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HEALTH CANADA EXTERNAL CHARGING GUIDELINES

Guideline On Complaint Resolution And Dispute Management for External Fees

This is one in a series of documents developed to supplement the Health Canada External Charging Policy and provide Health Canada managers with guidance on issues related to the use of external charging

REVISED: March 02, 2007





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For further information or to obtain additional copies, please contact:

Publications
Health Canada
Ottawa, Ontario K1A 0K9
Tel.: (613) 954-5995

Fax: (613) 941-5366 E-Mail: info@hc-sc.gc.ca

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COMPLAINT RESOLUTION AND DISPUTE MANAGEMENT PROCESS FOR EXTERNAL FEES

1. Purpose and Scope

- 1.1. This is one of a series of guidelines developed to provide Health Canada managers with guidance on issues related to the use of fees. The guidelines are intended to be applicable to most Health Canada programs, but it is the responsibility of the user to consider the specific circumstances in each case and adapt the guidance accordingly.
- 1.2. This guideline should be read in the context of the Health Canada External Charging Policy, the Treasury Board Policy on Service Standards for External Fees and the *User Fees Act*.
- 1.3. This document outlines Health Canada's process for resolving complaints concerning proposed new or amended fees (Track "A" and Appendix A), and for managing disputes once fees are in place (Track "B" and Appendices B and C).
- 1.4. The aim of this process is to provide complainants with a range of options to facilitate resolution of complaints with respect to proposed or amended fees and management of disputes arising in relation to existing fees. It is also to assist Health Canada staff in managing and resolving complaints and disputes in a manner that is cost effective, efficient, open and fair to all those involved.

2. Introduction

- 2.1. The *User Fees Act* was proclaimed in force as of March 31, 2004. It establishes several legislative requirements pursuant to ss. 4 and 4.1 with respect to resolving complaints regarding proposals for new or amended user fees. The scope of this dispute resolution process (Track A) includes all aspects of the proposed new or amended fees, including the fees themselves, service standards, costing, etc.
- 2.2. While meaningful and effective consultation is expected to reduce the number and frequency of disputes, there is always potential for unresolved disputes. Track B establishes guiding principles for a departmental dispute management process to deal with those disputes that arise in relation to external charging once fees are in place.

3. Discussion

- 3.1. Track A Complaint Resolution for Proposed Fees
 - 3.1.1. Establishment of Independent Advisory Panel
 - 3.1.1.1. Amongst the other requirements of s. 4 of the *User Fees Act*, before a regulating authority (as defined in the *User Fees Act*) fixes, increases, expands the application of or increases the duration of a user fee, it must establish an independent advisory panel to address a complaint submitted by a client regarding the proposed user fee or change.
 - 3.1.2. Stage One: Complaint Resolution by Regulating Authority
 - 3.1.2.1. A regulating authority that receives a complaint about a proposed user fee within the period set out in a notice (as per the *User Fees Act*) issued by that authority must:
 - 3.1.2.1.1. Try to resolve the complaint; and
 - 3.1.2.1.2. Give the complainant notice in writing of proposed measures for its resolution.
 - 3.1.3. Stage Two: Referral to Independent Advisory Panel
 - 3.1.3.1. If the complaint is not resolved to the complainant's satisfaction within 30 days after the expiry of the period set out in the notice, the complainant may request in writing that the regulating authority refer the complaint to an independent advisory panel.
 - 3.1.3.2. Within 40 days after the expiry of the period set out in the notice, the regulating authority and the complainant must each select one member to sit on the panel and those members must select a third member. Procedures for panel process may be found in Appendix A.
 - 3.1.3.3. The regulating authority may decide, for reasons of economy and efficiency, that two or more complaints about a particular proposal to be dealt with by the same panel. In such case, the panel member to be selected by the complainants is selected by a majority vote.
 - 3.1.3.4. The panel must, within 30 days after all members have been selected, send a report in writing of its findings and recommendations for resolving the dispute to the regulating authority and the complainant.
 - 3.1.4. Costs of Complaint Resolution Processes
 - 3.1.4.1. The panel has the power to award costs of the proceedings, including the cost of the fees and expenses of panel members.
 - 3.1.4.2. If, in the opinion of the panel, a complaint is frivolous or vexatious, the complainant bears all the costs.

