A. The Client represents and warrants that the person signing this Agreement on behalf of the Client has legal authority to bind the Client.

B. The Client represents and warrants that, to the best of its knowledge or belief, no person has initiated or threatened litigation against the Client or any health care provider relating to or arising from the health care services described in any of the medical records that the Client has or will provide to the Reviewer.

C. The Client represents and warrants that, to the best of its knowledge or belief and as of the date of this Agreement, none of the physicians, nurses, other health care

providers or office staff who work at the Office has initiated litigation, or any other adversarial proceeding, against the Client. The Client agrees that it shall immediately notify ACOG if such litigation or proceeding is threatened or commenced during the term of this Agreement.

D. The Client represents and warrants that it is the copyright holder, or that it has suitable permission from the copyright holder, in the documents that the Client will submit to ACOG as part of the SCOPE process. The Client hereby grants ACOG permission to make sufficient copies of such documents as needed to accomplish the SCOPE review of the Office.

VI. INDEMNIFICATION AND LIMITATION ON LIABILITY

A. The Client, on its own behalf and on behalf of its predecessors, successors, parents, subsidiaries, and affiliates, and each of their respective officers, directors, employees, agents, representatives, and attorneys, agrees to release, indemnify, and hold harmless ACOG, the College, and each of their respective past and present officers, employees, members, volunteers, agents, attorneys, and subcontractors, including but not limited to the Reviewer, from and against any and all claims, actions, damages, judgments, amounts paid in settlement, and expenses (including reasonable attorneys' fees) arising from or in any way related to this SCOPE review, including without limitation, the selection of the Reviewer, the performance of the review, including but not limited to the performance of the site visit if applicable, the written assessment, and/or the award or denial of certification.

B. The Client agrees that ACOG shall not be liable for any indirect, consequential, or incidental damages (including damages for loss of profits, revenue, data, or use) arising out of this Agreement, the SCOPE program, and/or any disclosures of information received or created under this Agreement, whether in a legal action in contract or tort, even if ACOG is on notice of the possibility of such damages. The Client further agrees that ACOG's total liability for damages relating to this Agreement and the SCOPE certification program is limited to an amount equal to the amount of fees actually paid to ACOG by Client under this Agreement.

C. This Section VI shall survive the termination or expiration of this Agreement.

VII. HIPAA and HITECH

Performance of this Agreement may involve Protected Health Information (as defined in below) that is subject to the Privacy Rule and the Security Rule issued pursuant to HIPAA (hereinafter collectively referred to as "HIPAA") and HITECH (as defined below). The purpose of this Section VII is to allow for the Client's and ACOG's compliance with HIPAA and HITECH with respect to this Agreement, if applicable.

A. Definitions

1. Unless otherwise specified in this Section VII, all capitalized terms used in this Section VII not otherwise defined have the meaning established for purposes of HIPAA and HITECH, as each is amended from time to time.
2. "Breach" shall mean the acquisition, access, use or disclosure of PHI in a manner not permitted by the Privacy Rule that compromises the security or privacy of the PHI as defined, and subject to the exceptions set forth, in 45 C.F.R. § 164.402.
3. "Compliance Date" shall mean, in each case, the date by which compliance is required under the referenced provision of HITECH and/or its implementing regulations, as applicable; provided that, in any case for which that date occurs prior to the Effective Date of this Agreement, the Compliance Date shall mean the Effective Date.
4. "Electronic PHI" shall mean Electronic Protected Health Information, as defined in 45 C.F.R. § 160.103, limited to the information received from or created or received on behalf of the Client by ACOG pursuant to performance of the Services.
5. "HITECH" shall mean Subtitle D of the Health Information Technology for Economic and Clinical Health Act provisions of the American Recovery and Reinvestment Act of 2009, 42 U.S.C. §§17921-17954, and any and all references in this Agreement to sections of HITECH shall be deemed to include all associated existing and future implementing regulations, when and as each is effective.
6. "PHI" shall mean Protected Health Information, as defined in 45 C.F.R. § 160.103, limited to the information received from or created or received on behalf of the Client by ACOG pursuant to performance of the Services.
7. "Services" shall mean, to the extent and only to the extent they involve the creation, use or disclosure of PHI, the services provided by ACOG to the Client under this Agreement, as amended by written agreement of the Parties from time to time.

