Reproductive endocrinology and infertility

Background

Reproductive endocrinology and infertility (REI) is a subspecialty of obstetrics and gynecology (OB/GYN). Reproductive endocrinologists are OB/GYNs who are capable of managing complex problems relating to REI, according to the American Board of Obstetrics and Gynecology (ABOG). These physicians have the advanced education, research, and professional skills in REI to treat reproductive disorders that affect children, men, and women of all ages.

To become a reproductive endocrinologist, a physician must first complete the medical education and training requirements necessary to practice OB/GYN. Then, he or she must complete additional fellowship training in reproductive endocrinology.

REI fellowship programs are a minimum of three years in duration, with a minimum of 18 months for research and didactic efforts and a minimum of 12 months in clinical REI. The remaining six months may be tailored to electives or focused in a specific clinical or research area at the discretion of the training program director.

While there are other practitioners who request REI privileges, this paper focuses on physicians who have completed residency training in REI. For additional information, see Clinical Privilege White Paper, Obstetrics and gynecology—Practice area 147.

Involved specialties

Reproductive endocrinologists, obstetricians, and gynecologists

Positions of specialty boards

ABOG

According to the ABOG’s General and Specific Requirements for Graduate Medical Education in the Subspecialty Area of Reproductive Endocrinology and Infertility, a fellowship program must ensure the individual is able to manage complex endocrine problems related to the function of the reproductive system and to select and conduct appropriate therapies for the infertile couple. The individual also is expected to:

➤ Understand endocrine assay methodology and the principles of molecular biology
➤ Be skilled in laboratory techniques, clinical research design, and statistical analysis
➤ Be proficient in the clinical diagnosis and surgical management of structural problems related to fertility and developmental abnormalities of the reproductive tract, as well as contemporary techniques involved in assisted reproductive technology
➤ Be capable of continued research endeavors and of preparation of research grants

Also, a fellowship program in REI must be developed along the following guidelines to ensure a clinical and research experience consistent with the educational objectives of the Guide to Learning in Reproductive Endocrinology and Infertility. The apportionment of time must be constructed to achieve the following major objectives:
➤ **Clinical**: Experience in the management of a wide variety of clinical problems affecting the development, function, and aging of the human reproductive system. This experience should include disorders related to both men and women.
➤ **Medical and surgical**: Adequate and diverse medical and surgical experience related to infertility and reproductive disorders (including management of ovulation defects and techniques of assisted reproduction, which must include an adequate number of procedures and success rate), contraception, aging, and the surgical management of acquired and developmental abnormalities of the reproductive tract.
➤ **Techniques and limitations**: Knowledge of the techniques and limitations of the diagnostic, surgical, and laboratory procedures used in clinical REI.

A fellowship program in REI must be a minimum of 36 months in length. Each program must include:
➤ Eighteen months of block time for research/didactics (it is preferable that research blocks not be fragmented, and a sequential 12-month block is recommended)
➤ Twelve months of clinical REI
➤ Six months of electives, which may be focused on a specific clinical and/or research area at the discretion of the program director

In regard to curriculum, the ABOG requires a fellowship program to include basic science education. The basic science aspect of REI is of great importance and must include the study of:
➤ Anatomy
➤ Biochemistry
➤ Pathology
➤ Physiology
➤ Molecular biology
➤ Cell biology
➤ Experimental design
➤ Statistics
Training in specialized surgical techniques must include, but not be limited to:
➤ Endoscopy
➤ Microsurgery
➤ Oocyte retrieval
➤ Embryo transfer

Direct hands-on experience with transvaginal ultrasound imaging techniques is considered to be an integral part of the training experience. A fellow must have direct experience in the interpretation of all imaging.

In order to develop an appreciation for the scope and limitations of laboratory techniques, a fellow must become familiar with the relevant laboratory procedures in REI. He or she should acquire a thorough understanding of the theory and special methodology utilized to perform:
➤ Hormonal assays
➤ Tissue culture techniques
➤ Receptor assays
➤ Molecular biological procedures
➤ Chromosomal analyses
➤ Gamete manipulation
➤ Embryo culture and cryopreservation

Following the completion of training, candidates for certification must successfully pass written and oral examinations. All certified physicians are also required to enroll in the ABOG’s maintenance of certification (MOC) program and complete the required MOC activities each year to maintain certification.

