

FUNDAÇÃO FACULDADE DE MEDICINA

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PURCHASING AND CONTRACTING REGULATION OF FUNDAÇÃO FACULDADE DE MEDICINA (FFM)

The President Director of Fundação Faculdade de Medicina (FFM), Fundação de Apoio ao Ensino, Pesquisa, Assistência e Inovação do Hospital das Clínicas da Faculdade de Medicina de São Paulo and Faculdade de Medicina da USP, a private, non-profit entity, governed by the rules of Civil Law, Federal Law No. 10.406, of 01/10/2002, recognized as a State and Municipal Public Utility entity, qualified under the terms of State Complementary Law No. 846 of 06/04/1998 and Municipal Law No. 14.270, of 12/12/2018, as a Social Health Organization, in the use of its legal powers, and with the approval of the Board of Trustees, in a session of 10/27/2022, ratified with amendments at the session of 11/23/2022, establishes this Regulation for contracting purchases, works, leases, disposals, assignments, and services of any nature, of mandatory observance within the scope of the Foundation.

CHAPTER I – GENERAL PROVISIONS

Art. 1. The purpose of this Regulation is to establish rules, routines, and criteria to be observed by FFM in the acquisition of goods of any nature and contracting of works and services. It is intended to select the most advantageous proposal, through the objective judgment of the prices and conditions offered by the bidders, which must fully meet the established requirements.

Art. 2. The rules and procedures provided for in this Regulation shall be implemented following the constitutional principles of equality, legality, publicity, impersonality, morality, efficiency, and economy.

Art. 3. In the case of contracts arising from an Agreement, Contract, Cooperation Agreement, or any other analogous legal instrument entered into with bodies of the Direct or Indirect Public Administration, as well as with other entities of promotion, teaching, and research, FFM may adopt bidding rules provided for by law, when the adjustment between the parties so determines.

Art. 4. In the procedures and contracts referred to in this Regulation, the proper characterization of the object, deadlines for the submission of proposals, the conditions of supply or provision of services, execution deadlines, value, the origin of financial resources, payment method, fine for default and others that may be necessary shall be observed.

Art. 5. FFM may, at any time, revoke the procedures referred to in this regulation, including those of exemption and unenforceability, for reasons of institutional interest arising from a relevant and sufficient supervening fact to justify such conduct, and shall cancel them for illegality, ex officio or by the provocation of third parties, upon written and reasoned opinion.

Paragraph 1. The nullity of the procedure due to illegality does not give rise to an obligation to indemnify.

Paragraph 2. In the case of the undoing of the procedure, the adversary and the ample defense to the participants are ensured.

Art. 6. The submission of a proposal in a procedure initiated implies the acceptance by the bidder, in an unrestricted and irreversible manner, of both the conditions provided for in the Notice and those expressed in this Regulation.

Art. 7. For the certification of the authenticity of documents in the contracting processes, the following rules shall be observed:

- I. The correspondence of copies with original documents submitted by the interested parties may be certified by FFM itself, upon presentation of the original copy; and
- II. The identification and digital signature by an individual or legal entity in an electronic medium are allowed, employing a digital certificate issued within the scope of the Brazilian Public Key Infrastructure (ICP–Brasil).

Art. 8. For this Regulation, it is considered:

- I. Purchase: any remunerated acquisition of goods for supply at once or in installments;
- II. Service: activity or set of activities aimed at obtaining certain usefulness, intellectual or material;
- III. Price registration minutes: binding, obligatory document, with characteristics of commitment for future contracting, in which the object, prices, suppliers, and conditions of supply are recorded, following the provisions contained in the Notice;
- IV. Common goods and services: those whose performance and quality standards can be objectively defined in the Notice through usual specifications in the market;
- V. Common information and communication technology goods and services: those available in the market and whose performance and quality standards can be objectively defined in the Notice, employing specifications strictly usual in the market;

- VI. Special information and communication technology goods and services: those that cannot be described in the form of item V of this article, because they present, in the object, heterogeneity or complexity of the technological environment, a high degree of interaction with other technological systems and significant added value in technological innovation;
- VII. Work: any activity established, by force of law, as private of the professions of architect and engineer that implies intervention in the environment through a harmonious set of actions that, in aggregate, form a whole that innovates the physical space of nature or entails alteration substantial of the original characteristics of immovable property;
- VIII. Mode of admission:
- a. contract for Lump Sum: contracting of the work or service for a certain and total price;
 - b. contract for Unit Price: contracting the work or service for the right price of certain units;
 - c. task: manpower adjustment for small jobs at the right price, with or without the supply of materials;
 - d. integral contract: contracting of an enterprise in its entirety, comprising all stages of the work, service, and necessary facilities, under the responsibility of the contractor until delivery to the contractor in conditions of entry into operation, in compliance with the technical and legal requirements for its use in conditions of structural and operational safety and with the characteristics appropriate to its purposes.
- IX. Basic design: the set of necessary and sufficient elements, with an adequate level of precision, to characterize the work or the service to be contracted, prepared based on the indications of the preliminary technical studies that ensure the technical feasibility and the appropriate treatment of the environmental impact of the enterprise, and that allows the evaluation of the cost

of the work and the definition of the methods and the execution period, containing a detailed budget of the cost of the work, according to the quantities of services and materials, as well as their specifications, which ensure the best results for the enterprise, without frustrating the competitive character for its execution;

