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Health Canada External Charging Policy

REVISED: March 02, 2007



Prepared by:
Revenue and Costing Section
Financial Operations Directorate
Chief Financial Officer Branch
In conjunction with
Health Canada Committee on External Fees

Canada

Health Canada is the federal department responsible for helping Canadians maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

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HEALTH CANADA EXTERNAL CHARGING POLICY

1. Effective Date

- 1.1. This policy comes into effect March 02, 2007.

2. Definitions

- 2.1. See Appendix A for definitions.

3. Policy Objectives

- 3.1. The Health Canada External Charging Policy establishes Health Canada's framework for external charging by:
 - 3.1.1. Encouraging sound management practice through effective, responsive service delivery, and efficient use of the department's resources;
 - 3.1.2. Interpreting and clarifying the requirements defined by the *User Fees Act* (March 2004) and the Treasury Board Policy on *Service Standards for External Fees* (November 2004) in concert with the Health Canada External Charging Guidelines and Costing Methodology and Treasury Board's Guide to Costing;
 - 3.1.3. Promoting an equitable and consistent program funding approach within Health Canada by fairly charging for services that primarily benefit only specific individuals or groups; and
 - 3.1.4. Fostering an understanding that fees may be charged for goods and services offered by Health Canada.

4. Policy Statement

- 4.1. Health Canada Branches and Agencies must assess the suitability of introducing or updating fees as part of their overall funding strategy. This generally means assessing the need for charging fees based on the following criteria:
 - 4.1.1. Fees should be charged when activities falling within the mandate of the organization benefit identifiable external recipients (i.e., specific individuals or groups) more than the general public, unless analysis demonstrates that:
 - 4.1.1.1. The projected cost of introducing and managing a fee is more than its potential monetary and non-monetary benefits.
 - 4.1.1.2. A strong argument can be made for the federal government to fund the activity/ program from appropriations (i.e., tax revenues), on the grounds that introducing a fee would appreciably compromise program objectives or severely undermine a stated federal government commitment (e.g., adversely impact Canadians' equitable access to government services or support for designated industries, humanitarian objectives), and these effects could not be mitigated satisfactorily through fee exemptions or reductions.

5. Application

- 5.1. This policy applies to Health Canada, including all Branches and Regions, and the Pest Management Regulatory Agency. It applies to all fees, except those that fall within the “Exceptions” category (Section 6.3). It covers fees meeting the criteria of the *User Fees Act* and those established under authority of an Act of Parliament or ministerial contracting authority, and for both mandatory and optional transactions.

6. Policy Requirements

6.1. General Requirements

- 6.1.1. Programs must assess the potential for recovering all identifiable costs incurred in providing a product or service. The recovery of less than all identifiable cost may be justified on policy, program or administrative grounds.
- 6.1.2. Few fees generate enough revenue to cover all identifiable costs of the associated departmental activities, but the fees should generate revenue to the extent possible to cover all identifiable cost; taking into account departmental objectives, such as availability of products and regulatory compliance and broader government objectives, such as the innovation agenda, and protecting small business. Any net voted revenue shortfall as a result of collecting less than all identifiable costs must be covered by the appropriation.
- 6.1.3. All Treasury Board submissions requesting appropriation funding must include an indication that fees have been considered and, if fees are appropriate, an estimate of the revenue potential and how and when they will be implemented.
- 6.1.4. Proposals to introduce or amend fees must be supported by the best available information—on rationale, costs, current service levels and service commitments, relevant comparators, the proposed fee approach, and the expected impact on fee payers and non-payers and any measures proposed to mitigate these impacts.
- 6.1.5. The information identified in paragraph 6.1.4 must be communicated in an open and transparent manner to both fee payers and non-payers, who must be given a reasonable opportunity to provide input, such as suggestions on how to make the service more efficient or effective (i.e. process improvement, alternative service delivery). The department must give these suggestions due consideration.
- 6.1.6. A timetable for periodic review of the fee must be established at the time of introducing or amending the fee to ensure its continuing viability and appropriateness.
- 6.1.7. Where the legislation under which a fee is amended or implemented allows, consideration must be given to establishing and including rules for future adjustment (ex. inflationary factors), including rates and time periods.
- 6.1.8. All fees collected are public monies governed by the *Financial Administration Act*. To spend fee revenues, a department must have express legal authority or prior Treasury Board approval (e.g., net voting authority).

