

COMPLAINTS PROCEDURE FOR PATIENTS PRINCESS MÁXIMA CENTER FOR PEDIATRIC ONCOLOGY

1. Purpose of the complaints procedure

- To provide accessible and effective support and handling of signals of dissatisfaction and complaints, leading to a sustainable solution for the patient and the preservation or restoration of trust in the care provided by the Princess Máxima Center.
- To improve the quality of care.

2. Ombudswoman: role and responsibilities

The ombudswoman:

- Plays a central role in receiving and handling signals of dissatisfaction and complaints by:
 - a. offering a listening ear and mediating between the patient or parent(s) and care professional(s) in order to resolve dissatisfaction and foster mutual understanding;
 - b. encouraging the patient or parent(s) to discuss their dissatisfaction with the involved care professional, manager, or lead physician;
 - c. informing the patient or parent(s) about the complaints procedure or the submission of a claim for damages and, if requested, guiding them in this process.
- Registers signals of dissatisfaction and complaints and keeps a file on the handling of complaints. This file is stored separately from the medical record. The retention period for the complaints file is five years after the date on which the signal of dissatisfaction or complaint is resolved.
- Has a signaling role when, in carrying out her duties, she observes that the quality of care is at risk.
- Reports periodically on signals of dissatisfaction and complaints, addressing structural shortcomings in the report and, where possible, linking these to recommendations to improve the quality of care.
- Performs her duties independently and with balanced impartiality, in accordance with the law, applicable professional standards, and her job description. She is not involved in the care to which the signal of dissatisfaction or complaint relates.
- The Princess Máxima Center refrains from interfering in the manner in which she performs her duties in a specific case.

3. Who can submit a signal of dissatisfaction or a complaint?

- A patient, their legal representative, or a surviving relative of the patient may submit a signal of dissatisfaction or a complaint.
- Patients or parent(s) may be assisted by a person designated by them.

A legal representative means the parent(s) with parental authority or the guardian. In this procedure, the term parent(s) is used throughout. Surviving relatives are understood to mean former legal representatives. See also the definition of surviving relative in Article 1 of the Quality of Care Complaints and Disputes Act.

4. Confidentiality

- Anyone involved in the handling of a signal of dissatisfaction or a complaint who gains access to confidential information is obliged to maintain confidentiality. This obligation continues after the complaints procedure has been completed.
- Complaints files are confidential and accessible only to the ombudswoman.

5. Mediation of signals of dissatisfaction and complaints by the ombudswoman

- The patient or parent(s) first discuss a complaint or signal of dissatisfaction about the care provided with the involved care professional, manager, or lead physician. If the outcome is not satisfactory, the patient or parent(s) may contact the ombudswoman.
- The patient or parent(s) report a signal of dissatisfaction orally or in writing to the ombudswoman.
- A complaint must be submitted in writing.
- Anonymous submission of complaints or signals of dissatisfaction is not possible.
- As soon as possible after submission, the ombudswoman discusses the signal of dissatisfaction or complaint with the patient or parent(s) and asks about their wishes, needs, and expectations.
- With the consent of the patient or parent(s), the ombudswoman may access the medical record if this is necessary for proper handling of the signal of dissatisfaction or complaint.
- The ombudswoman strives for a sustainable solution to a signal of dissatisfaction or complaint by applying the principle of hearing both sides and mediating where possible. In performing her duties, she focuses on restoring the relationship between the care provider and the patient or parent(s). If necessary, she seeks legal advice from the Princess Máxima Center health law attorney.
- When a signal of dissatisfaction or complaint is closed, she confirms this orally and or in writing and records it in the patient or parent(s)' complaints file.
- If the ombudswoman and the patient or parent(s) conclude that mediation of a complaint has not been resolved satisfactorily, the ombudswoman may provide information about possible next steps, including submitting a complaint to the Review Committee. If the patient or parent(s) wish to pursue this option, the ombudswoman forwards the complaint to the Review Committee.

6. Review Committee: composition

- The Review Committee consists at a minimum of the following members:
 - a. an external chair, preferably a lawyer with knowledge of and experience in complaints handling;
 - b. an external 'patient perspective member'. The Client Council is involved in appointing this member;
 - c. a member who is a pediatric oncologist;
 - d. a member who works as a nurse at the Princess Máxima Center;
 - e. two alternate members who work as pediatric oncologists at the Princess Máxima Center and are familiar with the conduct of clinical trials.
- On the nomination of the Review Committee, the Board of Directors appoints the members and alternate members for a period of three years. Reappointment is possible.
- The Review Committee is supported by a secretary. The secretary is responsible for careful and adequate correspondence with all parties involved, including providing information about the course of the procedure, timely summoning of those involved for a hearing, monitoring deadlines, and informing the Board of Directors about the complaint and its handling.