- X. Executive project: the set of elements necessary and sufficient for the complete execution of the work, detailing the solutions provided for in the basic project, the identification of services, materials, and equipment to be incorporated into the work, as well as their technical specifications following the relevant technical standards;
- XI. Term of reference: document necessary for the contracting of goods and services, which must contain the following parameters and descriptive elements:
- a. a clear and objective definition of the object, without indication of the brand;
 - b. definition of units and quantities to be purchased;
 - c. the reasoning for the request for contracting;
 - d. form of execution of the object;
 - e. place of delivery of the products or performance of the services;
 - f. specific rules for a provisional and definitive receipt;
 - g. term for completion.
 - h. maintenance conditions, technical assistance, and required guarantees;
 - i. in the case of works and renovations, place, days, and hours for the technical visit.
- XII. Specialized Professional Technical Services: those performed in work related to:
- a. technical studies, planning, and complete or executive projects;
 - b. opinions, expertise, and evaluations in general;
 - c. technical advisory or consultancy and financial or tax audits;
 - d. supervision, supervision, or management of works or services;

- e. sponsorship or defense of judicial and administrative proceedings;
 - f. training and improvement of personnel;
 - g. restoration of works of art and goods of historical value.
- XIII. Notorious specialization: quality of professional or company whose concept in the field of their specialty is due to previous performance, studies, experience, publications, organization, equipment, technical team, or other requirement related to their activities that allow inferring that their work is essential and arguably the most appropriate to the satisfaction of the object of the contract;
- XIV. Reference value: the amount that, through objective criteria of price study, economic, budgetary, and past contracts, is taken as a beacon for a new contracting procedure.

Art. 9 - The reference value, taken as a parameter for contracting, will be determined through one or more of the options below:

- I. Value practiced in the last purchase provided it is compatible with the specificity of the object;
- II. The value presented by the applicant, considering the following requirements:
 - a. compatibility of the value with the object of the contract;
 - b. information on the date of obtaining the value; and
 - c. in the case of price measurement by quotation, this is with a validity period in force.
- III. The constant value of the project, as long as compatible with the object of the contract;
- IV. Market research to obtain an updated quotation, except that the company that was quoted may participate in the process; and
- V. Through search in electronic sites of market reference, being forbidden the electronic sites of individual.

Sole Paragraph. The reference value will be defined employing a previous study, to be instructed by calculation memory and other documents that support the calculation.

CHAPTER II – AGENTS INVOLVED IN PROCUREMENT AND CONTRACTING PROCEDURES AND RESPECTIVE RESPONSIBILITIES

Art. 10. Employees with an active relationship with the Fundação Faculdade de Medicina and/or the Hospital das Clínicas da Faculdade de Medicina da USP (HCFMUSP) may not dispute the hiring procedures provided for in this Regulation, nor participate, directly or indirectly, in the execution of contracts signed based on this Regulation.

Art. 11. It is forbidden to directly hire a legal entity that has an administrator or partner, with management power, who maintains a relationship of kinship, including affinity, up to the third degree with a director of FFM or the Entity supported by it.

Art. 12. The rules provided for in articles 10 and 11 may be exempted upon justification and authorization of the Presidency of FFM, in which case the contractual instrument shall impose specific restrictions to be observed by the parties.

CHAPTER III – PROCEDURAL MODALITIES FOR PURCHASES AND CONTRACTING

Art. 13. The hiring of FFM may be carried out in compliance with the following procedures:

- I. Direct contracting;
- II. Auction;
- III. Competition;
- IV. Admission Examination:

- V. Auction;
- VI. Competitive dialogue.

Art. 14. The procedures provided for in art. 13 shall be carried out by the Supply and Operations Department and shall be instructed, at least, with:

- I. Justification of the need to contract;
- II. Description of the object, clearly and precisely;
- III. Opinions of the technical areas, when necessary;
- IV. Form of execution, payment term, and term of validity of the contract, if applicable;
- V. Expense estimate, with support in the prices, practiced in the market;
- VI. Indication of the auctioneer and support team, in case of a trading session;
- VII. Need for the requirement of certificates of technical capacity and the registration of the asset in control bodies, when applicable;
- VIII. Responsible for the analysis and judgment of the proposals for the supply of goods and services, and, in the case of trading sessions, with the indication of the Auctioneer and the support team and, when applicable, the technical expert;
- IX. Draft of the contract, when applicable;
- X. The origin of the financial resources for the expenditure;
- XI. Other information and legal requirements may be necessary, due to the characteristics and purpose of the good or service to be contracted.

