

MEMORANDUM TO CABINET COMMITTEE ON EDUCATION AND HEALTH

HEALTH AND DISABILITY COMMISSIONER AMENDMENT BILL: PROPOSALS TO STREAMLINE COMPLAINTS PROCESSES

PROPOSAL

1. I propose to amend the Health and Disability Commissioner Act 1994 to enable the streamlining of complaints processes for health and disability services consumers. I also propose an amendment to the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996 to make the informed consent provisions for the storage, preservation and utilisation of body parts more practicable.

EXECUTIVE SUMMARY

2. Currently there are three main avenues through which complaints are made by health and disability services consumers. They are the Health and Disability Commissioner (HDC), registration bodies and the Accident Compensation Corporation (ACC). In many cases this creates confusion for consumers about who to lodge a complaint with, and how. This paper proposes a number of amendments to the Health and Disability Commissioner Act 1994. These amendments will improve the assessment, investigation, and resolution of complaints from health and disability consumers. The proposals take into account the recommendations in Robyn Stent's *Review of the Health and Disability Commissioner Act 1994* (October 1999), the Cull Report on *Review of Processes Concerning Adverse Medical Events* (March 2001), and the *Ministerial Inquiry Into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region* (April 2001).
3. I propose to amend the Health and Disability Commissioner Act 1994 to improve the streamlining of complaints processes for health and disability services consumers (as outlined in Appendix 1 to this paper). The proposed changes include:
 - Giving the HDC more flexibility to assess complaints and refer them to the appropriate registration body, provider, or other agencies;
 - Giving the HDC the power to delegate the writing of reports and recommendations to the Deputy Commissioner(s); and
 - Developing statutory provisions regarding the disclosure and sharing of information on complaints and medical misadventure claims between the HDC, the registration bodies, ACC, and the Ministry of Health on the grounds of public safety.

4. I also propose an amendment to the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996 to make the informed consent provisions for the storage, preservation and utilisation of body parts more practicable.
5. The proposals are aimed at simplifying the complaints process by giving the HDC the power to refer complaints directly to the appropriate investigation body (eg, the Medical Council, the ACC etc), without having to complete an investigation first. This will improve the timeliness of investigations by the appropriate agency. The implementation of legal obligations and protocols between the HDC, the registration bodies, ACC, and the Ministry of Health regarding the sharing of information on medical misadventure claims and consumers' complaints should mean that issues regarding the competence of health professionals or concerns regarding public safety should be identified and followed-through more quickly than is presently the case. The agencies intend developing joint education programmes to ensure that consumers are aware of the respective roles of each agency and their rights to complain or seek compensation in relation to a health and disability service that they have received.
6. It is anticipated that the HDC Amendment Bill will form part of a proposed Comprehensive Bill aimed at improving consumer safety in the health and disability sector. The Bill will include: new legislation governing the regulation of health professionals (a Health Professionals Competency Assurance Bill); amendments to the Health Act 1956; amendments to the Medicines Act 1981; and the amendments proposed in this paper. The proposed Comprehensive Bill has a proposed priority 4, which requires a draft Bill to be referred to Select Committee before the end of 2001. The proposals in this paper are consistent with recommendations in the accompanying paper on the Health Professionals Competency Assurance Bill – complaints and discipline provisions.

BACKGROUND

The Cull Report

7. In March 2001, Helen Cull, QC completed a report for the Minister of Health, *Review of Processes Concerning Adverse Medical Events*, which recommended a number of procedural, legislative and regulatory changes aimed at streamlining the current complaints mechanisms. The changes primarily relate to the HDC Act 1994 and the Medical Practitioners Act 1995. Helen Cull, QC's proposals include:
 - A need for the HDC to have greater flexibility in dealing with complaints.
 - Making the HDC the repository of all complaints about breaches of the Code of Health and Disability Services Consumers' Rights, guilty findings of the Medical Practitioners Disciplinary Tribunal, medical error findings from ACC and medical mishap claims where health or public safety is at risk.
 - Compulsory reporting of medical practitioners who are believed to be practising below an acceptable standard.
 - The suspension of medical practitioners prior to the laying of a disciplinary charge.

- A single disciplinary tribunal for all health professionals.
 - Legislative obligations on ACC, the HDC, and the Medical Council to share and disclose information on the grounds of public safety.
 - A long-term solution of a "one-stop shop" approach to complaints and streamlining remedies.
8. The Ministry of Health undertook public consultation on the Cull Report between March and May 2001. Fifty-one submissions were received. The majority of submissions agreed that the current complaints processes could be better streamlined and supported many of Helen Cull's proposed amendments to the Medical Practitioners Act 1995 and the Health and Disability Commissioner Act 1994. Just over half of the submissions supported a "one-stop shop" for complaints. Those submissions that did not support the "one-stop shop" proposal indicated that improved co-ordination and information sharing between the HDC, ACC and Medical Council would still achieve the purpose of improving the timeliness and appropriateness of investigations about health and disability services. Furthermore, those submissions indicated that a "one-stop shop" for handling complaints could in fact increase time delays and confuse the respective roles of the HDC, ACC and the registration bodies.

The Stent Review

9. Section 18 of the HDC Act 1994 requires the HDC to review the operation of the HDC Act 1994 as soon as practicable after the Act has been in operation for three years, and to make recommendations to the Minister about any changes that should be made. In February 1999, Robyn Stent, the then HDC, based on her own experiences with the operation of the legislation and feedback from providers, consumers and others, prepared and circulated a discussion document to the health and disability sector. Extensive consultation was undertaken with the sector and public. Over 3600 copies of the consultation document were distributed and public meetings and focus groups were also held. Over 200 submissions were received. Following consultation, Robyn Stent modified her original recommendations, and presented her final report to the Minister of Health in October 1999.
10. Robyn Stent's final recommendations included:
- Changes to definitions
 - Making advocates employees of the HDC
 - Changes to the way that complaints are referred to other jurisdictions so that complaints can be dealt with in a more timely manner
 - Clarification of the discretionary nature of some of the HDC's powers, including the HDC's power to take further action where investigation recommendations are not adhered to by providers
 - Wider access for consumers to the Complaints Review Tribunal
 - The abolition of the Director of Proceedings
 - The removal of redundant sections of the Act (eg, references to the development of the Draft Code of Health and Disability Services Consumers' Rights).

