

# **Report on the Consultation on the Health Act, 2004 (Part 9) – Complaints**

Prepared for the Department of Health and Children

By

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## **Acknowledgements**

Undertaking this consultation has been both a challenging and humbling experience. It has been challenging to try to incorporate the views of so many people who have dedicated time and energy to dealing with complaints over long periods of time and in the process have gained a wealth of knowledge and expertise in managing complaints. It has been humbling to experience the courage and commitment of so many individuals who have taken risks and dedicated so much of their time to finding a better way and to making our health system truly more people-centred.

My thanks to all who contributed so willingly to this task.

When I am listened to I feel important  
and what I have shared counts.  
When I'm heard I feel someone has offered me their hospitality of heart  
and mind.  
When I'm accepted I feel affirmed and comforted.  
When my pain is acknowledged I no longer feel a fraud.  
When the shattered fragments of my life are handled with compassion  
and respect, I can believe in their place in re-building my life.  
When I am understood I feel my burden has been shared  
and the journey of healing can begin.  
When I am met at my point of need, I know I have a  
travelling companion for the journey ahead.

Sandra Orr.

This poem was presented at one of the consultation workshops by someone who had reason to make a complaint about the health services. I have reproduced it here as a reminder to complaints officers of the importance of paying attention to the basic needs of complainants.

## **Executive Summary**

The Health Strategy “Quality and Fairness - A Health System for You” calls for the development of a statutory framework for complaints to achieve greater clarity and uniformity of approach in dealing with complaints, structured local resolution procedures and processes as well as an opportunity for independent review. Health services in this country are now for the first time the responsibility of one entity, the Health Services Executive (HSE). This affords a unique opportunity to develop a consistent approach to the management of complaints throughout the health services, one that ensures that complaints lead to quality improvements in the delivery of care and that health services providers are fully accountable to the citizens they serve. As such a national framework and process for managing complaints provide the opportunity to embody the principles of equity, quality and accountability.

Part 9 of the Health Act 2004 makes provision for the introduction of a statutory complaints system within the HSE. The purpose of this Department of Health and Children Consultation is to establish a shared understanding of the requirements and priorities attaching to this particular part of the Act as well as providing an opportunity for those experienced in complaints handling to contribute to and inform the Regulations which will specify how the HSE will establish a statutory framework for dealing with complaints received under Part 9 of the Health Act, 2004. These Regulations will be introduced in the form of secondary legislation, a Statutory Instrument (S.I.) which will take its authority from the specific powers laid down in the Act (Part 9). The Act, primary legislation, sets out the general law and authorises the Minister to make Regulations dealing with details of the operational framework to be regulated for. It is important to note, in reading this report, that the Statutory Instrument cannot deviate in any way from what is laid down in the Act and to do so may result in the Regulations being regarded as “ultra vires” i.e. the Minister does not have the power, under the Act, to do what she is purporting to do by Regulation. This consultation has identified many examples of good practice amongst service providers. These are the result of careful analysis of the problems that have arisen in investigating complaints in the past and the experience and commitment that complaints officers and others have shown to improving their responsiveness to consumers and service users. Many provider organisations have attempted to balance

the negative image of complaints by expanding their systems to also receive comments or compliments. Responding to increasing consumer demands for transparency and independence, some have already introduced independent review panels or external investigation of complaints. Others have successfully engaged staff in the investigation of complaints relating to clinical practice.

However, there remain some significant problems with complaints systems, amongst them the wide variability in procedures from one provider to the next. A significant frustration for complainants is the time taken to investigate complaints, with delays being commonplace and lapses in communication serving to add to the frustration. Complainants are also increasingly demanding independent reviews of their complaints and are concerned that those conducting independent review may not be sufficiently independent of the system.

The complexity of existing complaints systems is a problem both for complainants and for complaints officers. Complaints officers are not always sure where to direct a complaint and complainants become perplexed by the number of parallel processes that exist for investigating different types of complaints. Not all investigation processes have a requirement to provide regular feedback to the complainant.

Complaints officers too face difficulties such as limited resources, poor training and preparation for the role of complaints officer, numerous other demands on their time (due to the part-time nature of the complaints officer role in most provider organisations), non-compliance of staff under investigation and limited powers to make improvements in the system.

