

Starting a practice in Allergy & Immunology: what do I need?

Construindo o consultório do Alergista e Imunologista: o que é preciso?

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ABSTRACT

What do I need to start a practice in Allergy & Immunology? This has been a frequent concern for young specialists, one that often goes unanswered. The Statute, Regulations, and Standards Committee of the Brazilian Association of Allergy and Immunology (CERN-ASBAI) proposes the publication of a series of articles to provide guidance on the essential steps for establishing good practices in the clinical care of allergic patients.

Keywords: Allergology, immunology, good practices.

RESUMO

O que é preciso para abrir o consultório do especialista em Alergia e Imunologia? Esta é uma preocupação frequente dos jovens especialistas, que muitas vezes fica sem resposta. A Comissão de Estatuto, Regulamentos e Normas da Associação Brasileira de Alergia e Imunologia (CERN-ASBAI) propõe a publicação de uma série de artigos com o objetivo de orientar sobre os passos essenciais para o estabelecimento de boas práticas no atendimento clínico de pacientes alérgicos.

Descritores: Alergia, imunologia, boas práticas.

Introduction

The Statute, Regulations and Standards Committee of Brazilian Association of Allergy and Immunology (Comissão de Estatuto, Regulamento e Normas da Associação Brasileira de Alergia e Imunologia - CERN-ASBAI) presents a practical guide on how to structure the practice of an Allergy and Immunology specialist, based mainly on the regulations of the Brazilian Federal Board of Medicine (Conselho Federal de Medicina - CFM), including updates to the rules for supervising physicians' practices, 1 which are already in force. Other precepts deriving from ASBAI own Statutes and those of other medical organizations,

such as the Brazilian Medical Association (Associação Médica Brasileira - AMB), and the Brazilian Health Regulatory Agency (Agência de Vigilância Sanitária - ANVISA), and other Brazilian public bodies.¹⁻³

CFM Resolution No. 2.214/18 asserts that the enforcement department acts through its regional offices (Conselhos Regionais de Medicina/CRMs) through official acts, but also at the behest of society and the Public Prosecutor's Office (Ministério Público - MP). This enforcement department has the fundamental task of standardizing quality health care for the population. According to current regulations,

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medical practices and clinics have been categorized into three groups based on complexity of care and procedures they provide, 1 as follows.

- Group 1: practices or facilities where primary health care is provided with no procedures, local anesthesia, or sedation.
- Group 2: practices where consultations and basic allergic tests (prick and patch tests) are performed.
- Group 3: practices or facilities where local anesthesia without sedation, desensitization, and provocation tests are performed.

It should be emphasized, however, that after graduating from medical school and, as a rule, then qualifying through the AMB/scientific entities representing specialties or medical residency/Ministry of Education (Ministério da Educação - MEC),5 doctors are repeatedly unaware of the legal and ethical rules necessary for perfectly executing their professional practice.

As a result, physicians are likely to comply with a variety of directives, fees, and regulations from time to time, both from the CFM,1 through CRMs, and from ANVISA² in every state, thus requiring prior knowledge on the part of the physician in order to meet their demands.

Opening and running an allergist and immunologist's practice

"What would be necessary, regarding legal requirements, to open a medical office?"

Official documentation

It should be noted that in the private health care sector, when physicians' practice in a locality, they are required to have an official operating license, which is mandatory for this purpose. This documentation is made up of registrations with the various public bodies specified below.^{2,6}

- Local operating license (ALF): Local administration.
- Local health surveillance license (may vary according to state regulations): Local administration.
- Environmental license; Fire department permit (ACVB): Local fire department.
- National registry of health facilities (CNES)4: Local or state health secretariat.

Self-employed registration: Local administration.

Taxes/Individuals

Physicians should be aware of taxes such as tax on services of any kind (ISS or ISSQN), levied monthly by the local government, the National Social Security Institute (Instituto Nacional do Seguro Social - INSS), paid monthly, and the Individual Income Tax (Imposto de Renda de Pessoa Física - IRPF) or Carnê Leão, which must be paid monthly and represents the equivalent of income tax for earnings that the taxpayer (physician) receives from individuals/private patients.