**AOBOG**

The American Osteopathic Board of Obstetrics and Gynecology (AOBOG) administers all examinations for certification and recertification in OB/GYN and its subspecialties. According to the AOBOG, physicians must maintain membership in good standing of the American Osteopathic Association (AOA) or the Canadian Osteopathic Association for a continuous period of two years immediately prior to the date of certification. Upon the successful completion of examination requirements, the AOBOG submits a recommendation for a physician’s certification, including a complete and accurate medical training profile, to the AOA. The AOBOG does not publish guidelines for requirements, but instead directs candidates to the AOA’s certification requirements.

**Positions of societies, academies, colleges, and associations**

**SREI**

The Society of Reproductive Endocrinology and Infertility (SREI) does not publish specific guidelines on the requirements for a subspecialty in REI.
To become eligible for membership in the SREI, an individual must complete training in OB/GYN followed by an REI fellowship. Both programs must be approved by the ABOG.

**ASRM**

The American Society for Reproductive Medicine (ASRM) is a multidisciplinary organization dedicated to the advancement of the art, science, and practice of reproductive medicine. The ASRM does not publish guidelines for the delineation of privileges in REI, but offers its members guidelines, statements, and opinions about clinical practice in REI.

**AOA**

According to the AOA’s *Basic Standards for Fellowship Training in Reproductive Endocrinology and Infertility*, graduate educational programs in REI must be developed consistent with the educational objectives of the AOBOG’s *Guide to Learning in Reproductive Endocrinology & Infertility*. The fellow must have completed an AOA-approved residency in OB/GYN.

All REI fellowship programs must be 36 months in duration. A minimum of 18 months is required for research/didactic efforts, and a minimum of 12 months is required in clinical REI. The remaining six months may be tailored to electives or be focused in a specific clinical or research area at the discretion of the program director.

The program must ensure the fellow obtains:

- Diverse medical and surgical experience related to infertility and reproductive disorders (including management of ovulation defects and techniques of assisted reproduction, which must include an adequate number of procedures and success rate), contraception, aging, and the surgical management of acquired and developmental abnormalities of the reproductive tract
- Training in specialized surgical techniques, which must include endoscopy, microsurgery, oocyte retrieval, and embryo transfer as a prerequisite to the development and enhancement of surgical skills
- Direct hands-on experience with transvaginal ultrasound imaging techniques
- Direct experience in the interpretation of all imaging procedures and histological material available from the surgical specimens

The program must also allow candidates to achieve five major objectives:

1. Experience in the management of clinical problems affecting the development, function, and aging of the human reproductive system, including disorders related to men and women
2. Diverse medical and surgical experience related to infertility and reproductive disorders, including management of ovulation defects and techniques of assisted reproduction, contraception, aging, and the surgical management of acquired and developmental abnormalities of the reproductive tract
3. Knowledge of the techniques and limitations of diagnostic, surgical, and laboratory procedures utilized in clinical REI
4. A research experience centered on an intensive specific area of investigation that will provide a thesis for the fellow and also stimulate future independent study
5. Osteopathic philosophy, principles, and practices as they relate to REI

According to the *Guide to Learning in Reproductive Endocrinology & Infertility*, its statements are intended to identify the minimal acceptable level of achievement and should not be interpreted as describing the ideal or setting upper limits on learning and achievement. The guide mandates knowledge and specific requirements in the following areas:

- Mechanisms of hormone action
- Clinical pharmacology of hormones
- Pathology
- Immunology
- Embryology
- Genetics
- Endocrinology of pregnancy
- Laboratory capability
- Statistics
- Clinical diagnostic techniques
- Neuroendocrine function and disease states
- Ovarian function and disease states
- Thyroid function and disease states
- Adrenal function and disease states
- Androgen disorders
- Abnormal uterine bleeding
- Amenorrhea
- Puberty
- Female infertility
- Male infertility
- Recurrent abortion
- Psychological and sexual implications of reproductive disease
- Surgical techniques
- Techniques of assisted reproduction
- Physiology and endocrinology of the climacteric contraception

**ACGME**

The Accreditation Council for Graduate Medical Education (ACGME) only provides program requirements for a fellowship in reproductive endocrinology for the pediatric population; however, according to the *ACGME Program Requirements for Graduate Medical Education in Obstetrics and Gynecology*, the resident must develop measurable competencies as specified in the educational curriculum written and provided by the program for each resident. This education must include REI.
CMS

CMS has no formal position concerning the delineation of privileges for REI. However, the CMS Conditions of Participation (CoP) define a requirement for a criteria-based privileging process in §482.22(c)(6) stating, “The bylaws must include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.”