This report draws on the contributions during the consultation process, as well as a review of complaints systems in other jurisdictions to make recommendations for a more standardised, more transparent and less complex approach to managing complaints that will hopefully address some of the problems set out above.

The adoption of standard time frames for acknowledging and investigating complaints would help to manage complainants' expectations and ensure that they are kept informed of progress. It is recommended that complaints should be acknowledged

within 5 working days and investigated within 20 working days. If the complaint is complex and requires more time for investigation the complainant should be given an explanation and a timeframe and should receive an update on progress every two weeks. If a complaint has not been fully investigated within 6 months of receipt it must be passed on to the Independent Reviewer. Often time delays occur because of slow responses from staff against whom a complaint is made. In order to remedy this situation it should be a requirement that staff reply to the complaints officer within 10 working days of receiving a request.

The issue of “matters solely related to the exercise of clinical judgment” being excluded from the complaints system was the most debated issue during the consultation workshops. The experience of complaints officers suggests that it is difficult to classify complaints on the basis of this criterion, as many complaints have a combination of clinical and non-clinical or administrative elements. Additionally the limited powers of the regulatory bodies in investigating complaints relating to negligence suggest that such complaints (the majority of which are currently being pursued through the legal system) should be accommodated by this system. It is strongly recommended that a Patients’ Bill of Rights and Responsibilities be introduced as a key component of the regulations in order to provide a benchmark or set of standards against which to measure complaints. This would help to overcome the problem of having professional standards as the benchmark and the necessity for adherence to professional standards to be judged by the professionals themselves. It is also recommended that Healthcare Governance Committees take on the role of agreeing with the regulatory bodies and other agencies involved in the investigation of complaints a comprehensive set of guidelines on the referral of complaints from the HSE to other agencies. Such guidelines should form the basis of standardising practice throughout all HSE healthcare facilities and HSE-funded healthcare facilities in relation to the inclusion and exclusion criteria for the investigation of complaints.

It is suggested that the complaints system could be much more effective and efficient if the resources invested in the various steps of internal investigation were re-invested to support a one-step local resolution model. This has implications for the post of complaints officer - it needs to be at a more senior level and should be supported by appropriate access to advice and support from healthcare governance and senior

management. It is also strongly recommended that it be a dedicated post based in each local health office and each hospital. Where HSE contracted provider organisations are too small in size to appoint a dedicated complaints officer at senior level, the CEO of the organisation may take on this function or he/she may appoint a person who reports directly to the CEO and has a strong working relationship and support and advice from the HSE local health office complaints officer. The complaints officer should hold responsibility for the complaint from the time it is referred from a front line staff member to the time the HSE has finalised the investigation and reported back to the complainant. This means that all staff involved in the investigation and resolution of the complaint, whether they are senior clinicians, senior managers or the CEO of the organisation, should work through the complaints officer's office. This should significantly reduce the time delays that are created by the current common practice of referring the complaint up the hierarchical chain of the organisation.

An additional recommendation, that aims to address the most common reason for complaints (“to ensure that it doesn't happen to anybody else”), is that a contingency fund should be provided by the HSE to support the implementation of priority recommendations for service improvements (arising from complaints).

The integration of the complaints function with other areas of Healthcare governance is perceived to be important in monitoring performance and implementing service improvements. There is a need for some integrating mechanism at regional level to facilitate this. Complaints officers will be required to provide quarterly reports to the Regional Office/ Hospital Network as well as to a Complaints Monitoring Committee that should be established at HSE Corporate.

Another significant issue for many consumers is access to an independent review of their complaint. This report draws the distinction between the role of the Ombudsman's Office in *re-investigating* a complaint and the role of an Independent Reviewer in *reviewing* the complaint to determine if the internal review procedures were fairly and properly applied. A recommendation is made for the establishment of the post of Independent Reviewer to conduct independent reviews of complaints that have not been resolved through local resolution. The Independent Reviewer needs to

have sufficient independence (defined as having no other contractual or financial relationship with HSE and not being a practicing healthcare professional) and the authority (conferred by Statutory Instrument) to conduct reviews in an impartial and transparent manner and to make recommendations for improvements in the complaints procedures. The Independent Reviewer should have the power to audit any provider organisation's complaints procedures. A key function of his role is to encourage organisational learning and improvement in the management of complaints. He will be expected to provide an annual report of his activities and findings to the HSE, which should in turn be forwarded to the Minister for Health.