Taxes/Legal entities

If the practice is a legal entity,3-5 it can apply for federal tax through the Simples Nacional system, which is a type of tax regime based on a unified payment of taxes: Programa de Integração Social (PIS), Contribuição para o Financiamento da Seguridade Social (COFINS), Imposto sobre a Renda das Pessoas Jurídicas (IRPJ), Contribuição Social sobre o Lucro Líquido (CSLL), and ISS, also a monthly payment.

Specialist Registration/RQE

Individuals

It is essential for physicians to be registered in a particular speciality to have their RQE (Specialist Registration) - a legally binding document that certifies medical training in a speciality with the CRM.7 An RQE in Allergy and Immunology provides primacy in the care of immunoallergic diseases of the pediatric and adult population, and can be obtained through successful completion of the annual qualifying examination held by the ASBAI/AMB.5

Practice/Directorate in the speciality of Allergy and *Immunology*

For specialized immunoallergic disease practice, in addition to availability of a technical/clinical director, an RQE in Allergy and Immunology is mandatory.8 Therefore, it is recommended that ASBAI specialist members, in order to strengthen their speciality in Allergy and Immunology, when practicing as a legal entity, avoid assisting as a director in any activities that are not directly linked to the practice, thus ensuring that their work is ethical, in accordance with ASBAI statutory regulations.9

Management of allergenic extracts in the allergist and immunologist's practice

The indication, guidance, supervision and interpretation of skin tests with allergens (prick test and patch test), and the prescription, planning, and supervision of the application of subcutaneous or sublingual allergen-specific immunotherapy, are exclusive medical practices.10

The CFM and CRMs, the AMB, and the Brazilian National Medical Residency Commission (Comissão Nacional de Residência Médica - CNRM), through Resolution CNRM No. 12/2019, recognize that the handling of allergenic extracts is the usual practice of trained doctors, especially those qualified in Allergy and Immunology, and therefore establish that allergists and immunologists are the best prepared to handle them. 10-14

In practices of groups 2 and 3, the CFM recognizes that the conditions of the place used to perform immediate (prick) and delayed (contact) allergic tests, dilution of allergenic extracts, and application of subcutaneous allergen-specific immunotherapy, provocation tests and desensitization with medicines and food are Allergy and Immunology practices. 10

It should be mentioned that the journal Arquivos de Asma, Alergia e Imunologia (Archives of Asthma, Allergy and Immunology) has recently reported on the need for quality certification for prick tests in order to safeguard the health of allergic patients and guarantee the quality of the service provided to professionals.15

Fee-for-service earned for allergists' and immunologists' practice

When itemizing a receipt or invoice for a procedure performed in the practice, for example, handling/ applying allergenic extracts, it must be stated, in accordance with CFM Resolution No. 2.215/2018, that the specialist is being paid a fee for planning and/or following up on the handling of these allergens.8

Informed consent form

In recent years there has been a significant increase in legal proceedings in the health system in general, including the medical sector. The importance of the Informed Consent Form in favor of medical ethics for patients has therefore arisen.

The CFM considers that the informed consent form consists of the decision-making, agreement, and

approval of the patient or their surrogate, following adequate information and explanations, under the responsibility of the physician, regarding the diagnostic or therapeutic procedures recommended for the patient.

As such, allergists and immunologists should consider an informed consent form, included in the annex to CFM Recommendation No. 1/2016,16 for procedures performed in their practices, thus demonstrating zealousness in their practices, and significantly improving standards in the services provided to their patients.

No obligation to hire health care personnel for speciality practice in medical practices and clinics

Medical practices and clinics are not required to hire other health care personnel to supervise physician aides in the professional practice of allergists and immunologists.

The CFM has even ruled that medical practices and other medical facilities are not subject to the rules of the Brazilian Board of Nursing (Conselho de Enfermagem), which apply their regulations only to nursing professionals, whereas CRMs are responsible for supervising medical services within their jurisdiction.¹⁷

Advertising your speciality

The speciality of Allergy and Immunology is often advertised on stamps, prescriptions, signs, and other advertisements with various names, for example: Allergology, Clinical Allergy, Allergy and Immunopathologist, Clinical Immunologist, and Allergoimmunologist. The CFM recognizes this speciality as Allergy and Immunology, in accordance with CFM Resolution No. 1.092/1983.