- 3.2. Track "B" Dispute Management for Existing Fees
 - 3.2.1. Definition of Dispute
 - 3.2.1.1. A dispute is a disagreement over matters related to existing fees including service standards.
 - 3.2.2. Dispute Management Process
 - 3.2.2.1. Issues or disputes related to external charging once fees are in place will progress through three stages.
 - 3.2.2.2. Unless otherwise agreed by both parties, a complainant is required to complete each stage of the process before a dispute can be referred to the next stage.
 - 3.2.2.3. Time lines for dispute management processes can be extended by agreement between the parties.
 - 3.2.3. Stage One: Branch-level Dispute Management
 - 3.2.3.1. Parties must attempt to resolve a dispute regarding external charges through branch-level Dispute Management mechanisms.
 - 3.2.3.2. Agreement should be in writing.
 - 3.2.4. Stage Two: Referral to Chief Financial Officer (CFO)
 - 3.2.4.1. If a dispute or issue is not resolved within 90 calendar days from the date of referral to a branch-level dispute management mechanism, or no such mechanisms exist, the complainant may request a Stage Two review by sending a written request to the CFO of Health Canada. The written request shall:
 - 3.2.4.1.1. Where a branch level dispute management mechanism exists, be sent within 30 calendar days from the later of:
 - The date of response or decision from the branch on the issue or dispute, or
 - The date upon which such decision or response should have been issued;
 - 3.2.4.1.1. Specify the nature of the issues in dispute;
 - 3.2.4.1.2. Provide a brief summary of the reasons for the dispute; and
 - 3.2.4.1.3. May contain such other information that the complainant feels is relevant, including new material.

- 3.2.4.2. Within 14 calendar days of the receipt of the written request referred to above, the CFO will send a written acknowledgment of receipt to the complainant.
- 3.2.4.3. If the complainant has not attempted to resolve the dispute through the existing branch dispute resolution mechanisms, the dispute will be referred to the appropriate branch-level mechanism, and the complainant advised accordingly.
- 3.2.4.4. In conducting a review the CFO may:
 - Identify and analyse all relevant information relating to the dispute, including any information with respect to Stage One Processes;
 - Collect and share relevant facts with all the complainants and branch representatives;
 - Identify areas needing further clarification;
 - Collect any needed additional information; and
 - At their request, contact or meet with the complainant and branch representatives involved in the dispute.
 - 3.2.4.5. Within 30 calendar days from the date of receipt of the request for CFO's review, the CFO will send a written response to the parties informing them of the results of the Stage Two review process with the reasons for his or her decision, of the remedial action if any being taken, and costs, if any.
- 3.2.5. Stage Three: Written Submission to Minister of Health
- 3.2.5.1. In the event that the issue or dispute has not been resolved to the satisfaction of one or more parties at the Stage Two review, they may within 30 days of the date of the formal response from the CFO by notice in writing submit the issue or dispute to the Minister of Health for final decision. The notice shall specify the nature of the issues in dispute, provide a brief summary of the reasons for the dispute and may contain such other information that the complainant(s) feel is relevant.
- 3.2.5.2. The Minister of Health, may at his/her discretion, at any time in the Stage Three Review, and having regard to the nature of the dispute, the request(s) of the complainant(s) for mediation or panel process, and whether there is an impasse, invite the complainant(s) and the departmental representatives involved in the dispute to participate in one of the following processes:
 - 3.2.5.2.1. Mediation in accordance with Appendix B; or
 - 3.2.5.2.2. Advisory panel process in accordance with Appendix C.
 - 3.2.5.2.3. (Herein referred to as "Mediation", "Advisory Panel Process" or collectively "facilitated process")
- 3.2.6. Any agreement reached as a result of a process agreed to under the previous section will be recorded in writing, signed by authorized representatives of the parties to the agreement, and delivered to the parties; and be binding upon only the parties who have signed the agreement.