- 6.1.9. User fees may be set under the following authorities:
- 6.1.9.1. Service agreement by virtue of the Minister of Health's inherent authority to contract;
 - 6.1.9.2. *Financial Administration Act*; and
 - 6.1.9.3. *Department of Health Act*.
- 6.1.10. Fees can be set through a service agreement by virtue of the Minister of Health's inherent authority to contract where the service is not mandatory and the other party is entering into a free and willing contract. Fees established in this manner are not subject to the legal requirements of the *User Fees Act* but are subject to the Treasury Board Policy on Service Standards for External Fees.
- 6.1.11. Fees established by service agreement must be published in a notice in the *Canada Gazette, Part 1*, to notify stakeholders of the fees.
- 6.1.12. Under the authority of the *Financial Administration Act*, the Governor in Council, on the recommendation of the Treasury Board, may by regulation prescribe the fees to be paid for a service, the use of a facility, or a right or privilege. Such fees are subject to the legal requirements of the *User Fees Act*.
- 6.1.13. Under the authority of the *Department of Health Act*, the Minister of Health may fix the fees to be paid for a service, the use of a facility or in respect of products, rights and privileges. Such fees are subject to the legal requirements of the *User Fees Act*.
- 6.1.14. Proposals for fees subject to the legal requirements of the *User Fees Act* must be tabled in each House of Parliament detailing:
- 6.1.14.1. The service, product, regulatory process, facility, authorization, permit or license for which the fees is being proposed;
 - 6.1.14.2. The reason for any change in user fee rate;
 - 6.1.14.3. The service standards as well as performance levels attained;
 - 6.1.14.4. Estimates of amounts to be collected in the first three years and the costs the fee will cover;
 - 6.1.14.5. Description of the establishment of an independent advisory panel and how complaints were dealt with; and
 - 6.1.14.6. Reasons if user fees are higher than those existing in comparable countries.
- 6.1.15. When a program has several types of legal authorities that can establish or amend fees (e.g., the *Department of Health Act*, *Financial Administration Act*), legal advice on the appropriate option should be sought.
- 6.1.16. Fees will be based on either the cost of the service and activity, or the value of the right and privilege obtained by the identifiable external recipients. Fees for voluntary activities under the authority of the Minister's right to enter into contracts may be designed to recover more than the full cost of providing the service but the decision to do so must be warranted and defensible.

6.2. Specific Requirements

- 6.2.1. Ultimate responsibility for decisions to establish or amend fees rests with the Minister, within the context of the relevant legal authorities and the requirements of the User Fees Act (UFA) and the Policy on Service Standards for External Fees. This includes the legislative responsibility to submit proposals before Parliament for new or amended fees that meet the definition of the User Fees Act, and to report user fee information annually.
- 6.2.2. The Minister is also ultimately responsible for ruling on disputes over existing fees. Disputes over existing fees should be resolved, if possible, at the Branch and Agency level; however, if unresolved, these disputes are then administered via the Departmental Complaint Resolution and Dispute Management Process.
 - 6.2.2.1. The Departmental Complaint Resolution and Dispute Management Process is a tiered process, which includes an independent advisory panel to consider complaints about fees, performance standards, consultation, and pricing. This process complements the statutory panel process set out in s. 4.1 of the *User Fees Act*, which must be used in the event complaints arise with respect to new or amended fees.
- 6.2.3. Branch heads are responsible for initiating fee proposals and the related analysis. To demonstrate sound management and accountability, Health Canada programs must consult with both paying and non-paying stakeholders on all aspects of proposals to introduce or amend fees. These consultations should cover:
 - 6.2.3.1. Rationale to justify fees;
 - 6.2.3.2. Costing methodology;
 - 6.2.3.3. Fee structure and revenue expectations;
 - 6.2.3.4. Impact of the proposed fees on fee payers and non payers;
 - 6.2.3.5. Mechanisms to mitigate negative impacts of fees, if applicable;
 - 6.2.3.6. Services to be delivered;
 - 6.2.3.7. Service standards; and
 - 6.2.3.8. Dispute resolution mechanisms
- 6.2.4. The Chief Financial Officer has been designated as the Departmental Champion for External Charging in accordance with the Treasury Board Policy on Service Standards for External Fees.
 - 6.2.4.1. Responsibilities of the Departmental Champion include:
 - 6.2.4.1.1. A challenge role relative to the overall merits of fee proposals;
 - 6.2.4.1.2. Sign-off on the financial viability of fee proposals; and
 - 6.2.4.1.3. Oversight on tracking and reporting as required under the *User Fees Act* (Section 7) and the Policy on Service Standards for External Fees, including accuracy of performance data against service standards on which fee reductions under Section 5.1 of the *User Fees Act* apply
- 6.2.5. Roles and responsibilities for this policy are further defined in Appendix B.