It is important to note that the name of the scientific organization is determined in the statutes as the Brazilian Association of Allergy and Immunology (Associação Brasileira de Alergia e Imunologia), and is included as part of ASBAI's assets. Thus, standardizing the name of the speciality in practices will certainly strengthen Brazilian Allergy and Immunology equally, and given that the speciality has its own particularities in terms of care for all age groups, ASBAI advocates advertising in practices, in addition to other advertisements of any kind, as shown below.²⁵

NONONONO NONONONO, M.D. ALLERGY AND IMMUNOLOGY - RQE 123 CHILDREN AND ADULTS **CRM-UF 1234**

Allergist and Immunologist's scope of practice, according to age group in practices

In accordance with CFM Resolution No. 1.627/2001, allergists and immunologists are not, nor can they be, a fragment of a specialist who specializes in a fraction of human immune systems, but rather qualified doctors who are able to act with greater resourcefulness and capacity in allergic and immunological pathologies in all age groups. As such, the speciality is not limited to a certain age group, as acknowledged in ASBAI's own Articles of Incorporation in Article 5, item 9, AMB Secretariat Official Letter No. 123/2021, endorsed by the Brazilian Society of Pediatrics (Sociedade Brasileira de Pediatria) and also in the Diário Oficial da União (D.O.U., Federal Official Gazette) of December 3, 2018, section 1, page 231, which states that "for the exclusive care of pediatric patients, clinical responsibility is to be held by a physician with an RQE in Allergy and Immunology or an RQE in Pediatric Allergy and Immunology."

As such, there is no legal restriction on health insurance companies limiting allergists and immunologists to practice in their practices.

Follow-up appointments, according to CFM Resolution No. 1.958/2010

Appointments consist of anamnesis (interview about the patient's history and, if applicable, the disease), physical examination, drawing up diagnostic hypotheses or conclusions, requesting complementary tests (when necessary) and therapeutic prescription, and it is the doctor's prerogative to set deadlines for follow-up appointments.

In the case of tests whose results cannot be analyzed during the appointment, the medical practice will be continued at a follow-up appointment, and no additional fees should be charged.

However, if there are changes in signs or symptoms that require a new anamnesis, physical examination, formulation of diagnostic hypotheses or conclusions, and therapeutic prescription, the medical practice will be considered a new appointment and should be remunerated.

In cases of illnesses that require prolonged treatment, with follow-up examinations and therapeutic modifications, appointments may be charged for at the physician's discretion. It is also up to physicians to set follow-up appointments.

The time needed to examine the patient and their tests is determined by technical and medical criteria. rather than administratively.

Health insurance providers cannot interfere in the autonomy of the physician or in their relationship with the patient, nor can they set an interval between appointments. These institutions' technical directors will be held ethically responsible if they fail to comply with the provisions of this resolution.²²

How to proceed when a patient is referred from another medical practitioner

According to the Code of Medical Ethics, the doctor in his practice "cannot fail to refer a patient who has been sent for a specialized procedure back to the treating doctor and, immediately afterwards, provide them with the appropriate information about what happened during the period in which they were responsible for the patient.".23

Thus, when a patient is referred to an allergist and immunologist, they should always seek the patient's benefit and, ethically speaking, they should provide feedback to the referral doctor by means of appropriate documentation, providing information on their practice.

Allergists and immunologists and professional advertising

It is increasingly important to communicate well with people and it is no different in medicine. In order for allergists and immunologists to disseminate information correctly and ethically in their practices, it is important to be aware of the rules of medical advertising and to keep up to date with the specific regulations on this subject, avoiding abuses that could lead to ethical and disciplinary proceedings.²⁵

Each CRM has its own Commission for the Dissemination of Medical Matters (Comissão de Divulgação de Assuntos Médicos - CODAME), which is responsible for guidance, education, and supervision of physicians on issues related to advertising in their medical practice.

This body verifies whether the physician is (through posts on social media or other means of communication, such as interviews) practicing breaches of confidentiality, undue exposure of the patient's image, promising results, unfair competition, sensationalism, among others.