CHAPTER IV – DIRECT CONTRACTING PROCESS

Art. 15. Direct Contracting comprises the cases of waiver and unenforceability of bidding.

Art. 16. FFM may perform Direct Contracting in the following cases:

- I. Contracting with at least 3 (three) budgets provided by companies in the same industry:
 - a) for contracting that involves amounts less than R\$330,000.00

(three hundred and thirty thousand reais), in the case of engineering works and services;

b) for contracts involving amounts less than R\$180,000.00 (one hundred and eighty thousand reais), in the case of other services and purchases;

II. Exemption;

III. Unenforceability.

Sole Paragraph. The price compatibility can be proven by verifying, in an isolated or combined manner, among others, the following criteria:

- I. On specialized or broad domain websites, preferably those containing date and time of access;
- II. Prices charged by public agencies or entities;
- III. Directly with suppliers among other reliable means;
- IV. Amounts spent on the last purchase, if updated, as long as compatible with the specificity of the object.

Art. 17. Contracts financed exclusively with private resources may be carried out based on three budgets, observing the limits to be disciplined by regulation of the FFM Presidency, based on a reasoned study, emphasizing market values and competitiveness. Examples include contracts related to clinical and/or scientific research, the area of innovation, the operation of the teaching unit, and the Rebouças Convention Center.

Art. 18. Upon receipt of the Material or Service Request, the Supply, and Operations Department of FFM, as applicable, will disclose a "Notice" with a request for quotation on the electronic site, without prejudice to its forwarding, by electronic means, to the companies in the field, containing the information relevant to the contracting.

Paragraph 1. The request for quotation shall establish the deadline for the submission of the proposal, preferably also by electronic means.

Paragraph 2. If there is a need for a technical visit, the location, times, and deadline must be included in the communication.

Paragraph 3. Once the proposals have been received, the classification and technical approval of the requester will be made, when requested; after the negotiation, a spreadsheet of the quoted prices will be prepared and the most advantageous proposal will be indicated, which, after being validated by the financial officer, will be submitted to the FFM Executive Board for the authorization of the contracting.

Paragraph 4. The company holding the most advantageous proposal will be communicated by electronic means and the result of the contract will be disclosed on the official website of FFM.

Art. 19. When the market limitation or disinterest of the companies makes it impossible to obtain the three budgets, the circumstance must be recorded in the file dealing with the contracting of the purchase or the provision of services, under penalty of extending the deadline for extending the participation or repetition of the procedure.

Art. 20. The circumstance referred to in the previous article does not exempt the price justification, which must be made through the use of other means of research in the market, such as consultations on the websites of companies in the field of the object or comparison with the latest prices charged by FFM.

CHAPTER V - DISMISSAL

Art. 21. The procedures of Auction, Competition, Tender, Auction, and Competitive Dialogue are exempt in the following cases:

- I. In cases of emergency, when characterized urgency of care, duly justified;
- II. When they are not interested in the previous procedure and this, justifiably, cannot be repeated without prejudice to FFM and/or the agreed entity;
- III. For the acquisition or lease of property intended for the fulfillment of the statutory purposes of the FFM and/or for the agreed entity;
- IV. In the hiring of a Brazilian institution in charge, regimentally or statutorily, of research, teaching, or institutional development, provided that the contractor has an unquestionable ethical-professional reputation and is not for profit;
- V. In the contracting of a remainder of the work, service, or supply, as a result of contractual termination, provided that the order of classification of the previous procedure carried out is met and the same conditions offered by the winner of the bidding process are accepted, including the price, duly corrected. If companies decline, search the market;
- VI. For the contracting, which has as its object products for research and development, limited, in the case of engineering works and services, to the amount of R\$300,000.00 (three hundred thousand reais);
- VII. For the acquisition of goods, inputs, and services intended exclusively for scientific, clinical, and technological research with resources from sources that do not impose restrictions or procedures for contracting and use of resources;
- VIII. For the hiring of professional services as coordinator or executor of a project of his/her own or of a professional who has previously