There was strong consensus that there should be a standardised approach to managing complaints throughout the HSE. The effective management of complaints should form part of the contractual agreement between the HSE and its contracted service providers. These service providers should be subject to review of their complaints procedures by the Independent Reviewer in the same manner as HSE providers.

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## **1. Introduction**

The Health Strategy “Quality and Fairness - A Health System for You” calls for the development of a statutory framework for complaints to achieve greater clarity and uniformity of approach in dealing with complaints, structured local resolution procedures and processes as well as an opportunity for independent review. The introduction of a statutory complaints process is an important part of the people centred health care system central to the vision of healthcare in Ireland that is articulated in the Health Strategy. Health services in this country are now for the first time the responsibility of one entity, the Health Services Executive (HSE). This affords a unique opportunity to develop a consistent approach to the management of complaints throughout the health services, one that ensures that complaints lead to quality improvements in the delivery of care and that health services providers are fully accountable to the citizens they serve. As such a national framework and process for managing complaints provide the opportunity to embody the principles of equity, quality and accountability.

The Department of Health and Children indicates clearly in the consultation document the important role the HSE must play in the provision of a statutory complaints process.

“Each citizen must have confidence in the administration of the complaints process, must feel that it is inclusive of them, allowing them the right to appeal and access to the Ombudsman. The HSE must provide the citizen with a statutory complaints process based on effective mechanisms capable of demonstrating adherence to the law coupled with fair and consistent decision making.

The HSE in establishing this statutory complaints process will be facilitating the citizen in exercising his or her right to have a complaint investigated but will also be putting in place an effective mechanism not only to resolve individual complaints but also to improve the overall quality of health care for the citizen. This quality improving function will form an integral and underlying element of the complaints process, improving the standards of care delivered to the citizen across the service and informing the governance / risk management procedures being developed by the

HSE.” (DoHC, Consultation document on Part 9 of the Health Act - Complaints, 2005:2)

## **2. Purpose of the Consultation**

The purpose of the consultation was to examine the provisions of Part 9 of the Health Act, 2004, Sections 45 to 55, dealing with “Complaints”. An important part of this exercise was establishing a shared understanding of the requirements and priorities attaching to this particular part of the Act as well as providing an opportunity for those experienced in complaints handling to contribute to and inform the Regulations which will specify how the HSE will establish a statutory framework for dealing with complaints received under Part 9 of the Health Act, 2004.

These Regulations will be introduced in the form of secondary legislation, a Statutory Instrument (S.I.) which will take its authority from the specific power laid down in the Act (Part 9). The Act, primary legislation, sets out the general law and authorises the Minister to make Regulations dealing with details of the operational framework to be regulated for.

It is important to note, in reading this report, that the S.I. cannot deviate in any way from what is laid down in the Act and to do so may result in the Regulations being regarded as “ultra vires” i.e. the Minister does not have the power, under the Act, to do what she is purporting to do by Regulation.

The Terms of Reference for the consultation are set out in the Consultation document on Part 9 of the Health Act - Complaints, 2005. This document is reproduced in Appendix A. Clarification on these terms of reference indicated that the investigation of incidents and the appeals process do not come within the scope of Part 9 of the Health Act and they have not therefore been directly addressed as part of this consultation exercise.

### **3. Contributors**

The consultation was targeted at the widest possible group of stakeholders within the limits of the timeframe available. Statutory and voluntary service providers, professional bodies, trade unions, the Ombudsman and the Ombudsman for Children were all invited to attend workshops that were held throughout the country. A workshop was also arranged for consumer groups, advocacy groups and interested members of the public including those who had experience of complaints systems. In addition to four national workshops, a number of individual and group meetings were held to explore in depth particular issues that emerged from the workshops. Appendix B contains a list of organisations invited to the workshops. All service provider organisations were also given the opportunity to provide details of the complaints systems in existence in their organisations. In addition many individuals submitted helpful comments in writing. These inputs are summarised in the section “Current Practice”. Every effort has been made to draw on existing good practice to inform the recommendations for the statutory framework.