Requirements for each type of practice, depending on the level of medical procedures inherent to the speciality

The requirements for establishing an Allergy and Immunology medical practice are different due to the definitions set out in the CFM classifications, although they also safeguard the privacy and confidentiality guaranteed in all instances. Within these definitions, they have been categorized into the following types of medical practice, namely Group 1, Group 2, and Group 3.1,20

Group 1

These are practices or facilities where basic medicine is practiced with no procedures, local anesthesia, or sedation.

In practice, they are intended for medical appointments with no procedures or immunotherapy.

According to the Manual Soma SUS of the Ministry of Health, all the items listed below that are not optional are deemed essential and should be included in the practice.

Furniture

- Two chairs or armchairs one for the patient and one for their carer.
- A chair or armchair for the physician and a table/ desk.
- A simple padded stretcher, covered in waterproof material.
- A two- or three-step ladder for patient access to the stretcher.

If the practice has medicines subject to special control

 A lockable storage area for medicines subject to special control (essential; Ordinance MS/SVS 344/1998 art. 67).

Clinical materials

- Paper towels.
- Liquid soap for hygiene.

- Pedal garbage cans.
- Disposable sheets for stretchers.
- A sphygmomanometer.
- A clinical stethoscope
- A clinical thermometer.
- A flashlight with batteries.
- Disposable tongue depressors.
- Disposable gloves.
- A negatoscope or other digital medium that enables image reading.
- An otoscope (optional).
- An anthropometric scale suitable for each age group (optional).
- An inelastic flexible plastic tape measure (optional).
- An ophthalmoscope (optional).
- A reflex hammer for neurological examination (optional).
- Peak expiratory flow meter (optional).
- Oximeter.
- Nasal speculum.
- A sink or toilet (recommended by CENR-ASBAI) with a clinical hospital tap.
- Gel or spray sanitizer.
- Derma alcohol.

Group 2

These are practices or facilities where procedures are performed with no local anesthesia or sedation.

For these services, in addition to the equipment listed in the basic practice (see Group 1) for propedeutics, equipment for therapeutic procedures is also required.

These are practices where appointments and basic allergic tests (prick and patch tests)¹ are performed, and should meet the requirements below.

If the practice has medicines subject to special control1

- A lockable storage area for medicines subject to special control (essential; Ordinance MS/SVS 344/1998 art. 67).
- All the items contained in Group 1, plus material for asepsis/sterilization in accordance with sanitary standards and a rigid container for the disposal of sharps.

Whether immediate reading skin tests (Prick test) or contact tests (Patch test) are performed1

- Room tiled or covered in a waterproof material (epoxy or ceramic).
- Cold floor for easy cleaning.
- A sink or toilet (recommended by CENR-ASBAI) with a clinical hospital tap.
- A refrigerator with a minimum and maximum thermometer for exclusively storing tests and vaccines (antigens registered with ANVISA).
- Countertop and cabinets with straight lines to facilitate cleaning.

Immunotherapy with antigens (inhalants and/or insects)1

- Room tiled or covered in a waterproof material (epoxy or ceramic).
- Cold floor for easy cleaning.
- A sink or toilet with a clinical hospital tap, as recommended by CENR-ASBAI.
- A refrigerator with a minimum and maximum thermometer for exclusively storing tests and vaccines (antigens registered with ANVISA).
- Countertop and cabinets with straight lines to facilitate cleaning.

Medicines available1

- Adrenaline (Epinephrine 1:1000 1 mg/mL).
- Antihistamines for parenteral use (Diphenhydramine) or Promethazine).
- Short-acting β2-agonist bronchodilators spray with spacer (e.g. Sabutamol 100 µg). Salbutamol solution for nebulization or flaconettes (1.25 mg/ mL) and nebulizer is recommended by CENR-ASBAI.
- Glucocorticoid for parenteral use (Hydrocortisone or Methylprednisolone).
- H2 antihistamine for parenteral use (Ranitidine).
- Prednisolone (1 mL/3 mg).
- Second generation oral antihistamine.

Group 3

These are practices where, in addition to the procedures listed in groups 1 and 2, immunotherapy, desensitization, provocation tests, and intradermal allergic tests are performed.1

The materials described below are those required for Group 3, in addition to the materials mentioned in the previous groups.