11. Submissions indicated strong support for changes aimed at improving the flexibility of the HDC's role in facilitating the fair, simple, speedy and efficient resolution of complaints. There were, however, diverse views on the recommendations concerning changes to the employment of advocates and the role of, and need for, a Director of Proceedings. These two recommendations are not supported by the current HDC or myself so are not discussed in further detail in this paper.
12. Section 21 of the HDC Act requires the HDC to review the Code of Health and Disability Services Consumers' Rights, at three-yearly intervals, and to make recommendations to the Minister of Health. Robyn Stent consulted on recommended changes to the Code in conjunction with her review of the HDC Act. Although, Robyn Stent recommended a number of changes in her discussion document, following the analysis of submissions, she recommended to the Minister of Health that there be no change to the Code at this time. Robyn Stent noted that while a number of technical improvements to the Code could be made, she did not consider that any of these were sufficiently significant to warrant immediate amendment. Many submissions on the Code indicated that, taken as a whole, the existing rights of the Code are satisfactory.

Ministerial Inquiry Into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region

13. Consistent with the recommendations in the Cull Report and the Stent Review, the *Ministerial Inquiry Into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region* recommended, amongst other things, that there should be a legal obligation on ACC, the Medical Council and the HDC to inform the National Cervical Screening Programme's manager of complaints received about the professional performance of providers to the Programme and the treatment of a patient in relation to the Programme.

COMMENT

What are the problems that need to be addressed?

14. The Cull Report and the Stent Review identified a number of problems with the current complaints mechanisms. These problems include difficulties accessing the appropriate complaint mechanisms, time delays, multiple investigations, lack of agency interaction, and dissatisfaction with the ACC entitlements. These concerns indicate a need to improve: the simplicity of the complaints processes for consumers and to educate consumers on these processes; the timeliness of completing investigations; case management of consumers' complaints; and information sharing between agencies.

The assessment and referral of complaints

15. The Cull Report recommended that all complaints about health and disability services, including complaints that currently go to providers and ACC, should be referred to the HDC for assessment and subsequent referral to appropriate bodies. I agree, with the exception of complaints that currently go to providers. I do not consider it practicable for the HDC to receive all complaints from health and disability consumers that presently go to District Health Boards (DHBs) and providers. The objective of the HDC Act 1994 and Code of Health and Disability Services Consumers' Rights is to facilitate the fair, speedy and efficient

resolution of complaints relating to the infringement of those rights, at the lowest appropriate level. If a provider is able to resolve a complaint to a consumer's satisfaction, it does not seem sensible to add another step in the process, by referring the complaint to the HDC. DHBs and providers are already legally required under the Code to advise consumers that they may also make a complaint to the HDC. If a provider notices disturbing trends concerning the number or nature of complaints about a health professional, the provider should be required to share this information with the HDC.

16. The Ministry of Health consulted a sample of DHBs about their current complaints processes, and the number and nature of complaints resolved at the provider level. The DHBs indicated a wish to retain their current role in receiving, investigating and resolving complaints, as this is one of their obligations to consumers. Complaints also inform DHBs about issues and trends that need to be addressed in delivering health and disability services, and contribute to improvements in the quality and effectiveness of services. The DHBs noted that many of the complaints received are not about the health and disability services that consumers have received, but other issues such as the quality of the hospital food, waiting times, or complaints from providers about contractual issues. Over half of the DHBs resolve 70% of complaints within a month of receipt (compared to 34 weeks for the HDC's office). On average, the HDC receives 1,400 complaints a year. If the HDC's office was to investigate all complaints that currently go to DHBs, the number of complaints considered by that office would amount to an extra 9,000 complaints a year. This would have significant resource implications for the HDC's office. There is a risk that the HDC could become "bogged-down" with minor or inappropriate complaints, even taking into account proposals later in this paper to increase the HDC's discretion in referring complaints to other agencies. This view was supported by submissions on the Cull Report, which raised concerns about the HDC's office becoming overworked, resulting in more delays, and little improvement in the resolution of complaints. I therefore propose that DHBs and other providers continue to resolve complaints.

HDC to assess all complaints received

17. Taking into account the views expressed by DHBs and discussions with the HDC, ACC, Department of Labour, and Ministry of Health, I propose that the HDC be required to:
 - assess all complaints that he receives from health and disability consumers about potential breaches of the Code (within one to two weeks of receipt); and
 - refer complaints regarding potential medical misadventure claims to ACC; and
 - refer complaints regarding competence or fitness to practise issues and complaints about inappropriate behaviour (eg, fraud, breach of ethical standards) to the registration bodies;
 - refer complaints to other agencies, such as the Ministry of Health, as appropriate, where there are public safety or organisational concerns.

The respective agencies' role in processing complaints is depicted in Appendix 1. In some cases ACC and the registration boards will also receive complaints that require referral to the HDC.

The investigation of complaints

Respective jurisdictions of the agencies

18. Helen Cull proposed, in the long term, that a single agency should not only assess complaints, but investigate and resolve complaints. Whilst I have proposed that the HDC should assess all health and disability consumers' complaints that he receives, I do not consider it practicable for the HDC's office to investigate medical misadventure claims or professional issues. These issues are the prerogative of ACC and the professional bodies. Helen Cull also commented on multiple investigations by separate agencies. The purpose of the HDC, ACC and the registration bodies are distinct and therefore require separate investigations. Proposals later in this paper acknowledge the need to improve the co-ordination of investigations.

ACC

19. The purpose and philosophy underpinning ACC investigations is substantially different to HDC investigations. ACC provides "no fault" compensation for people who suffer personal injury. The scheme is an entitlement-based scheme where people cannot sue for damages for personal injury, including personal injury caused by medical misadventure. Because the scheme is founded on "no fault" principles ACC does not set out to apportion blame, simply to determine whether an injury has taken place that has cover under the Accident Insurance Act 1998¹. The HDC investigations focus on resolution of complaints where there have been breaches of the Code of Health and Disability Services Consumers' Rights. This resolution may include disciplinary proceedings against a health professional, an apology to the consumer, and the awarding of damages by the Complaints Review Tribunal to cover pecuniary loss, loss of benefit, humiliation etc. In cases of medical error² there will, however, be a link between the HDC and ACC regarding investigations, as medical error constitutes a breach of Right 4 of the Code in relation to providing a service of an appropriate standard.

20. Helen Cull's report did not acknowledge that a number of operational and legislative initiatives are being, or have been, implemented that will contribute to improvements in processing medical misadventure claims. These include:

- Reducing the claims processing ratio from 120 to 80 claims open at any one time for each claim assessor.
- Proposals in the Injury Prevention and Rehabilitation Bill to reintroduce the use of precedents for determining cover for medical mishap³.