- provided, to FFM, services of the same nature, or, also, a teacher appointed by an educational institution with which FFM maintains a cooperation agreement;
- IX. For the acquisition of components or parts of national or foreign origin, necessary for the preventive or corrective maintenance of the equipment during the warranty period of the original supplier;
- X. For financial remittances abroad, as well as for the payment of national expenses involving: biological material samples, associative annuity fees, course enrollment fees, symposium/congress registration, database access, software maintenance, and support, hardware maintenance, article publication, journal subscription, licenses, publishing, formatting and diagramming of scientific article, grammar review, proficiency essay, quality control, copyright, other travel education services, other technical, professional and administrative services;
- XI. In the purchases of fruit and vegetables, bread, and other perishable products, in the time necessary to carry out the normal contracting procedure, carried out directly based on the price of the day;
- XII. For the acquisition or restoration of works of art and historical objects, of certified authenticity, provided that they are compatible or inherent to the purposes of the affiliated entity;
- XIII. In the contracting of an association of people with physical disabilities, non-profit and of proven suitability, for the provision of services or supply of manpower, provided that the contracted price is compatible with that practiced in the market;
- XIV. In cases of war or serious disturbance of order.

CHAPTER VI – UNENFORCEABILITY

Art. 22. The procedures of Auction, Competition, Tender, Auction, and Competitive Dialogue are unenforceable when there is unfeasibility of competition, in particular:

- I. For the acquisition of materials, equipment, or genres that can only be supplied or provided by a producer, company, or exclusive commercial representative, the proof of exclusivity must be made by a certificate provided by a union, federation, or employer's confederation, by equivalent entities, or by the manufacturer (provided that the reason for not having the document issued by employers or similar entities is justified), and if the document in another language is presented with its sworn translation;
- II. For the contracting of specialized professional technical services, of a singular nature, with professionals or companies of notorious specialization; and
- III. For cases of additives in processes/contracts.

Paragraph 1. The requirements referred to in items I, II, and III of this article must be duly justified and proven in the hiring process.

Paragraph 2. If there is a need to determine a brand and/or supplier, the requester must issue a substantiated Technical Opinion detailing the reason and the justification may be approved or rejected by the FFM.

Paragraph 3. The act authorizing the direct contracting, or the extract resulting from the contract will be disclosed and kept available to the public on the FFM website.

CHAPTER VII – TRADING SESSION

Art. 23. The trading session is the appropriate modality of procedure for the contracting of common goods and services, whose judgment criterion may be the lowest price or the highest discount.

Sole Paragraph. The auction will be adopted for the onerous assignment of assets, whose judgment criterion will be the highest offer or that defined in the notice.

CHAPTER VIII – COMPETITION

Art. 24. Competition is the modality of procedure applicable to the contracting of special goods and services, works, and common and special engineering services, whose judgment criterion may be:

- I. Lower price;
- II. Better technique or artistic content;
- III. Technique and price;
- IV. Greater economic return;
- V. Increase discount.

Sole Paragraph. As long as resources are not implemented to carry out the procedure in electronic form, FFM will use the face-to-face trading session and the competition to contract common goods and services, including.

CHAPTER IX – ADMISSION EXAMINATION

Art. 25. The contest is the appropriate procedure for hiring for the choice of technical, scientific, or artistic work, whose judgment criterion will be the best technique or artistic content, and for awarding a prize or remuneration to the winner.

CHAPTER X – AUCTION

Art. 26. The auction is a modality of procedure applicable to the sale of immovable property or unserviceable movable property to those who offer the highest bidder.

CHAPTER XI – COMPETITIVE DIALOGUE

Art. 27. The competitive dialogue is a suitable procedure for the contracting of works, services, and purchases in which dialogues with suppliers are held

and previously selected service providers, through objective criteria, to develop one or more alternatives capable of meeting the needs of the FFM, and interested parties must submit a final proposal after the end of the dialogues.

Sole Paragraph. Competitive dialogue should be used in the following cases:

- I. When the object of the contract involves technological or technical innovation or it is impossible for FFM to satisfy its need without adapting solutions available in the market, or even if the technical specifications cannot be defined with sufficient precision by FFM;
- II. When there is a need to define and identify the means and alternatives that can meet the needs of the FFM with emphasis on the most appropriate technical solution, the technical requirements capable of implementing the solution already defined, and the legal or financial structure of the contract.

CHAPTER XII – PHASES OF THE PROCUREMENT PROCESS

Art. 28. Except for Direct Contracting, in all procedural modalities, the phases described in this chapter shall be observed.

Art. 29. The requesting area must complete a purchase request, service, or work at least five (5) business days before the beginning of the Contracting Process.

Art. 30. The FFM will publish a call notification on the official website of the institution and in a widely circulated newspaper, without prejudice to the faculty of direct communication with suppliers.