- Allergenic extracts registered with ANVISA.
- Material for minor surgery (optional).
- Material for dressings/stitches removal (optional)
- Material for local anesthesia (optional).
- Material for asepsis/sterilization in accordance with sanitary standards.
- A rigid container for the disposal of sharps.

Safety requirements for emergency care¹

- Within the doctor's practice or referred for appropriate care for any problems within 4 minutes.
- CERN-ASBAI recommends to take the ASBAI Advanced Life Support in Anaphylaxis and Asthma Course (AALS) for training in the appropriate medications and materials that can be used in the event of complications. We should bear in mind what is laid down in the Code of Medical Ethics: Physicians are not allowed to (...) "Art. 2 Delegate to other practitioners acts or attributions that are exclusive to the medical practice.".

Intradermal testing¹

- Room tiled or covered in a waterproof material (epoxy or ceramic).
- Cold floor for easy cleaning.
- A sink or toilet with a clinical hospital tap, as recommended by CENR-ASBAI.
- A refrigerator with a minimum and maximum thermometer for exclusively storing tests and vaccines concentrates.
- Allergenic extracts registered with ANVISA.
- Countertop.
- Cabinets with straight lines to facilitate cleaning.

Provocation and desensitization tests1

- Room tiled or covered in a waterproof material (epoxy or ceramic).
- Cold floor for easy cleaning.
- A sink or toilet with a clinical hospital tap, as recommended by CENR-ASBAI.
- A refrigerator with a minimum and maximum thermometer for exclusively storing tests and vaccines.

- Antigens registered with ANVISA.
- Countertop and cabinets with straight lines to facilitate cleaning.

Medicines available, according to MS/GM Ordinance No. 2048/02, annex, item 1.31

- Adrenaline (Epinephrine 1:1000 1 mg/mL). Antihistamines for parenteral use (Diphenhydramine or Promethazine).
- Short-acting β2-agonist bronchodilators spray with spacer (Salbutamol 100 µg).
- Salbutamol (solution for nebulization) or flaconettes (1.25 mg/mL) and nebulizer (recommended by CERN-ASBAI).
- Glucagon (recommended by CERN-ASBAI).
- Glucocorticoid for parenteral use (Hydrocortisone or Methylprednisolone).
- Prednisolone (1 mL/3 mg).
- H2 antihistamine for parenteral use (Ranitidine): see note on discontinuation of this drug by ANVISA.
- Oropharyngeal cannulas (Guedel).
- Automatic External Defibrillator (AED).
- Medicines for cardiopulmonary arrest and anaphylaxis.
- Distilled water (ampoule or floconet).
- Diazepam.
- Dipyrone or another option if the patient has a hypersensitivity reaction to it.
- Glucose 50% and Glucose 5% (recommended by CERN-ASBAI).
- Physiological saline 0.9%.
- Lactacto Ringer's Saline Solution (recommended) by CERN-ASBAI).
- Oxygen supply (fixed or cylinder) with applicator mask and humidifier (essential).
- Pulse oximeter.
- Manual self-inflating balloon ventilator with reservoir and mask (essential).
- Syringes, needles and equipment for intravenous application (essential).
- Needle scalpel.
- Butterfly and intracath (with all the material for insertion).
- Gauze.

- Cotton wool.
- Crepe bandages.
- Disposable gloves.
- Rigid collection box for sharps.

Conclusion

Hence, with a view to guiding and standardizing the services provided by the Allergy and Immunology specialty, while also providing adjustments for those existing practices, this initial publication has sought to provide technical information in the light of the requirements of the supervisory bodies for professional practice, while also providing a structure for the operation of each practice classification group, guaranteeing safety for the practice of the specialty in its ethical and scientific dimension.

It also reinforces, among the various particularities of practice, that applying allergic extracts registered with ANVISA is the usual activity of the Allergist and Immunologist, recognized by the main medical entities involved in medicine, and that the specialty's practice is not fragmented and therefore has no restrictions on care by age group, thus enhancing its job market.

Finally, the guidelines described in this guide will certainly serve to answer many of the specialty's questions, in view of the care that is desired and appropriate for the environment of the Allergist and Immunologist specialist and, consequently, for patient safety.

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