- 3.2.7. If the parties agree to participate in the proposed mediation or advisory panel process, the Stage Three review process shall be suspended until termination of the mediation or advisory panel process. The parties involved in the dispute will agree in writing to participate in the mediation or advisory panel process in accordance with this Dispute Management Process and the applicable rules attached as Appendices "B" and "C" hereto.
- 3.2.8. If a party does not agree to participate in the mediation or advisory panel process as proposed, or fails to respond to the Minister of Health's invitation to participate within 10 calendar days of the date of such invitation, the Minister of Health will complete the Stage Three review process in accordance with this part.
- 3.2.9. If the parties are unable to resolve the issue or dispute through the mediation or advisory panel process as applicable, the Stage Three review process shall resume in accordance with the foregoing provisions.
- 3.2.10. Within 30 calendar days from the date of receipt of the request for Minister of Health's review, or the receipt of a mediator's or advisory panel's report, whichever is later, the Minister of Health will send a written response to the parties informing them of the results of the Stage Three review process with reasons, and of the remedial action if any being taken.
- 3.2.11. The Minister has final authority with respect to the administration of external charges in accordance with the Financial Administration Act, and other applicable laws, regulations, and policies, including the responsibility for managing the issue or dispute. The Minister may prior to issuing a final decision on the issue or dispute, have regard to Stage Two review results, as well as any mediator report or panel recommendations.
- 3.3. Costs of Dispute Management Processes
 - 3.3.1. Any of the decision-making authorities in Stages Two or Three set out herein have the power to award costs of the proceedings in their discretion, including the cost of the fees and expenses of panel members.
 - 3.3.2. If, in the opinion of the panel, a complaint is frivolous or vexatious, the complainant bears all the costs.
 - 3.3.3. Costs shall include:
 - 3.3.3.1. Fees and expenses of the mediator, or panel members;
 - 3.3.3.2. Costs of meeting rooms;
 - 3.3.3.3. Administrative assistance;
 - 3.3.3.4. Technical support; and
 - 3.3.3.5. Actual and reasonable costs of communications, accommodations, meals and travel of the panel members, calculated in accordance with Treasury Board guidelines.

3.4. Notice

3.4.1. Unless otherwise specified, any notice or request or communication required under this process shall be in writing and deemed to be sufficiently given if sent by registered mail or by telegram or by fax or by delivery in person to the appropriate contact as detailed in Appendix D.

3.5. Review

- 3.5.1. Health Canada will review its dispute management process from time to time and make such adjustments as may be necessary so as to ensure that the processes and mechanisms provided for therein, respond to complainant and the department's needs.
- 3.5.2. Health Canada shall retain information on issues and disputes raised by complainant as well as on resolutions and remedial action taken, so as to improve programs and services where possible, and prevent disputes of a similar nature from occurring.

4. Reporting

4.0.1. Section 4(2) of the *User Fees Act* requires that information related to the establishment of an independent advisory panel and how complaints have been dealt with must be reported annually.

5. References

User Fees Act (March 2004)

Policy on Service Standards for External Fees – Treasury Board Secretariat (November 2004) Health Canada External Charging Policy

6. Enquiries

6.1. Enquiries should be directed to:

Revenue and Costing Section Chief Financial Officer Branch rcs_src@hc-sc.gc.ca

Tel: (613) 952-9936 Fax: (613) 957-7759

Track A: Complaint Resolution Advisory Panel Process Rules

- 1. The Complaint Resolution Advisory Panel may select its own chairperson.
- 2. The appointment of a panel member terminates if:
 - 2.1. The panel member withdraws from the panel for reasons beyond his/her control;
 - 2.2. The appointing party terminates the appointment of the member it selected; or
 - 2.3. The complainant and Health Canada jointly agree to terminate the appointment of the chairperson.
- 3. If the appointment of a panel member is terminated or a panel member withdraws, a replacement member will be appointed by the same party that appointed the outgoing member.
- 4. The panel should:
 - 4.1. Review relevant facts;
 - 4.2. Identify points of agreement and disagreement;
 - 4.3. Meet with the disputing parties representative(s) together or separately to discuss and review the facts; and
 - 4.4. Provide non-binding advice and recommendations on how the dispute might be resolved.
- 5. The representatives of the disputing parties and the representatives of Health Canada will:
 - 5.1. Co-operate fully with the panel; and
 - 5.2. Give prompt attention to and respond to all communications from the panel.
- **6.** The parties should provide the panel with the following information as soon as the panel is constituted:
 - 6.1. The name of their official representative(s); and
 - 6.2. A full description of the issue(s) in dispute.

- 7. The Panel should make every effort to conduct its business and fulfil its obligations under its mandate, by consensus.
- 8. The panel members, and parties involved in the dispute, will agree to keep confidential all oral and written information disclosed in the panel reference and the fact that this information has been disclosed unless otherwise required by law. However evidence that is independently admissible will not be rendered inadmissible or non-discoverable by virtue of its use during the panel process.
- 9. A member, or anyone retained or employed by the member, is not compellable in any proceeding to give evidence about any oral or written information acquired or opinion formed by that person as a result of the reference, and all parties will oppose any effort to have that person or that information subpoenaed.
- 10. A reference is terminated when any of the following occurs:
 - 10.1. The final report of the panel is received by the regulating authority and the complainant;
 - 10.2. The parties involved in the dispute resolve the issue(s) in dispute; or
 - 10.3. The complainant party withdraws from the panel process.

