



A practical guide to Allergy and Immunology practice. Starting an Allergy and Immunology practice – Part 1: What do I need?

Guia prático da especialidade em Alergia e Imunologia.

Construindo o consultório do Alergista e Imunologista – Parte 1: o que é preciso?

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ABSTRACT

What do I need to start an Allergy and Immunology practice? This is a common concern among young specialists, yet it 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 aimed at providing guidance on the essential steps for establishing good practices in the clinical care of allergic patients.

Keywords: Allergy, immunology, practice guidelines.

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 questionamento de boas práticas no atendimento clínico de pacientes alérgicos.

Descritores: Alergia, imunologia, guia de prática clínica.

Introduction

The Statute, Regulations, and Standards Committee of the Brazilian Association of Allergy and Immunology (CERN-ASBAI) has developed a practical guide on how to start an Allergy and Immunology practice. This guide is primarily based on the regulations of the Brazilian Federal Board of Medicine (Conselho Federal de Medicina, CFM) and includes updated rules for the inspection of medical offices,¹ which are already in effect. Additionally, several other principles of the ASBAI bylaws, as well as of organizations more

directly involved with medicine – such as the Brazilian Medical Association (AMB), the National Sanitary Surveillance Agency (Anvisa), and other Brazilian public bodies¹⁻³ – should be observed.

According to CFM Resolution 2214/18, medical office inspections are conducted by the Inspection Departments of Regional Medical Boards (Conselhos Regionais de Medicina, CRMs), either *ex officio* or in response to complaints from the public or the Public Prosecutor's Office. The Inspection Department

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plays a crucial role in regulating the quality of health care provided to the population. Under the updated regulation, medical offices and clinics are categorized into three groups based on the complexity and type of services and procedures they perform,¹ as described below.

- *Group 1:* Medical offices or services limited to providing basic care only – general procedures and those requiring local anesthesia or sedation are not permitted.
- *Group 2:* Medical offices authorized to perform consultations and simple allergy tests, such as the skin prick test and patch test.
- *Group 3:* Medical offices or services equipped to perform procedures that involve local anesthesia (without sedation), as well as desensitization and provocation tests with antigens.

After completing medical school and typically receiving training through the AMB/medical specialty societies or Medical Residency programs accredited by the Ministry of Education,⁴ physicians often remain unaware of certain legal and ethical standards necessary for the adequate execution of their professional activities in private practices.

As a result, they may be caught off guard by different guidelines, fees, and inspections that periodically arise from both the CFM¹ – through the CRMs – and Anvisa² in each state. Therefore, having prior knowledge of these requirements is essential for physicians to respond adequately and effectively to such demands.

Opening and operating an Allergy and Immunology practice

A common question often arises: “What are the essential legal requirements established by regulatory bodies for opening and operating a private practice?”.

Public documentation

In private practice, a physician who performs professional activities in a specific location must hold an active business license, which is mandatory documentation for this purpose. This documentation consists of different permits issued by several government agencies, as specified below.^{2,5}

- Location and operating license: Issued by the Municipal Government.

- Health permit (may vary according to the rules of each state): Issued by the Municipal Government.
- Environmental license and Fire Department operational permit: Issued by the Municipal Fire Department.
- National Registry of Health Establishments⁶: Issued by the Municipal or State Health Department.
- Self-Employed Registration: Issued by the Municipal Government.

Taxes – Individual

There are specific taxes that physicians must be aware of, including the 1) Municipal Service Tax (Imposto Sobre Serviços, ISS), paid annually; 2) contribution to social security (Instituto Nacional do Seguro Social, INSS), paid monthly; and the 3) Individual Income Tax (Imposto de Renda de Pessoa Física, IRPF), paid monthly. The IRPF corresponds to the income tax originating from earnings received directly from individuals/private patients.

Taxes – Legal entity

If the medical office is registered as a legal entity (company),^{3,4,6} it may opt for the “Simples Nacional,” a simplified taxation system. It includes the following monthly taxes: 1) Social Integration Program (Programa de Integração Social, PIS); 2) Contribution to Social Security Financing (Contribuição para o Financiamento da Seguridade Social, COFINS); Company Income Tax (Imposto sobre a Renda das Pessoas Jurídicas, IRPJ); Social Contribution on Profits (Contribuição Social sobre o Lucro Líquido, CSLL); and the ISS.