Art. 31. The notice must contain, according to the nature of the object to be contracted and the contracting modality, the following information:

- I. Annual serial number, the corporate name of the FFM, and the mention that the procedure will be governed by these Regulations or by a specific law;
- II. II. Place, day, and time of the opening session of the proposals;
- III. Description of the object in a clear and precise and quantitative manner;
- IV. Criteria for the representation of those present for participation in the bidding process, in the case of bidding, and for the presentation of bids and bids;
- V. Minimum allowable reduction between bids, in the case of the trading session;
- VI. Form of execution of the object;
- VII. Deadlines (validity of the proposal, the supply of the good, or the provision of the services);
- VIII. Payment conditions
- IX. Criteria for judgment, with clear provisions and objective parameters;
- X. Criteria of acceptability of the unit and global prices of the bids, as the case may be, allowed the fixing of maximum prices and forbade the fixing of minimum prices, statistical criteria, or ranges of variation concerning the reference price;
- XI. Deadline for submission of the proposals;
- XII. Obligations of the parties;
- XIII. The qualification requirements;
- XIV. Documents strictly necessary for the contracting referring to legal, economic-financial, labor, tax regularity, certificates of technical capacity, and records;
- XV. Technical catalogs, scientific works proving the effectiveness of the product, a sample of the well before the acceptance of the proposal or signature of the contract, certification of the quality of the product or the manufacturing process issued by a competent official institution or accredited entity and letter of solidarity issued by the manufacturer to ensure the execution of the contract, in the case of a reseller or distributor company;
- XVI. Sanctions for non-compliance with obligations and criteria for the filing of appeals;

- XVII. Origin and availability of financial resources to meet the expense;
- XVIII. Condition of the provision of a guarantee of performance of the contract, or its waiver;
- XIX. Date and time for an on-site technical visit, when required;
- XX. Information that the result will be disclosed on the official website of the FFM;
- XXI. Duration of the contract, the possibility of extension, appropriateness of price correction, and applicable index;
- XXII. Other relevant and pertinent conditions.

Paragraph 1. For engineering works and services, the Notice must also contain: basic and/or executive design, descriptive memorial, detailed budget spreadsheet with quantities per item of material and labor that will be used to determine the amount of the expense, other information that may be necessary and, depending on the object, dates and times for the technical visit.

Paragraph 2. The participation of the author of the project or the company that has been responsible for its preparation, as a consultant or technician, during the execution of the contract, in the inspection, supervision, or management functions, exclusively at the service of FFM, is allowed.

Paragraph 3. The provisions of the previous paragraph do not prevent the contracting of works or services that include the preparation of the complete and executive project or, only the latter, as contractor charges.

Paragraph 4. The provisions of this article apply, as applicable, to contracts with three (3) budgets.

Paragraph 5. The Legal Consultancy will be responsible for examining the minutes of the notices and contracts.

Art. 32. Any clauses of the notice containing requirements aimed at directing the Contracting Process are null and void.

Art. 33. Any citizen is a legitimate party to challenge the Contracting Process, detailing the flaws or irregularities that vitiate the notice, and must file the request up to two (2) business days before the date set for the delivery of the proposals.

Art. 34. In the Auction, Competition, and Auction modalities, interested parties must submit their proposals or bids in writing, on letterhead, or via institutional email, within a maximum period of five (5) business days after the publication of the notice in a widely circulated newspaper or disclosure on the FFM website, whichever occurs last.

Sole Paragraph. When the complexity of the contracting requires, as well as in the Competitive Dialogue modality, the deadline provided for in the notice shall be observed.

Art. 35. Proposals and technical or artistic works will be sent for technical analysis by the requester, who will have up to three (3) business days for evaluation. If there is a need for technical clarification and/or adjustment, the bidder will be asked to issue an opinion that contains the justification for the acceptance or disqualification of the proposals. In cases where there is no need for technical evaluation by the requester, the contracting shall be continued.

Art. 36. The company whose proposal has been disqualified will be communicated by electronic means, as well as by publication on the official website. The company shall have two (2) business days the filing an appeal. If the representatives expressly decline the application, the contracting shall be continued.

Art. 37. The judgment criteria specific to each contracting modality will be applied, complemented by the general judgment rules described in this

Chapter. To finalize and define the winning company, ensuring competitiveness and advantage, FFM may:

- I. Send a circular to the classified companies so that, if there is interest in improving and defining their final price, submit a new proposal within the stipulated period. In the omission, your proposal will be linked to the amount initially offered; or
- II. Send circulars to classified companies, inviting them to participate in negotiation by email, face-to-face, or virtual.

Art. 38. In the judgment of the proposals, the judgment criteria of each contracting modality will be considered, as well as the following general rules:

- I. Adequacy of the proposals to the object of the procurement procedure;
- II. Quality;
- III. Income;
- IV. Price;
- V. Deadline for the supply of the product or completion of the service or work;
- VI. Payment conditions
- VII. Adequacy of the bidder to internal compliance mechanisms; and
- VIII. Other criteria are provided for in the notice.