¹ The Injury Prevention and Rehabilitation Bill currently before the Select Committee will replace the Accident Insurance Act 1998.

² Medical error is defined under the Accident and Insurance Act 1998 as the failure of a health professional to observe a standard of care. Cover is provided for all medical error, regardless of rarity or severity.

³ Medical mishap means an adverse consequence of treatment when the treatment is given properly, the adverse consequence is suffered by the claimant, the adverse consequence is severe, and the likelihood that the adverse consequence is rare.

- Continuing to educate and inform health providers about medical misadventure claims.
 - Establishing protocols for sharing information with the HDC and the Medical Council and formalising referrals to more appropriate agencies as part of ACC's advice.
 - Provisions in the Injury Prevention and Rehabilitation Bill relating to information sharing with hospitals, the HDC and professional bodies.
 - Ongoing improvements to claims processing to reduce the duration for decisions on complicated claims.
 - The extension of medical error under the Injury Prevention and Rehabilitation Bill to cover systemic and organisational failure.
21. Given the different purposes of ACC and the HDC, and ACC's initiatives, I propose that the HDC continue to investigate complaints about breaches of the Code of Health and Disability Services Consumers' Rights, and ACC continue to investigate medical misadventure claims.

Registration bodies and disciplinary tribunal

22. The accompanying paper on complaints and discipline under the proposed Health Professionals Competency Assurance Bill explains in more detail the role of the registration bodies and a multi-disciplinary tribunal in relation to complaints. In brief it is proposed that:
- The registration bodies be responsible for: registering health professionals; undertaking reviews of competence and fitness to practise; and investigating complaints about inappropriate behaviour (eg, fraud, breach of ethical standards)
 - An independent multi-disciplinary tribunal be established to consider disciplinary issues for all registered health professionals.

Duration of investigations

23. Since Helen Cull completed her report, the HDC has considerably cut down the time that it takes to complete investigations. The average time taken by the HDC to investigate a complaint has decreased from 44 weeks to 34 weeks. Only 23% of complaints remain open after 12 months in 2000/2001 compared to 37% in 1999/2000. The average duration for ACC decisions on accepted medical error claims is 44 weeks. The HDC and ACC currently share medical expertise in terms of their investigations and there is more scope for this to develop. The concerns by Helen Cull about the duration of investigations, should be addressed by providing the HDC with more flexibility in assessing and referring complaints to other appropriate agencies, the sharing of information by agencies, and actual improvements in the time taken to complete investigations by ACC and the HDC.

The sharing and retention of information

24. The Cull Report did not acknowledge the proactive information sharing that takes place between ACC, the HDC, registration bodies and the Ministry of Health. To avoid any doubt about this exchange happening in practice, I propose that the registration bodies, the HDC, ACC and the Ministry of Health

be legally required to share information. Such a requirement is proposed under the Injury Prevention and Rehabilitation Bill and the Health Professionals Competency Assurance Bill. I propose that the HDC Act be similarly amended to require the HDC to share relevant information with the ACC, registration bodies, and the Director-General of Health, during an investigation where there is the risk of harm from the practice of a health professional or systemic or organisational practice, or where there are likely to be compensation issues. These proposals are consistent with the Gisborne Cervical Screening Inquiry's recommendation that there be a legal obligation on ACC, the Medical Council, and the HDC to advise the National Cervical Screening Programme's manager of complaints about the professional performance of providers made to those various organisations about the treatment of a patient in relation to the Programme.

25. Specifically, in relation to ACC, it is proposed that:

- Claimants continue to lodge medical misadventure claims directly with ACC (although this would not preclude claims being referred by the HDC's office if they are received by him).
- Where the HDC considers a complaint about an alleged breach of the Code might also be a complaint involving medical misadventure he refer the complaint to ACC and advise the complainant that they may wish to pursue a medical misadventure claim directly with ACC.
- ACC refer information on all accepted medical error claims to the HDC as they are likely to involve breaches of Right 4(1) of the Code, which states "*Every consumer has the right to have services provided with reasonable care and skill*" (see footnote 2). Following the completion of all medical error investigations, regardless of whether the error claim is substantiated or not, ACC advises the claimant of their right to make a complaint to the HDC about the health and disability service they received.
- ACC refer information on medical mishap trends to the HDC and the relevant registration bodies. If, for example, a number of medical mishap claims concerning the same medical practitioner were accepted by ACC, this would raise concerns about the competence of that medical practitioner.

Retention of information

26. I propose that the HDC retain information on complaints about breaches of the Code of Health and Disability Services Consumers' Rights, the registration boards and councils be the main repository of information on health professionals, and ACC retain information on medical error claims and medical mishap claims. I also propose that the HDC have the power to access information held by a registration body on a case-by-case basis. Some of the information relating to breaches of the Code of Health and Disability Services Consumers' Rights may be derived from significant competence issues (referred from registration bodies), and medical error claims and trends analysis of medical mishap claims referred by the ACC. Where the HDC refers a complaint to another agency, the other agency would have a legal obligation to inform the HDC of the outcome of the referral. These proposals are supported by the recommendations and submissions on the Cull Report and the Stent Review.

A single database for all complaints about a health and disability service

27. Helen Cull proposed a single database of information on all health and disability services complaints regarding breaches of the Code of Health and Disability Services Consumers' Rights, guilty findings of the Medical Practitioners Disciplinary Tribunal, medical error findings from ACC and medical mishap claims where health or public safety is at risk. Submissions on the Cull Report were divided. Some considered a single database would provide valuable information for analysis of adverse events and causes leading to them. Others considered it was unacceptable to store unsubstantiated allegations, that such a database would be unwieldy, and would duplicate information already held by the more appropriate bodies, such as the registration boards.
28. At present, ACC, the HDC, the Ministry of Health, registration bodies and DHBs have their own databases for the purposes of recording the outcomes of complaints and medical misadventure claims that fall within their respective jurisdictions. The HDC, ACC, the registration bodies, and the Ministry of Health share much of the information collected. This includes: copies of the HDC's opinions; monthly reports by ACC on medical error and mishap findings; registration boards' reviews of competence and fitness to practise; and disciplinary findings.
29. Officials from the Ministry of Health, ACC and the Department of Labour consider that a single database would not necessarily improve the current and proposed information sharing requirements between the different agencies. Databases such as this are valuable only if they do what they are set up to do and information is used for the public good. There would be significant resource implications in establishing such a database. In addition, such a database would include many complaints that would be "minor" in nature and unlikely to flag a potential public safety risk in relation to a particular health professional. The database would contain at least 15,000 complaints per annum.
30. In my view, better education to consumers about the respective roles of the different agencies, including that all complaints should be made to the HDC for assessment, and improved information sharing, are likely to achieve better results than having a single database of complaints. Collaborative approaches to investigating complaints should ensure that concerns about health professionals who pose a risk to public safety, or potential systems problems, are identified. The option of a database that included only major complaints could, however, be explored further by officials.