B. Responsibilities Of ACOG. ACOG agrees to:

1. use and/or disclose PHI only as necessary to provide the Services, as permitted or required by this Agreement, and in compliance with each applicable requirement of 45 C.F.R. § 164.504(e) or as otherwise Required by Law;

2. use appropriate safeguards to prevent use or disclosure of PHI other than as permitted or required by this Agreement;
3. without unreasonable delay, report to the Client any use or disclosure of PHI of which it becomes aware that is not permitted or required by this Agreement, in accordance with 45 C.F.R. § 164.504(e)(2)(ii)(C);
4. without unreasonable delay, and in any event no later than sixty (60) calendar days after Discovery, ACOG shall notify the Client of any Breach of Unsecured PHI. The notification shall include, to the extent possible and subsequently as the information becomes available, the identification of all individuals whose Unsecured PHI is reasonably believed by ACOG to have been Breached along with any other available information that is required to be included in the notification to the Individual, the Department of Health and Human Services ("HHS") and/or the media, all in accordance with the data breach notification requirements set forth in 42 U.S.C. § 17932 and 45 C.F.R. Parts 160 & 164 subparts A, D, & E.
5. require all its subcontractors and agents that create, receive, use, disclose or have access to PHI to agree, in writing, to the same restrictions and conditions on the use and/or disclosure of PHI that apply to ACOG under this Section VII;
6. make available its internal practices, books, and records relating to the use and disclosure of PHI to the Secretary of HHS for purposes of determining the Client's compliance with the Privacy Rule;
7. if applicable, within thirty (30) days of receiving a written request from the Client, make available information necessary for the Client to make an accounting of disclosures of PHI about an Individual, in accordance with 45 C.F.R. § 164.528.
8. notwithstanding subsection (7) above, in the event that ACOG in connection with the Services uses or maintains an Electronic Health Record of PHI of or about an Individual, then ACOG shall when and as directed by the Client, make an accounting of disclosures of PHI directly to an Individual within thirty (30) days, in accordance with the requirements for accounting for disclosures made through an Electronic Health Record in 42 U.S.C. 17935(c), as of its Compliance Date.
9. to the extent that the PHI maintained by ACOG constitutes a Designated Record Set, within twenty (20) days of receiving a written request from the Client, make available PHI necessary for the Client to respond to Individuals' Requests for access to PHI about them in accordance with the requirements of 45 C.F.R. § 164.524.

10. notwithstanding subsection (9) above, in the event that ACOG in connection with the Services uses or maintains an Electronic Health Record of PHI of or about an Individual, then ACOG shall provide an electronic copy of the PHI within ten(10) days, to the Client, sufficient to allow the Client to comply with 42 U.S.C. § 17935(e).
11. to the extent that the PHI maintained by ACOG constitutes a Designated Record Set, within fifteen (15) days of receiving a written request from the Client, incorporate any amendments or corrections to the PHI in accordance with 45 C.F.R. § 164.526.
12. request, use and/or disclose only the minimum amount of PHI necessary to accomplish the purpose of the request, use or disclosure; provided, that ACOG shall comply with 42 U.S.C. § 17935(b).
13. not directly or indirectly receive remuneration in exchange for any PHI as prohibited by 42 U.S.C. § 17935(d) as of its Compliance Date.
14. not make or cause to be made any communication about a product or service that is prohibited by 42 U.S.C. § 17936(a).
15. not make or cause to be made any written fundraising communication that is prohibited by 42 U.S.C. § 17936(b).
16. take all necessary steps, at the direction of the Client, to comply with requests by Individuals not to send PHI to a Health Plan in accordance with 42 USC 17935(a).
17. to the extent, and only to the extent, that ACOG receives Electronic PHI pursuant to the Services provided to the Client, ACOG further agrees to:
 - a. implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the Electronic PHI that it creates, receives, maintains, or transmits on behalf of the Client; and comply with the Security Rule requirements set forth in 45 C.F.R. §§ 164.308, 164.310, 164.312, and 164.316.
 - b. without unreasonable delay, report to the Client any Security Incident with respect to Electronic PHI of which ACOG becomes aware in accordance with 45 C.F.R. § 164.314(a)(2)(i)(C).
 - c. provide that all of its subcontractors and agents to whom it provides Electronic PHI agree to implement reasonable and appropriate safeguards to protect such Electronic PHI.

C. Permitted Uses And Disclosures Of PHI. Unless otherwise limited herein, in addition to any other uses and/or disclosures permitted or required by this Agreement or Required by Law, ACOG may:

1. make any and all uses and disclosures of PHI necessary to provide the Services under this Agreement to Client;
2. use the PHI in its possession for its proper management and administration and to fulfill any legal responsibilities of ACOG;
3. disclose the PHI in its possession to a third party for the purpose of ACOG's proper management and administration or to fulfill any legal responsibilities of ACOG; provided, however, that the disclosures are Required by Law or ACOG has received from the third party written assurances that (i) the information will be held confidentially and used or further disclosed only as Required by Law or for the purpose for which it was disclosed to the third party; and (ii) the third party will notify ACOG of any instances of which it becomes aware in which the confidentiality of the information has been breached;
4. perform Data Aggregation for the Health Care Operations of the Client in accordance with the Privacy Rule; and
5. De-identify any and all PHI created or received by ACOG under this Agreement; provided, however, that the de-identification conforms to the requirements of the Privacy Rule. Such resulting de-identified information would not be subject to the terms of Section VII and may be used and disclosed on ACOG's own behalf, all in accordance with the De-identification requirements of the Privacy Rule.