Paragraph 1. Any offer of advantage that is not provided for in the notice, nor price or advantage based on the offers of the other bidders will not be considered.

Paragraph 2. A proposal that presents a symbolic, derisory, or zero value global or unit price will not be accepted, except as provided for in the notice.

Art. 39. The lowest price judgment criterion and the highest discount criterion will consider the lowest expenditure for FFM, in compliance with the minimum quality parameters defined in the notice, as well as the following provisions.

- I. Indirect costs, related to the expenses of maintenance, use, replacement, depreciation, and environmental impact, among other factors, will be considered for the definition of the lowest expenditure, whenever objectively measurable;
- II. The judgment for a higher discount will be based on the condition outlined in the notice. The discount will also be extended to any additive terms;
- III. In the case of engineering works or services, the percentage of discount presented by the bidders will focus linearly on the prices of all items of the budget presented.

Art. 40. In the analysis of the qualification documents, the committee may remedy errors or failures that do not change the substance of the documents and their legal validity, employing a registered and accessible reasoned order, and assigning them effectiveness for qualification and classification purposes.

Sole Paragraph. If the winning company is disqualified, it will be notified of the act electronically and by publication on the FFM website and will have two (2) business days to file an appeal. Once the decision is upheld, the runner-up will be summoned, and so on.

Art. 41. The qualification documentation may be replaced by a Declaration of Non-Existence of Impeding Facts, observing the size of the contract and duly justified.

Art. 42. The CNPJ of the winning company must be consulted to verify the absence of restrictions to the contract.

Art. 43. Approval by the FFM Board shall be effected employing approval in the form called "Quotation Worksheet".

Art. 44. The award will be disclosed to the winning company, electronically, as well as in a widely circulated newspaper and on the FFM website.

CHAPTER XIII - REMEDIES

Art. 45. The acts of the Administration of FFM arising from the application of these Regulations may be appealed within two (2) business days, especially because of:

- a) rejection of the request for accreditation, pre-qualification, or a registration in registration, its amendment or cancellation;
- b) Assessment of the proposals
- c) act of qualification or disqualification;
- d) annulment or revocation.

CHAPTER XIV - ACQUISITION OF MEDICINES, MEDICAL MATERIALS, AND MATERIALS FOR LABORATORY USE

Art. 46. The contracting of medicines, medical materials, and materials for use in the laboratory for the FIM activity will comply with the procedures described in the previous chapters, as well as the following specific provisions:

- I. The requesting area will instruct the purchase request with information regarding the origin of the funds, product description, quantity, technical specification, reference value, and other pertinent;
- II. The documentation will be evaluated and, if necessary, clarifications or complementation will be requested. The reference value presented shall be validated and, in case of doubt, confirmed by the expansion of the research;
- III. FFM will make available on the website the detailed list of the products to be purchased, and may also send invitations to suppliers, setting a deadline for response, which will be up to three (3) business days, or higher, if applicable;

- IV. The negotiation will be individualized, per item, and the definition of the winning company must take into account the pharmacological, technical, and ANVISA restrictions.

Art. 47. FFM, to ensure the acquisition of medicines from reputable suppliers of known origin, as well as to comply with the standards issued by ANVISA, may require, among others, the following documents:

- I. Registration of products;
- II. Certificate of good practice for health products; and
- III. Letter of accreditation of the manufacturer, for distributing companies.

Art. 48. In determining the best offer, the necessary precautions must be taken to exclude those whose origin of medicines, medical materials, and laboratory use is doubtful.

CHAPTER XV – AUXILIARY PROCEDURES

Art. 49. To ensure greater efficiency in the Contracting Process, FFM may use five (5) auxiliary procedures in the purchase and contracting of services: (i) Accreditation; (ii) Pre-qualification; (iii) Expression of interest procedure; (iv) Price registration system; (v) Registration.

Accreditation

Art. 50. Accreditation is the mechanism by which FFM, taking into account the needs of the specific case, will seek to have at its disposal an indefinite number of possible contractors.

Paragraph 1. FFM shall disclose and make available to the public, on its official website, notices of call for interested parties describing standardized contracting conditions, to allow the permanent registration of

new interested parties, who must comply with the terms of the notices and remain able to execute the object when called.

Paragraph 2. The request for disqualification by the accredited party generates its immediate withdrawal from the respective listing.

Paragraph 3. Accreditation may be used in the following cases:

- I. Cases in which it is feasible and advantageous to carry out simultaneous contracting under standardized conditions. In this case, the notice must define the value of the contracting, and, when the object does not allow the immediate and simultaneous contracting of all accredited persons, it must also present objective criteria for the distribution of the demand;
- II. Cases where the selection of the contractor is the responsibility of the direct beneficiary of the benefit. In this case, the notice must define the value of the contract;
- III. Cases in which the constant fluctuation of the value of the installment and the contracting conditions makes it impossible to select an agent through the typical acquisition modalities.