Education

31. Consistent with my comments above, ACC, the HDC and some registration bodies have discussed the development of education programmes for consumers and health professionals on the respective roles and functions of each jurisdiction and how these can be accessed. The education programmes would make it clear to consumers that, in the first instance, they should lodge their complaints with the HDC. The Ministry of Women's Affairs notes that the education programmes should, in particular, include information about the role of advocacy services.

Proposed amendments to the Health and Disability Commissioner Act 1994 to provide the HDC with more flexibility in dealing with complaints

32. The Cull Report and the Stent Review suggest a number of technical and procedural changes to the HDC Act 1994, which are aimed at giving the HDC more flexibility to facilitate the fair, speedy and efficient resolution of complaints. Some of these have been discussed in the preceding sections and are repeated here for the sake of completeness. In particular, I propose that the HDC Act 1994 be amended to:

- (a) ***Provide the HDC with the power to assess all complaints from consumers about a health or disability service and to use his discretion to refer complaints directly to providers (having regard to the nature of the complaint), registration bodies (on issues concerning competence and/or inappropriate behaviour by a registered health professional), ACC (on matters likely to involve medical misadventure claims), and other agencies, such as the Ministry of Health, where there are public safety or systemic concerns (please refer to Appendix 1).***

This proposal is consistent with proposals in the Cull Report and the Stent Review. It would considerably reduce time currently spent by the HDC on unnecessary investigations, since he would be able to use his discretion to refer complaints, upon receipt, to the most appropriate body for action, without the need for a full investigation. As outlined in (d) below, the HDC would maintain his “watchdog” role by asking the agency to which the complaint was referred to report back on the action taken. The Ministry of Women’s Affairs considers the circumstances in which the HDC may refer complaints to other agencies should be specified in the legislation. I do not agree, as I do not consider it is possible to list all the circumstances in which the HDC may decide to exercise his discretion. It also has the potential to encroach on the HDC’s statutory independence in carrying out his functions.

- (b) ***Place an obligation on the HDC to share relevant information with ACC, registration bodies, and the Director-General of Health, during an investigation where there is the risk of harm from the practice of a health professional or systemic or organisational practice, or where there are likely to be compensation issues.***

Again, this proposal is consistent with recommendations in the Cull Report and the Gisborne Cervical Screening Inquiry. Although most of the agencies have in place protocols regarding the sharing of information, this proposal, in conjunction with proposals for information sharing in the Injury Prevention and Rehabilitation Bill and the Health Professionals Competency Assurance Bill, should avoid any doubt about the exchange of information in practice. The Privacy Commissioner would be consulted on the proposed wording for this amendment.

- (c) ***Provide the HDC with the power to access information, including patient records, held by the registration bodies, ACC and other relevant bodies, in relation to specific investigations.***
- This proposal is also consistent with recommendations in Cull Report and the Stent Report, and will assist the HDC to more effectively undertake investigations. The Privacy

Commissioner would be consulted on the proposed wording for this amendment. The Ministry of Women's Affairs does not support the mandatory disclosure of personal information between agencies without the informed consent of the individual.

- (d) ***Place a legal obligation on the person or authority to whom the HDC refers a complaint, to report back to the HDC on the outcome of the referral and the action taken.*** The Stent Review recommended that if the HDC was to be given the discretion to refer complaints directly to other bodies such as providers, registration bodies, ACC, and the Ministry of Health, that the HDC should also be able to legally require the provider to report back the outcome of the referral. This would enable the HDC to retain his independent oversight of complaints and ensure that matters are satisfactorily resolved.
- (e) ***Require the HDC, instead of the Director of Proceedings, to give a provider an opportunity to be heard, and to weigh the wishes of the complainant and the public interest in determining whether a matter should be referred to the Director of Proceedings with instructions to prosecute and/or pursue the complaint.*** This would speed up the process for completing investigations, and ensure that there was no duplication of processes by the HDC and the Director of Proceedings. The HDC should also be able to refer complaints, which raise issues regarding public safety, directly to the Director of Proceedings for urgent action. This proposal is supported by the Cull Report and the Stent Review and by the majority of people and organisations who made submissions on the reviews.
- (f) ***Give the HDC the power to report to a registration body or relevant body the failure of a practitioner to give effect to the HDC recommendations with a power to name the person concerned.*** The Cull Report considers that without such a power, the HDC is at risk of being a “toothless tiger”. This provision is likely to provide a deterrent to health professionals for not meeting the HDC’s recommendations.
- (g) ***Allow consumers to bring proceedings to the Complaints Review Tribunal after the HDC has found a breach of the Code but has decided not to refer it to the Director of Proceedings, or in cases where it is referred to the Director of Proceedings but the Director of Proceedings decides to take no further action, or in cases where the Director of Proceedings decides not to lay a charge or prosecute.*** Both the Cull Report and the Stent Review recommended that consumers should have greater access to the Complaints Review Tribunal for damages and pecuniary loss. At present consumers are unable to bring their own action to the Complaints Review Tribunal where the HDC takes no action on a complaint, finds no breach of the Code, or finds a breach of the Code but does not refer the matter to the Director of Proceedings. I propose that the HDC Act be amended to allow greater access to the Complaints Review Tribunal by consumers, where a breach of the Code has been found by the HDC. This proposal is supported by the majority of submissions on the Cull Report and the Stent Review.