Track B: Dispute Management Mediation Process Rules

- 1. Mediation commences on the date that the parties agree in writing to participate in mediation.
- 2. Mediation will be conducted by a mediator jointly appointed by the parties.
- 3. A mediator will be:
 - 3.1. An experienced and skilled mediator, preferably with qualities or specialized knowledge that would be of assistance in the circumstances of the disagreement; and
 - 3.2. Independent and impartial.
- **4.** If the parties fail to agree on a mediator within 15 calendar days after commencement of a mediation, the appointment will be made by a neutral appointing authority on the written request of a party that is copied to the other.
- **5.** A mediator's appointment terminates if:
 - 5.1. The mediator withdraws from office for any reason; or
 - 5.2. The parties agree to the termination.
- 6. If a mediator's appointment terminates, a replacement mediator will be appointed using the procedure in sections 3 and 4 and the required time period commences from the date of termination of the appointment.
- 7. A party may attend a mediation with or without legal counsel.
- 8. If a mediator is a lawyer, the mediator must not act as legal counsel for any party.
- 9. At the commencement of the first meeting of a mediation, each party will advise the mediator and the other parties of any limitations on the authority of its representatives.
- 10. The parties will cooperate fully with the mediator and give prompt attention to, and respond to, all communications from the mediator.
- 11. A mediator may conduct a mediation in any manner the mediator considers necessary and appropriate to assist the parties to resolve the disagreement in a fair, efficient, and cost- effective manner.
- 12. Within seven calendar days of appointment of a mediator, each party will deliver a brief written summary to the mediator of the relevant facts, the issues in the disagreement, and its viewpoint in respect of them and the mediator will deliver copies of the summaries to each party at the end of the seven day period.

- 13. In order to assist in the resolution of a disagreement, a mediation will not be open to the public.
- 14. All information exchanged during the course of the mediation process shall be regarded as "without prejudice" communications for the purposes of settlement negotiations and shall be treated as confidential by the parties and their representatives unless otherwise required by law. However evidence that is independently admissible or discoverable shall not be rendered inadmissible or un-discoverable by virtue of its use during the mediation.
- 15. A mediator is not compellable in any proceeding to give evidence about any oral and written information acquired or opinion formed by that person as a result of the mediation, and all parties will oppose any effort to have that person or that information subpoenaed.
- 16. A mediator, or anyone retained or employed by the mediator, is disqualified as a consultant or expert in any proceeding relating to the disagreement, including any proceeding that involves persons not a party to the mediation.
- 17. A party may withdraw from a mediation at any time by giving written notice of intent to the mediator.
- 18. A mediation is terminated when any of the following occurs:
 - 18.1. The expiration of 30 calendar days after the appointment of the mediator, or any longer period agreed by the parties in writing;
 - 18.2. The parties have agreed in writing to terminate the mediation or not to appoint a replacement mediator;
 - 18.3. A party withdraws from the mediation; or
 - 18.4. The parties sign a written agreement resolving the issue or dispute.
- 19. If a mediation is terminated without the parties reaching agreement, the parties may agree to request the mediator to give a written non-binding recommendation for settlement, but the mediator may decline the request without reasons.
- 20. Within 15 calendar days after delivery of a mediator's recommendation, the parties will meet with the mediator to attempt to resolve the disagreement.
- 21. If the mediator declines the request to provide a recommendation, he/she shall issue a report in writing to the parties within 5 calendar days of the termination of the mediation, indicating that the issue or dispute has not been resolved.

Track B: Dispute Management Advisory Panel Process Rules

- 1. An advisory panel process commences on the date that the parties agree in writing to participate in an advisory panel process.
- 2. The panel shall be established in accordance with the mediation provisions of Track B and shall be composed of three members.
- 3. The panel members should be skilled and knowledgeable in the subject area of the dispute.
- 4. Within 10 calendar days from the date the parties agree to an advisory panel the complainant and Health Canada will each appoint one member to the panel.
- 5. The two appointed members shall together, within 5 calendar days after their appointment, select a third member to act as chairperson.
- 6. All panel members will accept their appointment and confirm their agreement to be bound by these guidelines in writing.
- 7. The appointment of a panel member terminates if:
 - 7.1. The panel member withdraws from the panel for reasons beyond his/her control;
 - 7.2. The appointing party terminates the appointment of the member it selected; or
 - 7.3. The complainant and Health Canada jointly agree to terminate the appointment of the chairperson.
- 8. If the appointment of a panel member is terminated or a panel member withdraws, a replacement member will be appointed by the same party that appointed the outgoing member.
- 9. Pending replacement, the panel's proceedings will be suspended unless otherwise agreed by the parties involved.
- 10. The panel members should be available to devote the time and energy required to conduct a panel reference and report to the parties involved in the dispute within 30 calendar days of their appointment.
- 11. The panel will:
 - 11.1. Review relevant facts;
 - 11.2. Identify points of agreement and disagreement;
 - 11.3. Meet with the disputing parties representative(s) together or separately to discuss and review the facts; and
 - 11.4. Provide non-binding advice and recommendations on how the dispute might be resolved.