- Members of the Review Committee may, other than at their own request, be dismissed during their term by the Board of Directors on the recommendation of the chair of the Review Committee if they fail to adequately fulfill the obligations arising from membership of the Review Committee or in the event of evident unsuitability.
- The chair of the Review Committee determines, in consultation with the secretary, the composition of the Review Committee depending on the content of the complaint. The Review Committee consists of four members. The composition is chosen in such a way that the members or care providers come from different professional groups and or departments, and that the members concerned are not involved in the complaint.

7. Decision of the Board of Directors and responsibilities of the Review Committee

- The Review Committee is responsible for investigating complaints and advising the Board of Directors on the basis of its findings.
- The Review Committee issues a reasoned opinion on whether the complaint is well founded or unfounded, assessing the actions of the Princess Máxima Center based on the facts established in the investigation.
- The Board of Directors issues a decision on the complaint. It may deviate from the advice of the Review Committee only with justification and informs the Review Committee accordingly.
- The Review Committee advises the Board of Directors, both on request and on its own initiative, on improvements in care relating to the complaint and on improvements in the way complaints are handled.

8. Handling of a complaint by the Review Committee

- The complainant submits the complaint in writing. The written complaint includes:
 - a. the name and contact details of the complainant(s);
 - b. the content and purpose of the complaint;
 - c. when the event to which the complaint relates took place;
 - d. who was involved;
 - e. which care professional(s) the complaint concerns.
- Based on the content of the complaint, the Review Committee determines the method of investigation and handling.
- The investigation includes at least:
 - a. review of the relevant medical information;
 - b. requesting one or more written responses to the complaint;
 - c. holding a hearing in the presence of the complainant and the most directly involved care professionals.
- The Review Committee may consult an internal or external expert if it does not have sufficient expertise to provide a well-founded opinion in response to the submitted complaint.
- The secretary ensures that the complainant(s) sign a medical authorization granting permission to the members and secretary of the Review Committee and the Board of Directors to access all relevant medical information, including, if necessary, information collected during the mediation phase.
- Employees are required to cooperate with the investigation.

9. Decision: timeframe and reasoning

- The Board of Directors aims to issue a decision on the complaint within six weeks after the complaint has been submitted to the Review Committee. If more than six weeks are required to assess the complaint, the secretary of the Review Committee informs the complainant and the care provider(s) to whom the complaint relates and extends the period by four weeks. If the complaint cannot be assessed within the extended period, the secretary informs the complainant and the care professional(s) concerned. The secretary explains why the complaint cannot be handled within the timeframe and indicates when a decision can be expected.
- The complainant may also request an extension of these timeframes, for example due to the patient's medical situation.
- The Board of Directors provides a reasoned explanation of the decision reached as a result of the investigation, taking into account the advice of the Review Committee. If necessary, the Board of Directors indicates which measures have been taken in response to the complaint.
- The secretary of the Review Committee sends the decision to the complainant, the care providers to whom the complaint relates, their manager, and the members of the Review Committee. A de-identified version of the decision and the improvement measures is sent to the head of the Quality Department.
- The secretary informs the complainant of the possibility to submit the complaint to the Hospitals Disputes Committee within one year after the decision has been sent.

10. Withdrawal and termination of complaint handling by the ombudswoman or the Review Committee

- The complainant may withdraw the complaint in writing or orally if they no longer wish to pursue further handling of the complaint. If the complaint is withdrawn orally, the withdrawal is confirmed in writing, stating the date of the telephone conversation and the reason for withdrawal.
- The ombudswoman or the Review Committee may decide to terminate the handling of a complaint if, due to the passage of time or other circumstances, the complaint can no longer reasonably be explored or properly investigated. The complainant is informed of this decision in writing, stating the reason for termination.
- In urgent cases, the Board of Directors may decide to discontinue the handling of the complaint. An urgent case may include situations in which the complainant behaves aggressively toward care providers and or staff or otherwise engages in serious misconduct, making it unreasonable to expect the Princess Máxima Center to continue handling the complaint. The complainant is informed in writing of the termination of the complaint handling and the reason for it.

11. Handling of a claim for damages

- If the patient or parent(s) believe that there has been culpable conduct by the Princess Máxima Center resulting in damage to the patient, a claim for damages may be submitted to the Board of Directors of the Princess Máxima Center. The patient or parent(s) may also submit a claim for damages through the ombudswoman. The ombudswoman forwards the claim to the claims handler responsible for processing the claim.
- The claims handler sends a written acknowledgment of receipt within five business days after receiving the claim.