- (h) **Allow the HDC to call a mediation conference into any complaint, where an investigation has not been commenced and notified, if the HDC is of the opinion that it would be appropriate to do so.** Both the Cull Report and the Stent Review recommended that the HDC should be able, upon the receipt of a complaint, to refer the complaint directly to mediation. At present, this can only occur where the complaint is the subject of an investigation by the HDC. Consistent with trying to achieve a more flexible approach to complaints, it would be preferable if the HDC could undertake a preliminary inquiry into a complaint and, if considered appropriate, to refer a complaint to mediation, without the need to formally commence an investigation. Submissions on the Cull Report indicated that mediation was a fast and effective way to deal with complaints and supported the HDC having more flexibility in using mediation conferences to resolve complaints.
- (i) **Provide the HDC greater discretion to decide to take no action, or no further action, on a complaint where it is considered unnecessary or inappropriate.** The Stent Review recommended that the HDC should have greater discretion to take no action on a complaint. This would free up the HDC's resources to address other more serious complaints. Submissions on the Stent Review supported this proposal. The HDC would need to provide to the consumer his reasons for deciding not to take any action. The Ministry of Women's Affairs considers the criteria for the HDC deciding to take no action should be specified in the legislation. I do not agree, as I do not consider it is possible to list all the circumstances in which the HDC may decide to exercise his discretion. It also has the potential to encroach on the HDC's statutory independence in carrying out his functions.
- (j) **Provide for the appointment of Deputy Commissioners by the Governor-General on the recommendation of the Minister of Health.** At present, the HDC Act allows the Governor-General to appoint a Deputy Commissioner on the recommendation of the Minister of Health. Given, that in the future it is likely that the HDC's workload and the size of his office may increase, it seems prudent to allow for the appointment of multiple Deputy Commissioners. This would assist in facilitating the speedy and efficient resolution of complaints. This proposal is supported by the current HDC.
- (k) **Allow the HDC to delegate the writing of reports and recommendations to the Deputy Commissioner(s).** The HDC Act 1994, whilst it permits the HDC to delegate certain functions to a Deputy Commissioner, does not allow the HDC to delegate the making of recommendations or reports under the Act. This is not sensible. The delegation of reports to Deputy Commissioner(s) would free up the HDC's time on other reports, and also assist in improving the timeliness of investigations.
33. In addition to these proposals, the Ministry of Consumer Affairs considers that legal obligations should be placed on ACC and the HDC to advise consumers about the respective agencies' purposes and processes.

Outstanding Issues

Complaints Review Tribunal - access by ACC claimants

34. The Cull Report proposes that ACC claimants should be able to access the Complaints Review Tribunal for reimbursement of pecuniary costs and the awarding of damages to a claimant. Although this paper recommends that the HDC Act be amended to allow greater access to the Complaints Review Tribunal by consumers in circumstances where the HDC finds a breach of the Code, or finds a breach of the Code but does not refer the matter to the Director of Proceedings, I consider the issue of whether ACC claimants, and consumers where there is no finding of a breach of the Code, should also be able to access the Complaints Review Tribunal, requires further consideration. The HDC Act precludes the awarding of damages by the Complaints Review Tribunal to people who have received ACC entitlements for personal injury under the Accident Insurance Act 1998 (to be replaced by the proposed Injury Prevention and Rehabilitation Bill). Officials from ACC, the Ministry of Health, and the Department of Labour will undertake further work on this issue.

Statute of Limitations

35. The HDC has raised concerns about the timeliness of some of the complaints made by consumers. Complaints dating back to 1996, when the Code of Health and Disability Services Consumers' Rights came into force, are still being received in 2001. Logistically, it may make sense to impose a time limit in which consumers must lodge a complaint after they first become aware of a concern about a health and disability service they have received. It is proposed that further consideration be given to this issue.

Amendment to the Code of Health and Disability Services Consumers' Rights

36. Section 21 of the HDC Act, requires the HDC to review the Code of Health and Disability Services Consumers' Rights, at three yearly intervals, and to make recommendations to the Minister of Health. Although Robyn Stent recommended a number of initial changes in her discussion document, following the analysis of submissions, she recommended to the Minister of Health that there be no change to the Code at this time. She noted that while a number of technical improvements to the Code could be made, none was sufficiently significant to warrant immediate amendment. Many submissions on the Code indicated that, taken as a whole, the existing rights of the Code are satisfactory.

37. The current HDC has, however, proposed one amendment to the Code. This is in relation to Right 7(10), the right to be fully informed. This states:

“Any body parts or bodily substances removed or obtained in the course of a health care procedure may be stored, preserved, or utilised only with the informed consent of the consumer.”

38. It is not always reasonably practical to obtain informed consent, and in some cases the Code's blanket prohibition on the use of blood and other tissue in such cases may hinder valuable public health research. Researchers and pathologists have concerns about the practicability of obtaining informed consent for the storage, preservation and/or use of body parts and bodily

substances and raised these concerns as part of Robyn Stent's initial consultation on proposed changes to the Code. Many ethical and legal commentators internationally accept that such research should be permitted, and New Zealand has recognised the need for an exception in the related privacy context (rule 10 of the Health Information Privacy Code).

39. Providers cannot know all possible future uses when obtaining consent at the time the body part or bodily substance is stored, nor is it always practicable or even possible to seek new consent from the original donor. For example, a strategy for monitoring the epidemic in women by neo-natal blood screening was abandoned because the informed consent requirements in Right 7(10) were considered to be impractical and likely to impact on the scientific validity of the study. Similar problems are likely to occur with the proposed monitoring studies of proteins linked to CJD by testing stored tonsils and appendices removed during surgery.
40. In response to the Stent Review, some researchers, pathologists, and ethics committees submitted that Right 7(10) should be amended to allow ethics committees to review specific research proposals to see whether the public interest should allow exceptions from compliance with the Code. Rules 10(e)(ii) and 11(2)(c)(iii) of the Health Information Privacy Code enable information to be disclosed without an individual's authorisation, where the information is to be used for research purposes, and the research has been approved by an ethics committee, and the information will not be published in an identifiable form.
41. There are, however, a number of arguments for retaining the current wording of Right 7(10). These include:
 - A concern that health professionals and providers could remove and/or retain body parts without the knowledge and/or consent of their whanau; and
 - A concern that the testing of bodily substances could occur without consent. The taking of vaginal swabs from newborn babies without parental consent was one of the practices at National Women's Hospital uncovered in the Cartwright Inquiry.
42. The Stent Review questioned whether clause 3 of the Code could also be used to provide an exception for providers where samples have been stored unlinked and it is not possible for consent to be obtained, but ethical approval for research has been obtained that has a valuable public health objective. In her view, this could satisfy the requirement of the provider's compliance with the Code, given that the provider has "taken reasonable actions in the circumstances to give effect to the rights".