§482.12(a)(6) states, “The governing body must assure that the medical staff bylaws describe the privileging process. The process articulated in the bylaws, rules or regulations must include criteria for determining the privileges that may be granted to individual practitioners and a procedure for applying the criteria to individual practitioners that considers:
➤ Individual character
➤ Individual competence
➤ Individual training
➤ Individual experience
➤ Individual judgment

The governing body must ensure that the hospital’s bylaws governing medical staff membership or the granting of privileges apply equally to all practitioners in each professional category of practitioners.”

Specific privileges must reflect activities that the majority of practitioners in that category can perform competently and that the hospital can support. Privileges are not granted for tasks, procedures, or activities that are not conducted within the hospital, regardless of the practitioner’s ability to perform them.

Each practitioner must be individually evaluated for requested privileges. It cannot be assumed that every practitioner can perform every task, activity, or privilege specific to a specialty, nor can it be assumed that the practitioner should be automatically granted the full range of privileges. The individual practitioner’s ability to perform each task, activity, or privilege must be individually assessed.

CMS also requires that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

CMS’ CoPs include the need for a periodic appraisal of practitioners appointed to the medical staff/granted medical staff privileges (§482.22[a][1]). In the absence of a state law that establishes a time frame for the periodic appraisal, CMS recommends that an appraisal be conducted at least every 24 months. The purpose of the periodic appraisal is to determine whether clinical privileges or membership should be continued, discontinued, revised, or otherwise changed.
The Joint Commission

The Joint Commission has no formal position concerning the delineation of privileges for REI. However, in its Comprehensive Accreditation Manual for Hospitals, The Joint Commission states, “The hospital collects information regarding each practitioner’s current license status, training, experience, competence, and ability to perform the requested privilege” (MS.06.01.03).

In the introduction for MS.06.01.03, The Joint Commission states that there must be a reliable and consistent system in place to process applications and verify credentials. The organized medical staff must then review and evaluate the data collected. The resultant privilege recommendations to the governing body are based on the assessment of the data.

The Joint Commission introduces MS.06.01.05 by stating, “The organized medical staff is responsible for planning and implementing a privileging process.” It goes on to state that this process typically includes:

- Developing and approving a procedures list
- Processing the application
- Evaluating applicant-specific information
- Submitting recommendations to the governing body for applicant-specific delineated privileges
- Notifying the applicant, relevant personnel, and, as required by law, external entities of the privileging decision
- Monitoring the use of privileges and quality-of-care issues

MS.06.01.05 further states, “The decision to grant or deny a privilege(s) and/or to renew an existing privilege(s) is an objective, evidence-based process.”

The EPs for standard MS.06.01.05 include several requirements as follows:

- The need for all licensed independent practitioners who provide care, treatment, and services to have a current license, certification, or registration, as required by law and regulation
- Established criteria as recommended by the organized medical staff and approved by the governing body with specific evaluation of current licensure and/or certification, specific relevant training, evidence of physical ability, professional practice review data from the applicant’s current organization, peer and/or faculty recommendation, and a review of the practitioner’s performance within the hospital (for renewal of privileges)
- Consistent application of criteria
- A clearly defined (documented) procedure for processing clinical privilege requests that is approved by the organized medical staff
- Documentation and confirmation of the applicant’s statement that no health problems exist that would affect his or her ability to perform privileges requested
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➤ A query of the NPDB for initial privileges, renewal of privileges, and when a new privilege is requested
➤ Written peer recommendations that address the practitioner’s current medical/clinical knowledge, technical and clinical skills, clinical judgment, interpersonal skills, communication skills, and professionalism
➤ A list of specific challenges or concerns that the organized medical staff must evaluate prior to recommending privileges (MS.06.01.05, EP 9)
➤ A process to determine whether there is sufficient clinical performance information to make a decision related to privileges
➤ A decision (action) on the completed application for privileges that occurs within the time period specified in the organization’s medical staff bylaws
➤ Information regarding any changes to practitioners’ clinical privileges, updated as they occur

The Joint Commission further states, “The organized medical staff reviews and analyzes information regarding each requesting practitioner’s current licensure status, training, experience, current competence, and ability to perform the requested privilege” (MS.06.01.07).