Prequalification

Art. 51. Pre-qualification is the selection procedure before the Contracting Process, called employing a notice, intended for the analysis of the conditions of qualification, in full or in part, of the interested parties. In other words, we seek to previously select (i) suppliers that meet the qualification conditions to participate in the future Contracting Process and (ii) goods that meet the technical or quality requirements established by FFM.

Paragraph 1. FFM shall disclose and make available to the public, on its official website, a notice describing the pre-qualification procedure, the definition

minimum of the object of the future contracting, the modality of the future Contracting Process, and the judgment criteria that will be adopted.

Paragraph 2. Prequalification may be partial or total, with some or all technical or qualification requirements necessary for contracting, ensuring, in any event, equal conditions between competitors.

Paragraph 3. The submission of documents shall be made before the body or committee indicated by FFM in the notice, which shall examine them within the period set and determine the correction or resubmission of documents, when applicable, to expand the competition.

Paragraph 4. Suppliers and pre-qualified goods must be disclosed and kept available to the public on the official website of FFM.

Paragraph 5. The Contracting Process that follows the pre-qualification procedure may or may not be restricted to pre-qualified suppliers or goods.

Expression of interest procedure

Art. 52. In the expression of interest procedure (PMI), FFM will publish a public call notice on its official website requesting the private initiative to propose and carry out studies, investigations, surveys, and projects of innovative solutions that contribute to issues of public relevance, possibly the object of future Contracting Process.

Paragraph 1. The winner of the Contracting Process shall reimburse the expenditures made with the studies, investigations, surveys, and projects related to the contracting.

Paragraph 2. The performance by the private initiative of studies, investigations, surveys, and projects as a result of the PMI will not grant the director a preemptive right in the Contracting Process, will not oblige FFM to carry out the Contracting Process, nor will it imply, by itself, the right to reimbursement of amounts involved in its preparation.

Price Registration System

Art. 53. The price registration system is the set of procedures for carrying out, through direct contracting or bidding or competition, formal registration of prices related to the provision of services, works, and the acquisition and lease of goods for future contracts.

Paragraph 1. FFM will publish, on its official website, a notice for price registration indicating (i) specificities of the future Contracting Process, (ii) the object of the future contracting, including the maximum quantity of each item that can be purchased; (iii) the minimum quantity to be quoted of units of goods or, in the case of services, units of measure; (iv) the judgment criteria that will be adopted.

Paragraph 2. The existence of registered prices will imply a commitment to supply under the established conditions, but will not oblige FFM to contract, with the possibility of carrying out a specific Process for the intended acquisition, provided that it is duly motivated.

Paragraph 3. The price registration minutes are the binding and obligatory document, with the characteristic of commitment for future contracting, in which the object, the prices, the suppliers, and the conditions to be practiced are recorded, according to the provisions contained in the notice, in the notice or instrument of direct contracting and the proposals presented.

Paragraph 4. The term of validity of the price registration minutes shall be one (1) year and may be extended for an equal period, provided that the advantageous price is proven. The contract resulting from the price registration minutes shall have its term established in compliance with the provisions contained therein.

Registration

Art. 54. The registration record consists of a unified register of suppliers and service providers available on the official website of FFM and permanently open to interested parties, who must provide the necessary elements for qualification in the future Contracting Process.

Paragraph 1. The FFM shall make a public call on its official website, at least annually, to update the existing records and for the entry of new interested parties.

Paragraph 2. FFM may initiate a procedure restricted to registered suppliers, meeting the criteria, conditions, and limits established in the notice, as well as the wide publicity for registration.

Paragraph 3. At any time, the registration of a registrant who no longer meets the requirements determined by these Regulations may be changed, suspended, or canceled.

CHAPTER XVI – FORMALIZATION AND EXECUTION OF CONTRACTS

Art. 55. The contracts signed based on these Regulations shall establish, with clarity and precision, the conditions for their execution expressed in clauses that define the rights, obligations, and responsibilities of the parties following the terms of the notice and the proposal to which they are bound.

Sole Paragraph. The contracts resulting from exemption or unenforceability of procedure provided for in articles 21 and 22 of these Regulations, shall comply with the terms of the act that authorized them and the corresponding proposal.

Art. 56. The contracts signed based on this Regulation may be amended provided that there is a reasoned justification for the need to add or delete its object, prior agreement between the parties, and term of amendment of the contract.

Paragraph 1. The additions and deletions of the object shall not exceed the limit of 25% (twenty-five percent) of the updated contracted value and, in the case of building and equipment renovation, the limit of 50% (fifty percent).