Board certification

Individual

Board certification is the process by which physicians demonstrate their expertise in a specific medical specialty. In Brazil, this certification is a legal requirement issued by the CRMs.⁷ Physicians board-certified in Allergy and Immunology are granted the authority to treat both adults and children with immune disorders and allergic diseases. To obtain the specialist title, physicians must successfully complete and pass an examination process, which is conducted annually by ASBAI in collaboration with the AMB.⁴

Technical Supervisor/Director in Allergy and Immunology

Specialized services that provide care for allergic diseases must not only have a designated Technical or Clinical Director, but it is also mandatory that this individual be board-certified in Allergy and Immunology.⁸ Therefore, it is recommended that ASBAI-certified specialists, when operating as legal entities, avoid acting as directors in services not directly linked to their specialty. This preserves the integrity of the profession and ensures their actions adhere to the ethical principles outlined in ASBAI's bylaws.⁹

Handling allergen extracts in the medical office

The indication, guidance, supervision, and interpretation of skin tests with allergens (such as the skin prick test and patch test), as well as the prescription, planning, and supervision of allergen-specific immunotherapy – whether subcutaneous or sublingual – are acts restricted to licensed physicians.¹⁰

The CFM, its regional branches (the CRMs), the AMB, and the National Medical Residency Committee (CNRM), through CNRM Resolution 12/2019, acknowledge that handling allergen extracts is a common and standard practice for trained physicians, particularly those specialized in Allergy and Immunology. Therefore, the allergist/immunologist is considered the most qualified professional to handle such materials and administer immunotherapy.¹⁰⁻¹⁴

The CFM recognizes that the conditions established for Group 2 and Group 3 offices are appropriate for the performance of immediate-reading (prick) and delayed-reading (patch) allergy tests, dilution of allergen extracts, and administration of subcutaneous allergen-specific immunotherapy. These offices are also suitable for performing provocation tests and desensitization with medications and food, specifically within the scope of Allergy and Immunology.¹⁰

Of note, the *Arquivos de Asma, Alergia e Imunologia* (AAAI), a scientific journal published by ASBAI, recently published a letter highlighting the need for proficiency testing for the performance of skin prick tests. This requirement aims to protect the health of allergic patients and ensure that professionals maintain a high standard of care.¹³

Professional fees charged for activities performed in the medical office

When issuing a receipt or invoice for a procedure performed in the medical office, such as the handling/application of allergen extracts, it is necessary to specify that the fees correspond to the planning and/or monitoring associated with the administration of allergen-specific immunotherapy, as outlined in CFM Resolution 2215/2018.

Informed consent

In recent years, there has been a significant increase in lawsuits in the health care sector, including those related to medical malpractice. This underscores the importance of the Informed Consent Form as a fundamental component of ethical and legally sound medical practice. According to the CFM, informed consent is a decision-making process in which the patient, or their legal representative, freely agrees to and authorizes the proposed diagnostic or therapeutic procedures after receiving all necessary information and explanations, under the physician's responsibility. Therefore, physicians should provide and obtain the Informed Consent Form (available as an attachment to CFM Recommendation 1/2016¹⁴) when performing procedures in their office. This practice demonstrates ethical diligence and significantly contributes to the quality and safety of patient care.

Hiring additional health care professionals

Allergy and Immunology clinics and private practices are not obligated to hire additional health care professionals to supervise the physician assistant during procedures.

In fact, the CFM has determined that medical offices and other medical services in general are not subject to the regulations of the Nursing Board. The scope of these regulations applies only to nursing professionals. Conversely, it is the CFM's responsibility to oversee and regulate registered medical services.¹⁵

On the specialty's title

Several terms are commonly used to refer to the specialty of Allergy and Immunology on stamps, prescription forms, office signs, and other materials. Some of these include Allergology, Clinical Allergy, Allergy and Immunopathology, and Clinical

Immunology. However, according to CFM Resolution 1092/1983, the specialty is officially recognized in Brazil under the title “Allergy and Immunology.”