- In certain cases, the claims handler consults with the ombudswoman about whether her involvement in handling the claim is desirable. If so, the ombudswoman contacts the complainant.
- The claims handler investigates the validity of the claim and involves the relevant care providers, their manager, and the patient or parent(s). The claim is handled in accordance with the Code of Conduct for Openness in Medical Incidents and Better Handling of Medical Liability.
- The handling of a claim results either in acceptance of the claim with corresponding compensation or in a reasoned rejection of the claim. If no agreement is reached on the handling of the claim and the patient or parent(s) are not assisted by a professional representative, the claims handler informs the patient or parent(s) of the option to submit the claim to the Hospitals Disputes Committee or to the competent court.
- The Princess Máxima Center considers whether to notify its liability insurer of the claim. If necessary, the insurer takes over the handling of the claim from the Princess Máxima Center.

12. Scope of the complaints procedure and combined handling of complaints with other centers

- This complaints procedure applies to care provided by employees of the Princess Máxima Center.
- The procedure also applies to complaints arising from participation in medical scientific research conducted by employees of the Princess Máxima Center.

Explanation

The Princess Máxima Center conducts a large amount of medical scientific research. Many patients participate in studies after giving their consent. The Princess Máxima Center considers it important that patients can also contact the ombudswomen with complaints in this area or request a decision from the Board of Directors.

The Hospitals Disputes Committee is not authorized to handle complaints arising from participation in medical scientific research, insofar as this does not involve clinical research that also has a treatment objective. There is no legally regulated procedure for this.

- If a complaint relates to care provided in conjunction with care delivered at University Medical Center Utrecht or Wilhelmina Children's Hospital, a shared care center, or another medical center with which the Princess Máxima Center has a cooperation agreement, the involved medical centers aim to handle the complaint jointly. The Princess Máxima Center has made written agreements about this. Combined handling requires the complainant's consent.
- If a complaint relates to the actions of a care provider employed by another medical center and the care was not provided in conjunction with care delivered at the Princess Máxima Center, the complaint is carefully transferred to the party whose actions are the subject of the complaint, unless the complainant does not give consent.

13. Submitting a dispute to the Hospitals Disputes Committee

- If a complaint is not resolved satisfactorily after handling in accordance with this complaints procedure, the complainant may submit the dispute to the Disputes Committee. A dispute must be submitted to the Disputes Committee no later than one year after the date of the decision of the Board of Directors or the claims handler.
- The complainant may submit a dispute directly, without requesting a decision, to the Disputes Committee only if, under the circumstances, it cannot reasonably be expected that the complainant

submit the complaint to the Princess Máxima Center.

Explanation

The Disputes Committee is an independent body that handles both complaints without a financial claim and complaints with a financial claim. The Disputes Committee is authorized to award compensation of up to €25,000. If you believe that the damage may be higher, it is advisable to go to court. The Disputes Committee issues a binding opinion on the disputes submitted to it. The binding opinion procedure ends with a ruling, the binding opinion. Once you choose to submit the dispute to the Disputes Committee, you are bound by this decision and, in principle, can no longer submit your financial claim to a court. The regulations of the Disputes Committee can be found on the website of the Hospitals Disputes Committee (<https://www.degeschillencommissie.nl>).

14. Final provisions

- The Princess Máxima Center does not charge any fees for handling complaints and claims under this procedure. The costs of support, legal assistance, and witnesses or experts engaged by the complainant on their own initiative are borne by the complainant.
- Regardless of the provisions of this procedure, the complainant may express dissatisfaction and or submit a complaint to other bodies. For example, the complainant may submit a complaint to the competent healthcare disciplinary board, report a complaint to the National Healthcare Report Center of the Healthcare and Youth Inspectorate, or, in the case of a claim for damages, initiate civil proceedings before the competent court.
- The Board of Directors brings this procedure to the attention of patients and their relatives by publishing it on the website and, upon request, providing them with a copy of the procedure.
- This procedure enters into force on January 1, 2026. With the entry into force of this complaints procedure, the 'Complaints Procedure for Clients of the Princess Máxima Center' dated January 1, 2021, is withdrawn.

This procedure was adopted by the Board of Directors of Princess Máxima Center for Pediatric Oncology B.V. on December 9, 2025, following approval by the Client Council, including the Children's Advisory Council, and a positive recommendation from the Medical Advisory Council.