- 12. The representatives of the disputing parties and the representatives of Health Canada will:
 - 12.1. Co-operate fully with the panel; and
 - 12.2. Give prompt attention to and respond to all communications from the panel.
- 13. The parties agree to provide the panel with the following information within 48 hours of the chairperson's selection:
 - 13.1. The name of their official representative(s); and
 - 13.2. A full description of the issue(s) in dispute.
- 14. The Panel shall make every effort to conduct its business and fulfil its obligations under its mandate, by consensus.
- 15. Within 30 calendar days of the panel's appointment the panel will provide a written report to the parties and the Minister.
- 16. The report shall identify the outstanding issues and provide non-binding advice and recommendations on how the dispute might be resolved.
- 17. Within 14 calendar days after receipt of the final written report of the panel, the parties may meet and make every effort to resolve the dispute taking into account the report of the panel and any other considerations.
- 18. The panel members, and parties involved in the dispute, will agree to keep confidential all oral and written information disclosed in the panel reference and the fact that this information has been disclosed unless otherwise required by law. However evidence that is independently admissible will not be rendered inadmissible or non-discoverable by virtue of its use during the panel process.
- 19. A member, or anyone retained or employed by the member, is not compellable in any proceeding to give evidence about any oral or written information acquired or opinion formed by that person as a result of the reference, and all parties will oppose any effort to have that person or that information subpoenaed.
- 20. A reference is terminated when any of the following occurs:
 - 20.1. The expiration of 14 calendar days after receipt of the final report of the panel, or any longer period agreed in writing by the parties involved;
 - 20.2. The parties involved in the dispute resolve the issue(s) in dispute; or
 - 20.3. Either party withdraws from the panel process.

Branch Contact Information

CFO and Minister of Health

Manager, Office of Revenue and Costing Departmental Planning and Financial Administration Corporate Services Branch, Health Canada Qualicum Building, Address Locator 3203D 2932 Baseline Road, 2nd Floor, Tower C, Room A200 Ottawa, Ontario K1A 0K9 Telephone: (613) 957-7324, Fax: (613) 957-2292

Health Products and Foods Branch

Human Drugs and Medical Devices

Director, Bureau of Operational Services Therapeutic Products Directorate Health Products and Food Branch Address Locator 3005D 5th Floor, Room 517, Holland Cross, Tower A 11 Holland, Ottawa, Ontario, K1A 0K9 Telephone: (613) 946-6586, Fax: (613) 941-3338

Veterinary Drug Products

Manager, Submission and Knowledge Management Division Veterinary Drugs Directorate Health Products and Foods Branch Address Locator 3000A Basement, Holland Cross, Tower A 11 Holland, Ottawa, Ontario, K1A 0K9 Telephone: (613) 957-3884, Fax: (613) 957-3861

Healthy Environments and Consumer Safety Branch

Workplace Health and Public Safety Program

Manager, Strategic Planning and Management Services Directorate Healthy Environments and Consumer Safety Branch Address Locator: 3709D

9th Floor, Vanguard Building, 171 Slater Street, Ottawa, Ontario K1A 0K9

Telephone: (613) 941-8625 / Fax: (613) 954-5822

Safe Environments Program

Director, Radiation Protection Bureau
Healthy Environments and Consumer Safety Branch
Address Locator: 6302A
2nd Floor, Radiation Protection Building
775 Brookfield Road, Ottawa, Ontario K1A1C1
Telephone (613) 954-6647 / Fax. (613) 952-9071

Pest Management Regulatory Agency

Application Fees:

Director, Submission Coordination Pest Management Regulatory Agency Address Locator: 6606D 2720 promenade Riverside Drive, Ottawa, Ontario K1A 0K9 Telephone: 613-736-3670, Fax: (613) 736-3666

Maintenance (Annual) Fees:

Director, Management Planning and Coordination Pest Management Regulatory Agency Address Locator: 6605C1 2720 promenade Riverside Drive, Ottawa, Ontario K1A 0K9

Telephone: 613-736-3411, Fax (613) 736-3410