It is important to note that the name of the scientific association – Brazilian Association of Allergy and Immunology – is defined in its bylaws and regarded as one of the institution’s core assets. Therefore, to help strengthen and unify the identity of the specialty in Brazil, ASBAI encourages the standardized use of the title “Allergy and Immunology” across all professional materials, including office signs and any form of public or professional advertising. This is especially important given the specialty’s broad scope of care, which encompasses patients of all age groups. An example of this standardization is provided in Figure 1.¹⁹

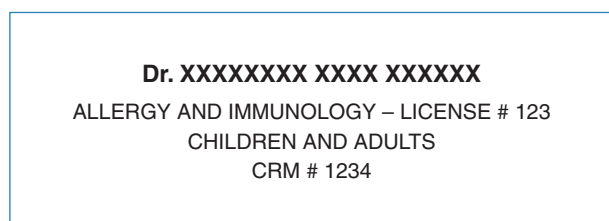


Figure 1

Standardization of the specialty's title in medical offices and other advertisements

Scope of practice in medical offices according to age group

According to CFM Resolution 1627/2001, Allergy and Immunology is not, and cannot be, a fragmented specialty restricted to only part of the human immune system. Specialists in this area are fully trained physicians qualified to manage allergic and immune disorders across all age groups. Therefore, the specialty is not restricted by age group, as recognized in Article 5, item 9, of ASBAI's bylaws; in Official Letter 123/2021 from the AMB Secretariat, supported by the Brazilian Society of Pediatrics; and in CFM Resolution 2215/2018, published in the Federal Official Gazette of Brazil on December 3, 2018 (Section 1, page 231). The latter states that when care is provided exclusively to pediatric patients, technical responsibility must be assumed by a physician board-certified in Allergy and Immunology or in Pediatric Allergy and Immunology.

There is no legal justification for health insurance providers to limit the practice of allergists/immunologists based on patient age.

Return appointments (per CFM Resolution 1958/2010)

During a consultation, the physician obtains the patient's medical history (focusing on specific conditions when applicable), performs a physical examination, formulates diagnostic hypotheses or conclusions, requests additional tests if necessary, and provides a therapeutic prescription. It is the physician's prerogative to determine the appropriate timeline for follow-up appointments.

If test results cannot be reviewed during the initial visit, a follow-up appointment should be scheduled and considered a continuation of the original consultation. In such cases, no additional fees should be charged.

However, if the patient presents with new symptoms or signs that require the physician to retake the medical history, perform a new physical exam, or develop a new diagnostic evaluation or treatment plan, the consultation is considered a new appointment and should be charged accordingly.

In cases of patients requiring long-term treatment, including reassessments and therapeutic adjustments, consultations may be charged at the physician's discretion. The follow-up schedule is also determined exclusively by the physician.

The time needed to evaluate the patient and interpret test results is determined solely by medical and technical criteria, not administrative ones.

Health insurance providers are not permitted to interfere with the physician's autonomy or the patient-physician relationship, nor can they impose mandatory intervals between consultations. If these regulations are violated, the technical directors of such institutions will be held ethically accountable, in accordance with CFM Resolution 1958/2010.²⁰

How to proceed when receiving a patient referred from another physician

According to the Medical Code of Ethics, a physician “must not fail to refer the patient who was sent for a specialized procedure back to the attending physician, and must also provide appropriate information regarding the care provided during the period for which they were responsible.”²¹

Thus, with the patient's best interest in mind, the allergist/immunologist, when receiving a patient referred from another physician, should act in accordance with ethical standards by providing a report to the referring physician. This should be done through appropriate documentation that clearly describes the actions taken.

Professional advertising

Clear communication is increasingly important in modern society – and medicine is no exception. To ensure that accurate and ethically sound information is shared in their practice, physicians must comply with medical advertising regulations and stay up to date with the specific rules governing public communication in health care. Compliance with these standards helps prevent ethical violations and potential disciplinary actions.²²

Each CRM has a Commission for the Dissemination of Medical Information (*Comissão de Divulgação de Assuntos Médicos*, CODAME), which is responsible for guiding, educating, and overseeing physicians on matters related to professional advertising.

This body evaluates whether physicians – through social media posts or other communication channels such as interviews – are engaging in actions that violate patient confidentiality, inappropriately expose patient images, promise specific outcomes, engage in unfair competition, sensationalism, or other unethical practices.