6.3. Exceptions

6.3.1. The policy does not apply to the following types of transactions:

- 6.3.1.1. Transactions between Health Canada and other governmental jurisdictions;
- 6.3.1.2. Real property transactions that are incidental to the department's core services;
- 6.3.1.3. Arrangements or accords negotiated with foreign governments, or international organizations (e.g., the United Nations, the North Atlantic Treaty Organization);
- 6.3.1.4. Transactions subject to the objectives and provisions of other, more specific federal policies and instruments applicable government-wide. These include:
 - 6.3.1.4.1. Transactions between departments and federal employees as part of collective agreements or terms and conditions of employment (e.g., parking, clothing, uniforms, housing);
 - 6.3.1.4.2. Real property transactions covered by the *Federal Real Property and Federal Immovable Act* and Federal Real Property Regulations.
- 6.3.1.5. The pricing of publications (which is subject to the Communications Policy of the Government of Canada);
- 6.3.1.6. Access to and disposition of Crown assets;
- 6.3.1.7. Royalties arising from Crown-owned intellectual property;
- 6.3.1.8. Transfer payments (e.g. grants or contributions); and
- 6.3.1.9. Fines or penalties.

7. Monitoring

- 7.1. Health Canada's fee activities are monitored by the program and through regular reviews, by the Audit and Accountability Bureau and the Departmental Performance Measurement and Evaluation Directorate and by sign-off by the Chief Financial Officer.
- 7.2. The revenues derived from all external fees, along with information on costs, dispute management, results of any fee consultations, service standards and actual results against them, should be clearly disclosed on program websites and must be reported in the Minister's annual report to Parliament (See Section 7 of the *User Fees Act* and/or the Policy on Service Standards for External Fees).
- 7.3. A full review of this policy, including an evaluation of its success in achieving the stated objectives, will be initiated within three years of its implementation.

8. References

User Fees Act (March 2004)

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

Financial Administration Act

Department of Health Act

9. Enquiries

- 9.1. Additional details on all aspects of this policy are provided in the Guidelines. Enquiries on the Policy or Guidelines should be directed to:

Revenue and Costing Section
Chief Financial Officer Branch
rsc_src@hc-sc.gc.ca
Tel: (613) 952-9936
Fax: (613) 957-7759

APPENDIX A - Definitions

Benefit

Benefit is the value of products, services, rights or privileges, access to or use of government-owned and controlled resources and assets, received by identifiable external individuals or groups.

The client or groups of clients paying the fee receives a benefit that is either unique to that client or distinct from and greater than benefits that could also accrue to any other person or business as a result of that user fee being paid.

Examples of benefits to fee payers include economic benefit from regulatory activities in the form of reduced risk and liability, improved market access for products or services, enhanced credibility as suppliers and enhanced public confidence in the industry sector and its products.