Proposal for amending Right 7(10)

43. To avoid any doubt about the application of clause 3, I propose that Right 7(10) be amended to allow health and disability ethics committees to review specific research proposals to see whether the public interest should allow exceptions from compliance with the Code of Health and Disability Services Consumers' Rights (similar to exceptions under Rules 10 and 11 of the Health Information Privacy Code). This would provide more practicable obligations on providers for

limited exceptions from compliance with the informed consent provisions for the storage, utilisation and preservation of body parts and bodily substances.

44. Te Puni Kokiri and the Ministry of Women's Affairs have concerns about this proposal for the reasons outlined in paragraph 41. In 1999, Te Puni Kokiri published guidelines for the removal, retention, return and disposal of Maori body parts, organ donation and post-mortem, *Hauora o te Tinana me ona Tikanga*, for Maori and their whanau, and service providers. These guidelines elaborate on the current requirements of Right 7(10). If Cabinet approves an amendment to Right 7(10) of the Code, the Ministry of Health will ensure that Te Puni Kokiri is consulted on the proposed wording for the amendment.
45. The onus will still be on providers to obtain consent at the time a body part of bodily substance is stored. Similarly, in obtaining and storing body parts or bodily substances, providers will be obliged to comply with Right 1(3) of the Code, and to take into account the needs, values and beliefs of different cultural, religious, social, and ethnic groups, including the needs, values and beliefs of Maori. The proposed amendment to Right 7(10) would only allow an exception from the informed consent provisions in limited circumstances. For example, a researcher may propose to use specific body parts for research, which was not envisaged at the time the samples were collected from the consumers, and it may not be practicable, or possible, to locate the consumers to seek new consent for the proposed use of those body parts. The ethics committee would need to review the specific research proposal and weigh up the public interest in allowing for an exception from the informed consent provisions of the Code.

CONSULTATION

46. Robyn Stent undertook extensive consultation in 1999 on proposed changes to the HDC Act 1994. Over 3600 copies of the consultation document were distributed and public meetings and focus groups were also held. Over 200 submissions were received. The Cull Report was also circulated to consumers and the sector earlier this year. Fifty-one submissions were received.
47. The HDC, ACC, the Privacy Commissioner, the Department of Labour, the Department of Prime Minister and Cabinet, the Treasury, Te Puni Kokiri, State Services Commission, and the Ministries of Economic Development, Consumer Affairs, Women's Affairs, Justice, Pacific Island Affairs, and Foreign Affairs and Trade have been consulted on the proposals in this paper. The Ministry of Health will ensure that the Privacy Commissioner is consulted on the drafting of the proposed information sharing provisions of the Bill, and that Te Puni Kokiri is consulted on the drafting of any change to Right 7(10) of the Code of Health and Disability Services Consumers' Rights.

FINANCIAL IMPLICATIONS

48. The Ministry of Health is not seeking any additional funding as a result of these proposals. The HDC has indicated that the proposed changes will considerably improve the flexibility he has in facilitating the fair, speedy and efficient resolution of complaints, without the need for more resources for his office.

LEGISLATIVE IMPLICATIONS

49. It is anticipated that the proposed changes to the HDC Act 1994 and the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996 will form part of a proposed Comprehensive Bill, aimed at improving consumer safety in the health and disability sector, which has a proposed priority 4 on the 2001 Legislative Programme.

HUMAN RIGHTS ACT 1993

50. The recommendations in this report do not have any human rights implications.

REGULATORY IMPACT STATEMENT

51. A regulatory impact statement is attached. There will be no direct financial implications for the Crown. There are no business compliance costs. The proposed change to Right 7(10) of the Code of Health and Disability Services Consumers' Rights will not impose any additional costs on providers or researchers.

PUBLICITY

52. A press release will be made when the legislation is ready for introduction to the House of Representatives.

ON 7 AUGUST 2001, CABINET CONFIRMED THE FOLLOWING DECISIONS ON THE WORK OF THE CABINET HEALTH AND EDUCATION COMMITTEE: [CAB (01) Min 25/2 refers]

EHC Min (01) 9/7

HEALTH AND DISABILITY COMMISSIONER AMENDMENT BILL: PROPOSALS TO STREAMLINE COMPLAINTS PROCESSES

Background

1. **noted** that Robyn Stent's Review of the Health and Disability Commissioner Act 1994 (October 1999), the Cull Report on Review of Processes Concerning Adverse Medical Events (March 2001), and the Ministerial Inquiry Into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region (April 2001) raise a number of concerns about the current complaints mechanisms for health and disability consumers, including:
 - 1.1. difficulties accessing the appropriate complaints mechanisms;
 - 1.2. time delays;
 - 1.3. multiple investigations;
 - 1.4. lack of inter-agency interaction;
 - 1.5. dissatisfaction with Accident Compensation Corporation (ACC) entitlements;
2. **noted** that since these reports were completed a number of initiatives have been undertaken to address these concerns, including:
 - 2.1. establishing protocols between the Health and Disability Commissioner, ACC and the Medical Council for sharing information on medical misadventure claims and complaints from health and disability consumers (see attached annex);
 - 2.2. provisions in the Injury Prevention and Rehabilitation Bill requiring ACC to report any incident it accepts as medical error to the relevant registration body and the Health and Disability Commissioner, and to report medical mishap trends to the relevant registration body, the Health and Disability Commissioner, the Director-General of Health, or the employer of the registered health professional;
 - 2.3. proposals for the Health Professionals Competency Assurance Bill to contain a legal obligation on registration bodies to provide information to employers, the Health and Disability Commissioner and ACC;
 - 2.4. significant improvements in the time taken to complete investigations by the Health and Disability Commissioner on complaints about alleged breaches of the Code of Health and Disability Services Consumers' Rights, and by ACC in relation to medical misadventure claims;

- 2.5. reintroducing precedents for determining cover for medical mishap, under the Injury Prevention and Rehabilitation Bill;
- 2.6. the extension of medical error under the Injury Prevention and Rehabilitation Bill to cover systemic and organisational failure;