Requirements for each type of office according to type of medical procedure

The requirements for establishing an Allergy and Immunology practice vary according to the classifications set by the CFM. Regardless of classification, patient privacy and confidentiality must be upheld in all circumstances. Offices are categorized into three groups based on the complexity of services provided: Group 1, Group 2, and Group 3.^{1,20}

Group 1

Group 1 refers to medical offices or services limited to providing basic care only – general procedures and those requiring local anesthesia or sedation are not permitted. These offices are designated for consultations only and cannot administer immunotherapy or other medical interventions.

According to the SomaSUS Manual from the Brazilian Ministry of Health, the following items (unless explicitly marked as optional) are deemed essential and must be present in the office to meet regulatory and clinical standards.

Furniture:

- Two chairs or armchairs – one for the patient and one for the accompanying person.
- One chair or armchair for the physician and one desk.
- One simple cushioned examination table with a waterproof cover.
- One two- or three-step stool to assist patients in accessing the examination table.

If the office stores controlled substances:

- A locked storage area (mandatory; Ministry of Health Ordinance MS/SVS 344/1998, Article 67).

Clinical materials:

- Paper towels.
- Liquid soap for hand hygiene.
- Pedal bins.
- Disposable sheets for the examination table.
- One sphygmomanometer.
- One clinical stethoscope.
- One clinical thermometer.
- One battery-powered flashlight.
- Disposable tongue depressors.
- Disposable gloves.
- One X-ray viewer (negatoscope) or a digital alternative.
- One otoscope (optional).
- One anthropometric scale suitable for the patient's age (optional).
- One flexible, non-stretch plastic measuring tape (optional).
- One ophthalmoscope (optional).
- One reflex hammer (optional).
- Peak flow meter (optional).
- Pulse oximeter.
- Nasal speculum.
- One sink or washbasin (with a hospital faucet as recommended by CERN-ASBAI).

- Hand sanitizer (gel or spray).
- Derma alcohol.

Group 2

Group 2 refers to medical offices or services that can perform procedures that do not require local anesthesia or sedation. In addition to the basic diagnostic equipment listed for Group 1, these offices must also be equipped with the necessary tools for performing therapeutic procedures.

These are offices where consultations and simple allergy tests, such as the skin prick test and patch test, are performed.¹ They must comply with the following requirements:

If the office stores controlled substances¹:

- A locked storage area (mandatory; Ministry of Health Ordinance MS/SVS 344/1998, Article 67).
- All items listed for Group 1 offices, as well as materials for asepsis and sterilization in accordance with sanitary regulations and a rigid container for the disposal of sharps and cutting instruments.

If allergy skin tests are performed, including for both immediate (eg, skin prick test) and delayed (eg, patch tests) reactions¹:

- A room with walls covered in tile or other impermeable material (e.g., epoxy or ceramic finishes).
- Cold floor to facilitate cleaning.
- Sink or washbasin (with hospital faucet as recommended by CERN-ASBAI).
- Refrigerator with a minimum/maximum thermometer, exclusively for storing tests and vaccines (antigens registered with Anvisa).
- Straight counters and cabinets to facilitate cleaning.

If allergen immunotherapy is administered (inhalants and/or insects)¹:

- A room with walls covered in tile or other impermeable material (e.g., epoxy or ceramic finishes).
- Cold floor to facilitate cleaning.
- Sink or washbasin (with hospital faucet as recommended by CERN-ASBAI).
- Refrigerator with a minimum/maximum thermometer, exclusively for storing allergen

extracts for skin allergy tests and immunotherapy, registered with Anvisa.

- Straight counters and cabinets to facilitate cleaning.

Medications¹:

- Adrenaline (epinephrine) 1 mg/mL (1:1000).
- Parenteral antihistamines (diphenhydramine or promethazine).
- Short-acting β_2 -agonists bronchodilators, inhalation aerosol with a spacer (eg, salbutamol 100 μ g); (CERN-ASBAI recommendation: salbutamol nebulizer solution or unit dose vials [1.25 mg/mL] and a nebulizer).
- Parenteral glucocorticoids (hydrocortisone or methylprednisolone).
- Parenteral H2 antihistamines (ranitidine).
- Prednisolone (1 mL/3 mg).
- Second-generation oral antihistamines.