In the EPs for standard MS.06.01.07, The Joint Commission states that the information review and analysis process is clearly defined and that the decision process must be timely. The organization, based on recommendations by the organized medical staff and approval by the governing body, develops criteria that will be considered in the decision to grant, limit, or deny a request for privileges. The criteria must be consistently applied and directly relate to the quality of care, treatment, and services. Ultimately, the governing body or delegated governing body has the final authority for granting, renewing, or denying clinical privileges. Privileges may not be granted for a period beyond two years.

Criteria that determine a practitioner’s ability to provide patient care, treatment, and services within the scope of the privilege(s) requested are consistently evaluated.

The Joint Commission further states, “Ongoing professional practice evaluation information is factored into the decision to maintain existing privilege(s), to revise existing privileges, or to revoke an existing privilege prior to or at the time of renewal” (MS.08.01.03).

In the EPs for MS.08.01.03, The Joint Commission says there is a clearly defined process facilitating the evaluation of each practitioner’s professional practice, in which the type of information collected is determined by individual departments and approved by the organized medical staff. Information resulting from the ongoing professional practice evaluation is used to determine whether to continue, limit, or revoke any existing privilege.
HFAP

The Healthcare Facilities Accreditation Program (HFAP) has no formal position concerning the delineation of privileges for REI. The bylaws must include the criteria for determining the privileges to be granted to the individual practitioners and the procedure for applying the criteria to individuals requesting privileges (03.01.09). Privileges are granted based on the medical staff’s review of an individual practitioner’s qualifications and its recommendation regarding that individual practitioner to the governing body.

It is also required that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

Privileges must be granted within the capabilities of the facility. For example, if an organization is not capable of performing open-heart surgery, no physician should be granted that privilege.

In the explanation for standard 03.01.13 related to membership selection criteria, HFAP states, “Basic criteria listed in the bylaws, or the credentials manual, include the items listed in this standard. (Emphasis is placed on training and competence in the requested privileges.)”

The bylaws also define the mechanisms by which the clinical departments, if applicable, or the medical staff as a whole establish criteria for specific privilege delineation.

Periodic appraisals of the suitability for membership and clinical privileges is required to determine whether the individual practitioner’s clinical privileges should be approved, continued, discontinued, revised, or otherwise changed (03.00.04). The appraisals are to be conducted at least every 24 months.

The medical staff is accountable to the governing body for the quality of medical care provided, and quality assessment and performance improvement (03.02.01) information must be used in the process of evaluating and acting on re-privileg ing and reappointment requests from members and other credentialed staff.

DNV

DNV has no formal position concerning the delineation of privileges for REI. MS.12 Standard Requirement (SR) #1 states, “The medical staff bylaws shall include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to those individuals that request privileges.”

The governing body shall ensure that under no circumstances is medical staff membership or professional privileges in the organization dependent solely upon certification, fellowship, or membership in a specialty body or society.
Regarding the Medical Staff Standards related to Clinical Privileges (MS.12), DNV requires specific provisions within the medical staff bylaws for:

➤ The consideration of automatic suspension of clinical privileges in the following circumstances: revocation/restriction of licensure; revocation, suspension, or probation of a DEA license; failure to maintain professional liability insurance as specified; and noncompliance with written medical record delinquency/deficiency requirements

➤ Immediate and automatic suspension of clinical privileges due to the termination or revocation of the practitioner’s Medicare/Medicaid status

➤ Fair hearing and appeal

The Interpretive Guidelines also state that core privileges for general surgery and surgical subspecialties are acceptable as long as the core is properly defined.

DNV also requires a mechanism (outlined in the bylaws) to ensure that all individuals provide services only within the scope of privileges granted (MS.12, SR.4).