Proposed Amendments to the Health and Disability Commissioner Act

3. **agreed** that the Health and Disability Commissioner Act 1994 be amended to:
 - 3.1. provide the Health and Disability Commissioner with the power to assess all complaints from consumers about a health or disability service and to use his discretion to refer complaints directly to:
 - 3.1.1. providers (having regard to the nature of the complaint);
 - 3.1.2. registration bodies (on issues concerning competence and/or inappropriate behaviour by a registered health professional);
 - 3.1.3. the Accident Compensation Corporation (on matters likely to involve medical misadventure claims); and
 - 3.1.4. other agencies, such as the Ministry of Health, where there are public safety or systemic concerns (see attached annex);
 - 3.2. place a legal obligation on the Health and Disability Commissioner to share relevant information with the Accident Compensation Corporation, registration bodies, and the Director-General of Health, during an investigation where there is the risk of harm from the practice of a health professional or systemic or organisational practice, or where there are likely to be compensation issues;
 - 3.3. provide the Health and Disability Commissioner with the power to access information, including patient records, held by the registration bodies, Accident Compensation Corporation and other relevant bodies, in relation to specific investigations;
 - 3.4. place a legal obligation on the person or authority to whom the Health and Disability Commissioner refers a complaint, to report back to the Health and Disability Commissioner on the outcome of the referral and the action taken;
 - 3.5. require the Health and Disability Commissioner, instead of the Director of Proceedings, to give a provider an opportunity to be heard, and to weigh the wishes of the complainant and the public interest in determining whether a matter should be referred to the Director of Proceedings with instructions to prosecute and/or pursue the complaint;
 - 3.6. give the Health and Disability Commissioner the power to report to a registration body or relevant body the failure of a practitioner to give effect to the Health and Disability Commissioner's recommendations with a power to name the person concerned;

- 3.7. allow consumers to bring proceedings to the Complaints Review Tribunal after the Health and Disability Commissioner has found a breach of the Code but has decided not to refer it to the Director of Proceedings, or in cases where it is referred to the Director of Proceedings but the Director of Proceedings decides to take no further action, or in cases where the Director of Proceedings decides not to lay a charge or prosecute;
- 3.8. allow the Health and Disability Commissioner to call a mediation conference into any complaint, where an investigation has not been commenced and notified, if the Health and Disability Commissioner is of the opinion that it would be appropriate to do so;
- 3.9. provide the Health and Disability Commissioner with greater discretion to decide to take no action, or no further action, on a complaint where it is considered unnecessary or inappropriate;
- 3.10. provide for the Governor-General to appoint Deputy Commissioners on the recommendation of the Minister of Health;
- 3.11. allow the Health and Disability Commissioner to delegate the writing of reports and recommendations to the Deputy Commissioner(s);

Outstanding Issues

4. **noted** that officials will undertake further work on:
 - 4.1. allowing ACC claimants to access the Complaints Review Tribunal for reimbursement of pecuniary costs and the awarding of damages;
 - 4.2. the need for a time limitation, under the Health and Disability Commissioner Act 1994, within which consumers must lodge a complaint about a health and disability service;

Amendment to the Code of Health and Disability Services Consumers' Rights

5. **noted** that it is not always reasonably practicable for researchers and pathologists to obtain informed consent for all possible future uses of body parts or bodily substances, which are obtained in the course of a health care procedure, as is currently required by Right 7(10) of the Code of Health and Disability Services Consumers' Rights;
6. **agreed** that Right 7(10) be amended to allow health and disability ethics committees to review specific research proposals to see whether the public interest should allow exceptions from compliance with the Code of Health and Disability Services Consumers' Rights (similar to exceptions under Rules 10 and 11 of the Health Information Privacy Code);

Legislative Processes

7. **noted** that it is anticipated that the proposed amendments to the Health and Disability Commissioner Act 1994 and the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996

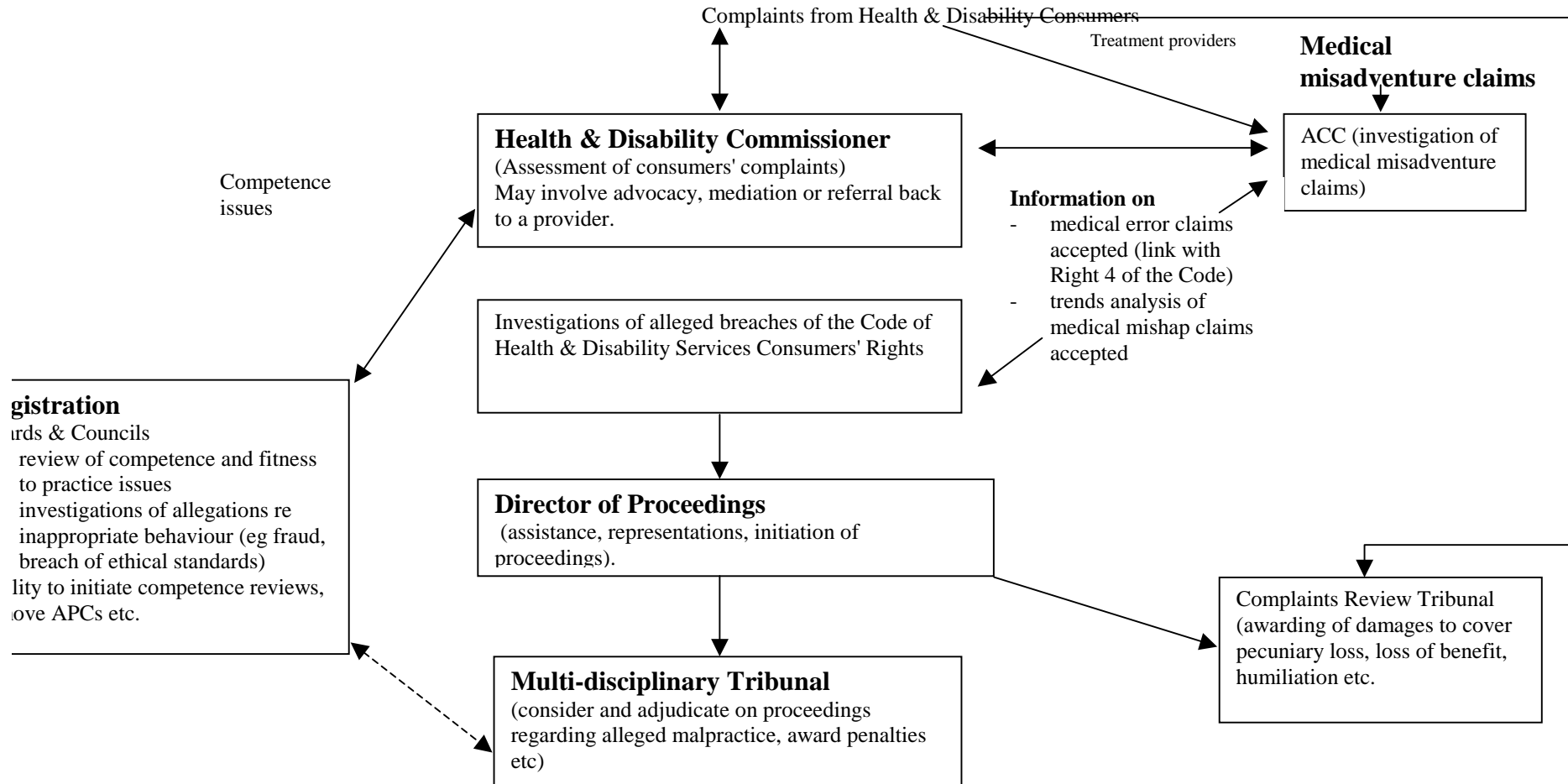
will form part of a proposed comprehensive Bill, aimed at improving consumer safety in the health and disability sector, which has a proposed priority of 4 on the 2001 Legislative Programme (to be sent to a select committee in 2001);