D. Responsibilities Of The Client. The Client agrees:

1. to identify which of the records it furnishes to ACOG it considers to be PHI for purposes of this Agreement.
2. to provide to ACOG only the minimum PHI necessary to accomplish the Services.
3. to obtain any consent, authorization or permission that may be required by the Privacy Rule or applicable federal, state, or local laws and/or regulations prior to furnishing ACOG the PHI pertaining to an individual;
4. to inform ACOG of any PHI that is subject to any arrangements permitted or required of the Client under the Privacy Rule that may materially impact in any manner the use and/or disclosure of PHI by ACOG under this Section

VII, including, but not limited to, restrictions on the use and/or disclosure of PHI as provided for in 45 C.F.R. § 164.522 and agreed to by the Client; and

5. that it shall not provide PHI to ACOG other than to make it available for inspection by ACOG's Reviewer during the site visit portion of the review.

E. Miscellaneous

1. The Parties agree to negotiate to amend this Section VII as necessary to comply with any amendment to any provision of HIPAA or HITECH, which materially alters either Party's or both Parties' obligations under this Section VII.
2. The terms of this Section VII shall be construed in light of any applicable interpretation or guidance on HIPAA and/or the Privacy Rule issued by HHS, the Office of Civil Rights, or the Centers for Medicare & Medicaid Services from time to time. The terms of this Section VII to the extent they are unclear shall be construed to allow for compliance by the Client and ACOG with HIPAA and HITECH.

VIII. CONFIDENTIALITY

ACOG will treat information provided by the Client in connection with the SCOPE program as confidential, and ACOG will disclose such information only as authorized in writing by the Client, except that no written authorization is required for disclosures to ACOG's employees or agents as needed to implement the SCOPE program or as may be required for tax, legal, accounting, regulatory, or other similar purposes. If the Client successfully completes the SCOPE process and receives certification, written authorization shall not be required for ACOG to disclose the Client's receipt of SCOPE certification, such as by including the Office on a list of offices who have received certification that ACOG may publish either in hard copy or on the internet or by responding to oral or written inquiries.

Information about the Client or the Office that is publically available, lawfully in the possession of ACOG without confidentiality restrictions, or that does not identify the Client will not be treated as confidential. The Client acknowledges that ACOG will use reasonable efforts to assert available evidentiary privileges to protect the Client's confidential information in ACOG's possession, but ACOG makes no representations about the applicability of such privileges and cannot guarantee that it will not be forced to disclose such information in legal proceedings.

IX. INTELLECTUAL PROPERTY

This Agreement does not confer on the Client any rights in SCOPE program-related procedures, measures, methods, programs, instruments, tools, technical specifications, scores or data. If the Office attains SCOPE certification, ACOG shall grant to the Client a limited, personal, nonexclusive, nontransferable, and revocable license to use the SCOPE

Certification Mark (the “Mark”) during the Term of this Agreement solely in connection with the SCOPE program and solely in compliance with the usage guidelines that ACOG will provide to Client if the Office achieves certification. A description of the Mark covered by this license and usage guidelines to which the Client must adhere as a condition of this license will be made available to the Client when the Office achieves certification status. ACOG may modify the usage guidelines from time to time with notice to the Client. The Client shall ensure that its affiliated physicians, employees, and other agents and representatives abide by the usage guidelines.

ACOG retains ownership of the Mark and may amend or modify the Mark at any time. ACOG will notify the Client of any such amendment or modification.

This Agreement does not confer on the Client any right to any trademark or service mark belonging to the American Congress of Obstetricians and Gynecologists or the American College of Obstetricians and Gynecologists other than the Scope Certification Mark identified in the usage guidelines.

X. TERM AND TERMINATION

A. This Agreement will become effective upon the date of execution by the last party to sign below (the “Effective Date”).

B. This Agreement shall terminate immediately, without any further action by the Parties,

- i. Thirty (30) days after ACOG notifies the Office of its failure to achieve certification status; or
- ii. Three (3) years after ACOG notifies the Office that it has been awarded SCOPE certification.