Department

“Department” refers to organizations within Health Canada, including Branches and the Pest Management Regulatory Agency.

Direct Activities

Direct activities are those Program activities fully committed to the provision or delivery of service, such as inspection, licensing, laboratory analysis, investigation, and pre-market submission review. For clarity, policy and regulatory development/maintenance are considered direct activities.

External Charging

External charging refers to fees that result in non-tax revenues generated by selling goods, regulatory and non-regulatory services, or rights and privileges, both in Canada or abroad, to identifiable individuals or groups external to Health Canada. Fees charged to other government jurisdictions and federal government employees are excluded from this definition.

External charging differs from taxation in a fundamental way. Taxes are used in ways that benefit all taxpayers more or less equally. Fees are charged in order to recover all or a portion of the cost of the services that primarily benefit only specific individuals or groups.

Indirect Activities

Indirect activities are not direct activities but are those performed in support of direct activities, including management, supervision, training, human resources, finance, administration, accommodation, purchasing, planning and information management & technology. Indirect activities are included in the development of a fee.

Identifiable Costs

Identifiable costs are those that can be clearly identified as being in support of an activity or service and incorporate direct and indirect costs as well as any relevant costs incurred by other departments.

Identifiable External Recipients

All individuals, groups or entities not defined as part of government jurisdictions are considered “external” recipients.

“Identifiable recipients” are those who can be reasonably viewed as distinct from the general public and who derive a benefit from a specific service or good provided by the department.

Net Voting

Net voting is an alternative means of funding selected programs or activities wherein Parliament authorizes a department to apply revenues towards costs incurred and votes the net financial requirements (estimated total expenditures minus estimated revenues).

Performance Measurement

Performance Measurement is the design, implementation and use of quantifiable indicators to judge success.

Privilege

Privilege is defined as a prerogative, entitlement, due, advantage or benefit that is conditional on a factor or series of factors.

Recoverable and Non-Recoverable Activities

Recoverable activities are those direct activities and indirect activities whose costs are appropriate for recovery through fees. They provide potential fee payers with benefits, such as licenses, regulatory approval, or other services.

Non-recoverable activities are those direct activities and indirect activities for which it is inappropriate to recover costs since they result from Health Canada obligations that are carried out regardless of specific external clients, such as international obligation and cooperation, maintenance of legislation and regulations, government cooperation, provision of information, and support for the internal machinery of government.

Regulatory Process

An instance in which the government has passed legislation or regulations directed at a particular industry, product or activity, which creates a system that must be adhered to by those participating in the regulated industry or activity.

Right

A Right is defined as an authority, power or permission that is not revocable or amendable except under extraordinary circumstances using extraordinary measures.

Service Standards

Description of delivery targets that provides aspects of service supplied (e.g., access, timeliness and accuracy, etc.) in which the stakeholders should expect, including the way that the services will be delivered.

Stakeholder

Stakeholders are all external parties with an interest in a federal program. This includes paying users and their associations, as well as individuals and groups who have an interest in the core functions or activities of the program.

User Fees

The term “user fees” refers to fees, charges or levies resulting in non-tax revenues for a product, regulatory process, authorization, permit, licence, facility or service provided only by the Department, which is fixed pursuant to an Act of Parliament and which provides a direct benefit or advantage to a client or group of clients that is unique to that client or group of clients or greater than the benefits or advantages accruing to others.