8. **invited** the Minister of Health to issue drafting instructions to Parliamentary Counsel to give effect to the decisions in paragraphs 3 and 6 above;

Website

9. **noted** that the paper under EHC (01) 46 will be placed on the Minister of Health's website following Cabinet approval.

APPENDIX 1: FRAMEWORK FOR CONSIDERATION OF HEALTH AND DISABILITY CONSUMERS' COMPLAINTS



REGULATORY IMPACT STATEMENT HEALTH AND DISABILITY COMMISSIONER AMENDMENT BILL

STATEMENT OF THE PUBLIC POLICY OBJECTIVE

The streamlining of complaints processes for health and disability services consumers should improve the timeliness and effectiveness of investigations into complaints about health and disability services, and ensure that issues of public safety are identified and followed-through more quickly than at present.

STATEMENT OF PROBLEM AND NEED FOR ACTION

There are a number of problems with the current complaints mechanisms for health and disability services consumers which indicate a need to improve: the simplicity of complaints processes for health and disability services consumers and to educate consumers on these processes; the timeliness of completing investigations; case management of consumers' complaints; and information sharing between agencies that receive and investigate complaints (ie, the Health and Disability Commissioner, the Accident Compensation Corporation, registration bodies and the Ministry of Health).

Proposed amendments to the Health and Disability Commissioner Act 1994 should assist the Health and Disability Commissioner in achieving his statutory purpose of facilitating the fair, simple, speedy and efficient resolution of complaints. These amendments, in conjunction with changes proposed under the Health Professionals Competency Assurance Bill (eg, mandatory reporting of concerns about the competence of health professionals, immediate suspension of health professionals considered to pose the public harm etc), and the Injury Prevention and Rehabilitation Bill (eg, information sharing provisions between agencies), should ensure that issues of public safety are identified and followed-through more quickly than at present.

STATEMENT OF OPTIONS FOR ACHIEVING THE DESIRED OUTCOME

Non-regulatory measures

Improved administrative arrangements regarding information sharing and education programmes for consumers would address some of the concerns about inter-agency interaction and co-ordination of complaints from health and disability services consumers. They would not, however, address impediments created by the inflexible statutory requirements that are currently imposed on the Health and Disability Commissioner (eg, the need to investigate a complaint before it can be referred to another agency).

Regulatory measures

Section 18 of the Health and Disability Commissioner Act 1994 requires the Health and Disability Commissioner to review the operation of the Health and Disability Commissioner Act 1994 as soon as practicable after the Act has been in operation for three years, and to make recommendations to the Minister of Health about the changes that should be made. This provision was included in the Health and

Disability Commissioner Act 1994 to ensure that the effectiveness of the operation of the Act could be reviewed and amended as appropriate. The former Health and Disability Commissioner, Robyn Stent, identified a number of problems with the way the Act is presently drafted and recommended a number of changes to the Minister of Health, following extensive consultation with the sector and public, in 1999. The current Health and Disability Commissioner supports the proposed amendments to the Health and Disability Commissioner Act 1994.

STATEMENT OF THE NET BENEFIT OF THE PROPOSAL

The proposed amendments to the Health and Disability Commissioner Act 1994 will provide the following benefits:

- More timely assessment, referral and investigation of complaints
- Earlier resolution of complaints
- Improved information sharing between the Health and Disability Commissioner, Accident Compensation Corporation, registration bodies, and the Ministry of Health
- Better education for consumers and health and disability providers about the respective roles of the different agencies
- Better co-ordination of investigation outcomes by different agencies
- Clearer complaints processes and ultimately less stress for consumers
- Enhanced protection for the public because issues of concern regarding the competence of health professionals or public safety, should be identified and followed-through more quickly by the appropriate agency
- Better co-ordination of investigation outcomes by different agencies.

COSTS

There are no costs to the Crown or health and disability providers as a result of the proposed amendments.

The Health and Disability Commissioner will have more flexibility in assessing, referring and investigating complaints. As a result considerable time spent on unnecessary investigations will be available for progressing investigations more quickly and making appropriate referrals to other agencies.

The Health and Disability Commissioner, the Accident Compensation Corporation, registration bodies and the Ministry of Health currently share information. It is not anticipated that there will be any extra costs associated with having these arrangements formalised in legislation.

If consumers are able to bring proceedings to the Complaints Review Tribunal after the Health and Disability Commissioner has found a breach of the Code without the need to refer it to the Director of Proceedings, or in cases where it is referred to the Director of Proceedings but the Director of Proceedings decides to take no further action, or in cases where the Director of Proceedings decides not to lay a charge or prosecute, consumers who wish to bring such proceedings will need to meet the costs of those proceedings, where they decide not to represent themselves. Where a consumer decides to employ a lawyer to represent them, legal aid may be

available, depending on the consumer's circumstances. It is not anticipated that there will be a significant impact on the workload of the Complaints Review Tribunal. To date, only two cases have been considered by the Complaints Review Tribunal in relation to the seeking of damages for breaches of the Code.

BUSINESS COMPLIANCE COST STATEMENT

The proposals do not create any business compliance costs.

CONSULTATION

The Regulatory and Compliance Cost Unit of the Ministry of Economic Development has been consulted.

The Health and Disability Commissioner, Accident Compensation Corporation, Department of Labour, Department of Prime Minister and Cabinet, the Treasury, Ministries of Justice, Women's Affairs, Consumer Affairs, Foreign Affairs and Trade, and Pacific Island Affairs, Te Puni Kokiri, State Services Commission, and the Privacy Commissioner have been consulted and concur with the proposed amendments to the Health and Disability Commissioner Act 1994.