C. ACOG may terminate this Agreement if:

- i. Client fails to correct a material breach of this Agreement to ACOG’s satisfaction within thirty (30) days of ACOG sending a written notification to Client of the breach;
- ii. ACOG learns of new information or a material change related to the Office which, had the change occurred before certification was awarded, would have disqualified the Office from obtaining certification and Client has not corrected or otherwise responded to ACOG’s satisfaction within thirty (30) days of receiving notice from ACOG of its intent to terminate this Agreement under this provision.
- iii. ACOG, in its sole discretion, terminates the SCOPE certification program

D. If either Party knows of a pattern of activity or practice of the other Party that constitutes a material breach or violation of Section VII then the non-breaching Party shall provide written notice of the breach or violation to the other Party that specifies the nature of the breach or violation. The breaching Party must cure the breach or end the violation on or before thirty (30) days after receipt of the written notice. In the absence

of a cure reasonably satisfactory to the non-breaching Party within the specified timeframe, or in the event the breach is reasonably incapable of cure, then the non-breaching Party may do the following:

1. if feasible, terminate this Agreement; or
2. if termination of this Agreement is infeasible, report the issue to HHS.

E. **Effect of Termination or Expiration.** Within sixty (60) days of the termination or expiration of this Agreement, ACOG agrees to return or destroy all PHI, including such information in possession of ACOG's subcontractors, if feasible to do so. If return or destruction of said PHI is not feasible, ACOG agrees to extend any and all protections, limitations and restrictions contained in Section VII to ACOG's use and/or disclosure of any PHI retained after the termination or expiration of this Agreement, and to limit any further uses and/or disclosures to the purposes that make return or destruction of the PHI infeasible. The Client agrees to comply with its obligations under Section VII(D) with respect to any PHI retained by ACOG after the termination or expiration of this Agreement. This Paragraph VIII(D) shall survive any termination or expiration of this Agreement.

XI. GENERAL PROVISIONS

A. **Representatives, Successors, and Assigns.** The provisions of this Agreement shall be binding upon, and shall inure to the benefit of, the parties hereto and each of their respective representatives, successors, and assigns.

B. **No Third Party Beneficiaries.** Nothing in this Agreement, including Section VII, shall confer upon any person other than the parties and their respective representatives, successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.

C. **Governing Law.** The terms of this Agreement shall be construed and interpreted under the laws of the District of Columbia without regard to conflict of law principles. All claims, actions, proceedings, and disputes arising out of this Agreement shall be adjudicated exclusively in the courts located in the District of Columbia and the Client hereby consents to personal jurisdiction and venue in the District of Columbia.

D. **Independent Contractors.** The Parties acknowledge and agree that their relationship to each other is that of independent contractors, and neither Party shall have the authority to legally bind the other to any obligations outside of this Agreement. Nothing in this Agreement shall constitute or be construed as creating any employer/employee relationship, a partnership or a joint venture between the Client and ACOG.

E. **No Warranty.** ACOG makes no guarantees or warranties of any kind, express, implied, or statutory, relating to or arising in any way out of this Agreement or the SCOPE program. This disclaimer of warranties includes, but is not limited to, the fact

that ACOG does not guarantee any benefits or results to the Client from its participation in the SCOPE program or from any use of the Marks as permitted by this Agreement. ACOG SPECIFICALLY DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

F. Entire Agreement. This Agreement, and all Exhibits and Attachments hereto, contains the full understanding of the parties hereto and supersedes any prior offers, negotiations, or agreements, written or oral. No waiver, alteration, or modification of any of the provisions hereof shall be binding unless it is in writing and signed by both parties. No waiver of any provision of this Agreement shall be deemed, or shall constitute, a waiver of any other provision of this Agreement

G. Survival. Sections VI, VIII, XI, and Paragraph X(E) and any other provisions that by their terms are intended to survive, shall survive termination of this Agreement.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be duly executed in its name and on its behalf.

The Client

The American Congress of Obstetricians and Gynecologists

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

EXHIBIT A

ACKNOWLEDGEMENT

_____ (the "Client"), hereby acknowledges that, through appropriate mechanisms, the Client has notified the physicians, nurses, other health care providers, and office staff in the Client's Office located at _____ of the upcoming review by the SCOPE program of the American Congress of Obstetricians and Gynecologists. The Client has made the name and credentials of the Reviewer available to the physicians, nurses, other healthcare providers, and office staff of the Office. The Client states that none of these individuals objected to the Reviewer, except as listed below:

(if none, write "none" below)

_____.

The undersigned is duly authorized to execute this Acknowledgment on behalf of the Client.

By: _____

Signature

Date

Name

Title