APPENDIX B – Roles and Responsibilities

1. Assistant Deputy Ministers, Program Branches are responsible for:

- 1.1. Considering external fees as an alternative source of funding;
- 1.2. Identifying opportunities for establishing/updating fees and proposing the fees to be levied with the appropriate fee structure;
- 1.3. Contacting the Chief Financial Officer Branch for guidance on costing, the overall external fee management process, Departmental Performance Reporting requirements and the implications of user fee legislation and related policy;
- 1.4. Submitting an impact analysis to introduce fees, or to increase or reduce existing fees, to the Chief Financial Officer and the Departmental Executive Committee for their concurrence. When the proposed fee is less than all identifiable cost associated with the activity or service, rationale must be included in the impact analysis. The sponsoring ADM may wish to obtain preliminary agreement from the Departmental Executive Committee prior to engaging in extensive public consultations;
- 1.5. Preparing the User Fee Proposal (See <http://www.tbs-sct.gc.ca/fin/euf-fue/documents/TemplateforTabling.rtf>) for tabling new fees or increases to existing fees, which meet the criteria of the *User Fees Act*, before Parliament;
- 1.6. Seeking sign-off from the Chief Financial Officer on the financial viability of fees and the annual information required by central agencies or Parliament to be reported in the Departmental Performance Report and from the Departmental Champion for External Fees on fee related documentation to be published on the Health Canada website;
- 1.7. Publishing relevant information related to fees on the Health Canada website or by other appropriate means that will reach relevant stakeholders;
- 1.8. Attempting to resolve disputes on existing fees within 90 calendar days from the date of referral to the branch level;
- 1.9. Establishing an independent advisory panel to address any potential complaints submitted by a stakeholder regarding a proposed fee change when the fee is subject to the *User Fees Act*;
- 1.10. Reducing fees established pursuant to the *User Fees Act* in situations where performance standards are not met, in accordance with Section 5.1 of the Act; and
- 1.11. Maintaining detailed documentation on fee-related consultations, costing, forecasts, development of service standards and performance measurement for complete reporting and to assist managers in defending fees when necessary.

2. The Chief Financial Officer, Chief Financial Officer Branch and the Health Canada Champion for External Fees is responsible for:

- 2.1. Developing the departmental policies, guidelines and procedures for external fees and related costing to establish a standardized approach across the Department, while allowing reasonable flexibility for programs;
- 2.2. Providing ongoing advice and guidance to programs in support of their fee activities;
- 2.3. Ensuring that alternate sources of funding have been considered as part of funding requests;
- 2.4. Performing a challenge role on the overall merits of fee proposals and reviewing, advising and signing off on the financial viability of fees;
- 2.5. Representing the Department in discussions with central agencies on external charging and related costing;
- 2.6. Implementing a monitoring program to ensure that the quality of standards, costing, performance against standards and continuing cost effectiveness of each fee are independently reviewed periodically in order to ensure good management practices throughout the life of each fee;
- 2.7. Reviewing and approving fee-related material for publication on the Health Canada website;
- 2.8. Reviewing and approving annual fee-related information required by central agencies or Parliament to be published in the Departmental Performance Report;
- 2.9. Responding to requests for dispute resolution on existing fee issues (following unsuccessful branch attempts to resolve disputes) within 30 calendar days of receipt of the request for CFO review;
- 2.10. Overseeing the reduction of a fee established pursuant to the *User Fees Act* in situations where performance standards are not met, in accordance with Section 5.1 of the *Act*;
- 2.11. In conjunction with program ADMs, establishing a contingent financial plan to be implemented in the event that fees have to be reduced for non-performance;
- 2.12. Ensuring that an infrastructure is in place to support the planning, recording, processing and reporting of approved fee related activities; and
- 2.13. Periodic evaluations of the performance of the External Charging Policy and related programs, initiatives and functions;

3. Audit and Accountability Bureau is responsible for:

- 3.1. Periodic audits of departmental fee activities as part of the audit program.

4. Legal Services is responsible for:

- 4.1. Legal interpretation on the relevant legislative authority applicable to the introduction of a new fee; and
- 4.2. Advice and interpretation on the steps required in the tabling of a User Fee Proposal in Parliament or in situations requiring Governor-in Council approval.

5. Public Affairs, Consultation and Regions Branch is responsible for:

- 5.1. Providing advice and guidance on external communications and consultation relative to the establishment/amendment of fees.

6. Departmental Executive Committee is responsible for:

- 6.1. Approving departmental policies related to External Charging and Costing; and
- 6.2. Approving impact analysis on establishing/amending fees prior to tabling in Parliament.