Group 3

Group 3 refers to medical offices authorized to administer immunotherapy and perform desensitization, provocation, and intradermal allergy tests, in addition to all procedures permitted for Groups 1 and 2.¹

In addition to all equipment listed for Groups 1 and 2, the following materials are also required:

- Allergen extracts registered with Anvisa.
- Materials for minor surgical procedures (optional).
- Materials for dressings/stitch removal (optional).
- Materials for local anesthesia (optional).
- Materials for asepsis/sterilization in accordance with sanitary regulations.
- Rigid container for the disposal of sharps and cutting materials.

Safety requirements for treating complications¹:

- Emergency care must be provided in the medical office or through referral to an appropriate service within 4 minutes.
- CERN-ASBAI recommends taking the Advanced Life Support in Anaphylaxis and Asthma course by ASBAI, for proper training on the medications and materials to be used in case of complications.

As outlined in the Medical Code of Ethics: It is forbidden for a physician to (...) “Article 2 – Delegate to other providers acts or duties restricted to the medical profession.”

If intradermal allergy tests are performed¹:

- A room with walls covered in tile or other impermeable material (eg, epoxy or ceramic finishes).
- Cold floor to facilitate cleaning.
- Sink or washbasin (with hospital faucet as recommended by CERN-ASBAI).
- Refrigerator with a minimum/maximum thermometer, exclusively for storing tests and vaccine concentrates.
- Allergen extracts registered with Anvisa.
- Counter.
- Straight cabinets to facilitate cleaning.

If desensitization and provocation tests are performed¹:

- A room with walls covered in tile or other impermeable material (eg, epoxy or ceramic finishes).
- Cold floor to facilitate cleaning.
- Refrigerator with a minimum/maximum thermometer, exclusively for storing tests and vaccines.
- Antigen registered with Anvisa.
- Straight counters and cabinets to facilitate cleaning.

Medications (per Ministry of Health Ordinance MS/GM 2048/02, Annex, Item 1.31)¹:

- Adrenaline (epinephrine) 1 mg/mL (1:1000).
- Parenteral antihistamines (diphenhydramine or promethazine).
- Short-acting β_2 -agonist bronchodilators (salbutamol 100 μ g) with spacer.
- Salbutamol solution for nebulization or unit-dose vials (1.25 mg/mL) and nebulizer (CERN-ASBAI recommendation).
- Glucagon (CERN-ASBAI recommendation).
- Parenteral glucocorticoids (hydrocortisone or methylprednisolone).
- Prednisolone (1 mL/3 mg).

- Parenteral H2 antihistamines (ranitidine – note: see Anvisa notice on discontinuation of this medication).
- Oropharyngeal airways (Guedel).
- Automated external defibrillator.
- Medications for cardiac arrest and anaphylaxis management.
- Distilled water (ampoule or vial).
- Diazepam.
- Dipyrone, or alternative if the patient is allergic.
- 50% and 5% dextrose (CERN-ASBAI recommendation).
- 0.9% saline solution.
- Lactated Ringer's solution (CERN-ASBAI recommendation).
- Oxygen supply (fixed or portable cylinder) with applicator mask and humidifier (essential).
- Pulse oximeter.
- Manual resuscitator (self-inflating bag) with reservoir and mask (essential).
- Syringes, needles, and IV infusion sets (essential).
- Scalp vein set.
- Butterfly needles and intravenous cannulas, with all insertion materials.
- Gauze.
- Cotton pads.
- Crepe bandages.
- Disposable gloves.
- Rigid container for the disposal of sharps and cutting materials.

Conclusion

With the objective of guiding and standardizing the practice of Allergy and Immunology, while also facilitating adaptations in existing medical offices, this initial publication seeks to provide technical guidance according to the requirements of regulatory authorities for the ethical and professional practice of the specialty. It presents a structured operational framework for each classification group of medical offices, thereby promoting a model of care that is safe, ethical, and grounded in scientific principles.

This guide underscores that the use of allergen extracts registered with Anvisa is a routine and recognized practice within the specialty, endorsed

by leading medical institutions. Furthermore, it reaffirms that the scope of Allergy and Immunology is comprehensive, not fragmented, and not limited by patient age group, thereby increasing the specialty's reach and relevance across the continuum of care.

Finally, the recommendations presented in this guide are intended to address common questions within the field and to support the delivery of high-quality, standardized care in the practice of Allergy and Immunology. By doing so, this guide aims to foster greater safety, uphold ethical standards, and increase patient confidence in all clinical settings dedicated to the specialty.

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