Clinical privileges (and appointments or reappointments) are for a period as defined by state law or, if permitted by state law, not to exceed three years (MS.12, SR.2).

Individual practitioner performance data must be measured, utilized, and evaluated as a part of the decision-making for appointment and reappointment. Although not specifically stated, this would apply to the individual practitioner’s respective delineation of privilege requests.

**CRC draft criteria**

The following draft criteria are intended to serve solely as a starting point for the development of an institution’s policy regarding REI. The core privileges and accompanying procedure list are not meant to be all-encompassing. They define the types of activities, procedures, and privileges that the majority of practitioners in this specialty perform. Additionally, it cannot be expected or required that practitioners perform every procedure listed. Instruct practitioners that they may strikethrough or delete any procedures they do not wish to request.

**Minimum threshold criteria for requesting privileges in REI:**

**Basic education:** MD or DO

**Minimal formal training:** To be eligible to apply for privileges in REI, the applicant must successfully complete an ACGME- or AOA-accredited residency in OB/GYN, plus an ABOG- or AOA-approved fellowship in reproductive endocrinology, and/or demonstrate current subspecialty certification or active participation in the examination process (with achievement of certification within [n]
years) leading to subspecialty certification in reproductive endocrinology by the ABOG or a completion of a certificate of special qualifications in reproductive endocrinology from the AOBOG.

**Required current experience:** At least [n] reproductive endocrinology procedures, reflective of the scope of privileges requested, in the past 12 months, or successful completion of an ACGME- or AOA-accredited residency or clinical fellowship within the past 12 months.

**References**

If the applicant is recently trained, a letter of reference should come from the director of the applicant’s training program. Alternatively, a letter of reference may come from the applicable department chair and/or clinical service chief at the facility where the applicant most recently practiced.

**Core privileges in REI**

Core privileges for REI include the ability to admit, evaluate, diagnose, treat, and provide inpatient or outpatient consultation to adolescent and adult patients with problems of fertility. Privileges may also include providing care to patients in the intensive care setting in conformance with unit policies, as well as the ability to assess, stabilize, and determine the disposition of patients with emergent conditions consistent with medical staff policy regarding emergency and consultative call services. The core privileges in this specialty include the procedures on the following list and such other procedures that are extensions of the same techniques and skills:

- Performance of history and physical exam
- Fertility restoration, including laparoscopy and laparotomy techniques used to reverse sterilization
- Diagnostic and therapeutic techniques, including hysterosalpingography, sonohysterography, tubal canalization, and endoscopy (laparoscopy and hysteroscopy)
- Infertility surgery, including all techniques used for reconstruction of uterine anomalies, myomectomies, resection of uterine synechiae, cervical cerclage, tuboplasty, resection of pelvic adhesions, ovarian cystectomies, staging and treating endometriosis, including pre- and postoperative medical adjunctive therapy
- Surgical treatment of developmental disorders, including all techniques used for neovaginal construction (dilatation and surgical methods), correction of imperforate hymen, removal of vaginal and uterine septae, and correction of müllerian abnormalities
- Surgical treatment of ambiguous genitalia, including construction of unambiguous, functional female external genitalia and vagina (e.g., vaginoplasty, clitoral reduction, exteriorization of the vagina, feminizing genitoplasty, and techniques for prophylactic gonadectomy)
Non-core privileges in REI

Non-core privileges in REI may be requested individually in addition to the core privileges. These privileges may include:

➤ Use of laser
➤ Use of robotic-assisted system for gynecologic procedures (hysterectomy, salpingo-oophorectomy, and microsurgical fallopian tube reanastomosis)
➤ Transcervical sterilization
➤ Administration of sedation and analgesia

Reappointment

Reappointment should be based on unbiased, objective results of care according to a hospital’s quality assurance mechanism. To be eligible to renew privileges in REI, the applicant must demonstrate current competence and an adequate volume of experience ([n] reproductive endocrinology procedures) with acceptable results, reflective of the scope of privileges requested, for the past 24 months based on results of ongoing professional practice evaluation and outcomes. Evidence of current physical and mental ability to perform privileges requested is required of all applicants for renewal of privileges. In addition, continuing education related to REI should be required.

For more information

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