Paragraph 2. Except for the limits referred to in the previous paragraph, the deletions of the object resulting from the agreement between the parties, as well as the additions resulting from exceptional situations, such as purchases with estimated quantities due to the unpredictability of consumption, execution of services of a continuous nature and works and reforms, due to a supervening and unpredictable fact, provided that the absolute need for the deletion or addition above the limits is duly justified and proven.

Paragraph 3. The amounts resulting from the change must be approved in advance by the expense's authorizing officer.

Paragraph 4. The changes in the works contract must observe the same values contained in the spreadsheet of the initial contracting and, if new items are included, the values established in the Reference Periodic Bulletins of costs of works in the civil construction area.

Paragraph 5. The service and continuous supply contracts may be extended up to a maximum of sixty (60) months and, exceptionally,

upon technical justification, assessment of economic advantage, analysis of Legal Consulting, and authorization of the FFM Board of Directors may be extended for a longer period.

Art. 57. FFM, with due motivation, may fail to contract with companies that, in previous procedures or contracts, with public or private entities, have unreasonably failed to comply with their obligations, or that reveal ineligibility or lack of technical or financial capacity for contracting.

Art. 58. The Contractor is liable for damages caused directly to FFM or third parties, arising from its fault or intent, in the performance of the contract.

Sole Paragraph. FFM may require civil liability insurance to cover extraordinary risks.

Art. 59. For this Regulation, the delivery of the goods, the provision of the service, the performance of the work, as well as any other contractual event, whose validity is certified by FFM, or by an agent indicated by it, is considered as compliance with the contractual obligation.

Art. 60. FFM may reject, in whole in part, supply, service, or work that, in its opinion, is in disagreement with the contract.

Art. 61. To the contracts referred to in this Regulation, the principles of the General Theory of Contracts and the General Provisions of Civil Law apply.

Art. 62. The term of the contract may be waived and its replacement may be allowed, at the discretion of FFM, with due justification.

CHAPTER XVII – WARRANTIES

Art. 63. FFM may, in each case, require the provision of a guarantee in the contracting of purchases, services, and works.

Paragraph 1. The guarantee shall be provided by:

- I. collateral in cash or government debt securities;
- II. surety bond;
- III. bank guarantee.

Paragraph 2. The guarantee referred to in the *caput* of this article shall not exceed 5% (five percent) of the contract value and shall have its value updated under the same conditions as that.

Paragraph 3. The guarantee provided will be released or refunded, after the execution of the contract or, in the case of its termination, for breach of the contractor's obligation, after the discounts of the fines due and, when in cash, monetarily corrected, as provided for in the Notice.

CHAPTER XVIII – ADMINISTRATIVE SANCTIONS

Art. 64. The contractor who incurs the total or partial non-performance of the contract may if there is a public notice in this regard, present written justification/defense to the contract manager, within 5 (five) days from the act of non-performance. The reasons will be analyzed and, once the contractor's liability has been verified, FFM will apply, in addition to the relevant contractual sanctions, the following administrative sanctions, alone or cumulatively:

- I. Warning;
- II. Temporary suspension from participating in FFM contracting processes, for a period of one (1) to three (3) years;
- III. Fines provided for in the agreement;
- IV. Contractual termination.

CHAPTER XIX – FINAL PROVISIONS

Art. 65. FFM may adopt bidding rules provided for in specific law, when:

- I. Understand the timely and convenient for its contracting and/or integration of procedures to these Regulations;
- II. In the event of an agreement or contract entered into with a public entity, when this is expressly required.

Sole Paragraph. In the event of one of the hypotheses of items I and II of this article, it shall be clarified in the Notice.

Art. 66. Circular No. 01/2022 is maintained, referring to the acquisition of goods and services, the use of which must observe the absence of a specific procedure indicated in this Regulation.

Sole Paragraph. Any changes to the Circular shall be considered an integral part of these Regulations.

Art. 67. The draft notice, contract, and other annexes may be standardized by the Legal Consultancy.

Paragraph 2. The use of standardized minutes shall prevail, except in the event of the need for specific changes to meet the peculiarities of a particular contract.

Art. 68. This Regulation, duly approved by the Board of Curators on 10/27/2022, will enter into force on the date of its publication, by extract, in the Official Gazette of the State of São Paulo and, in full, on the FFM website.

Sole Paragraph. The procedures already forwarded to the Supplies and Operations area, as well as those already established, will be conducted and concluded based on the previous Regulation.

Art. 69. The provisions to the contrary are revoked, especially the Purchasing and Contracting Regulations published in the Official State Gazette of December 7, 2018, as of December 31, 2022.

Art. 70. FFM may modify the provisions of these Regulations when deemed necessary, and shall comply with the procedures outlined in its Bylaws.