## **4. Current Practice**

During this consultation process many examples of good practice became evident. Not all providers submitted information on their complaints systems, although most indicated that they had systems in place in their organisation. This section presents some examples of good practice in a number of HSE areas and hospitals throughout the country. Much of what is described here refers to practice prior to the formation of the HSE and as such contains references to posts that may no longer exist. Additionally some findings from a recent ERHA survey are presented as they highlight some of the problems that exist for people who wish to make complaints about the health services.

Since this consultation, the findings of a national survey conducted in 2004 by the Irish Society for Quality and Safety in Healthcare have become available (ISQSH, 2005). The main findings from this survey raise serious issues in relation to the public's perceptions of health providers' complaints procedures. For example 74% of 4,821 respondents indicated that they were not aware of a complaints procedure within the hospital they attended. When asked if they wished to make a complaint about an area of dissatisfaction during their stay in hospital 20.1% or 925 respondents replied in the affirmative. Of those who discussed their complaint with a member of staff 26.8 percent indicated that they were satisfied with the outcome, 31% were somewhat satisfied and an alarming 42.3% were not satisfied (ISQSH, 2005).

### **4.1 Eastern Region**

The management of complaints has been undertaken in the east through the voluntary organisations and the statutory authorities for a number of years and the current provision in the statutory sector has been in existence since 1998. Since 1998, each Area Health Board has in place a Complaints procedure, supported by a central Complaints Department servicing the three area boards. This service was established against a background of legislative requirements, national and organisational policy following intensive research, consultation and a review of existing practices. In each board, every service has a designated complaints manager to whom formal complaints are addressed in the first instance. The emphasis is on local resolution so training in

customer services and complaints is targeted at front line staff dealing directly with the customer. Complaints are welcomed in any form: verbally, in writing, by telephone, in person, by a client or advocate or by a representative. If a complainant makes a written complaint, it is reviewed by the complaints officer. If the complainant remains dissatisfied the complaint can then be referred to the Director of Customer Services and Appeals, who may or may not include an independent review as part of the investigation procedure. One noteworthy aspect of the system is the speed of response, with all complaints being acknowledged within 3 working days and the outcome of investigation/ or a progress report being communicated to the complainant within 4 weeks. These timeframes also apply to the more complex re-investigation stage. Standards and quality of service are improved and weak gaps in service provision are identified and rectified. The ultimate aim is that of customer satisfaction based on customer involvement and people centred service.

A comprehensive review of complaints procedures, protocols and appeals in the region conducted in 2001 identified wide variations in practice across the provider agencies. Reaching consensus on an approach was also complicated by the legislative framework, which placed statutory providers of health services within the jurisdiction of the national ombudsman, whilst voluntary providers of services remained outside of this jurisdiction. This created a situation where quality control for complaints management was an internal matter for each individual voluntary organisation.

As part of the review, a survey was undertaken to establish people's experiences and expectations of health services. The survey findings showed a high level of satisfaction with care and treatment. The commitment, dedication and kindness of staff was acknowledged and valued by people who use health services in the region. However, the findings of the survey also showed that some 7% of those interviewed had made a complaint about their care and treatment with a significant proportion expressing dissatisfaction with the handling and outcome of their complaint. More than 50% of those who expressed dissatisfaction with the outcome of their complaint indicated that there was either no response, or the complaint had not been resolved in their opinion.

Following this review the ERHA established a committee to develop a framework for the management of complaints in the region using a participatory approach. This work was undertaken during the past 4 years and resulted in a comprehensive framework and set of guidelines which have subsequently formed the basis for a consultation exercise by the HSE. The HSE are currently adapting the guidelines based on the outcome of the consultation. The framework is notable because at its core is the belief that people matter. This belief is underpinned by a set of values that is reflected not only in the framework's slogan "People Matter: Complaints Matter" but in the people-centred principles that are an inherent part of this approach to managing complaints. These principles should be core to any complaints system. They are as follows:

- *Simple to understand and use*

A complaints system should make it easy for people to make complaints. A simple explanation of how to make a complaint and the procedures that will be followed in dealing with the complaint forms the basic component of an effective complaints system.

- *Speedy*

Complaints are often exacerbated by long and complicated responses to the complainant. It is important that complaints are dealt with in a timely manner and that there is an immediate response to the complainant.

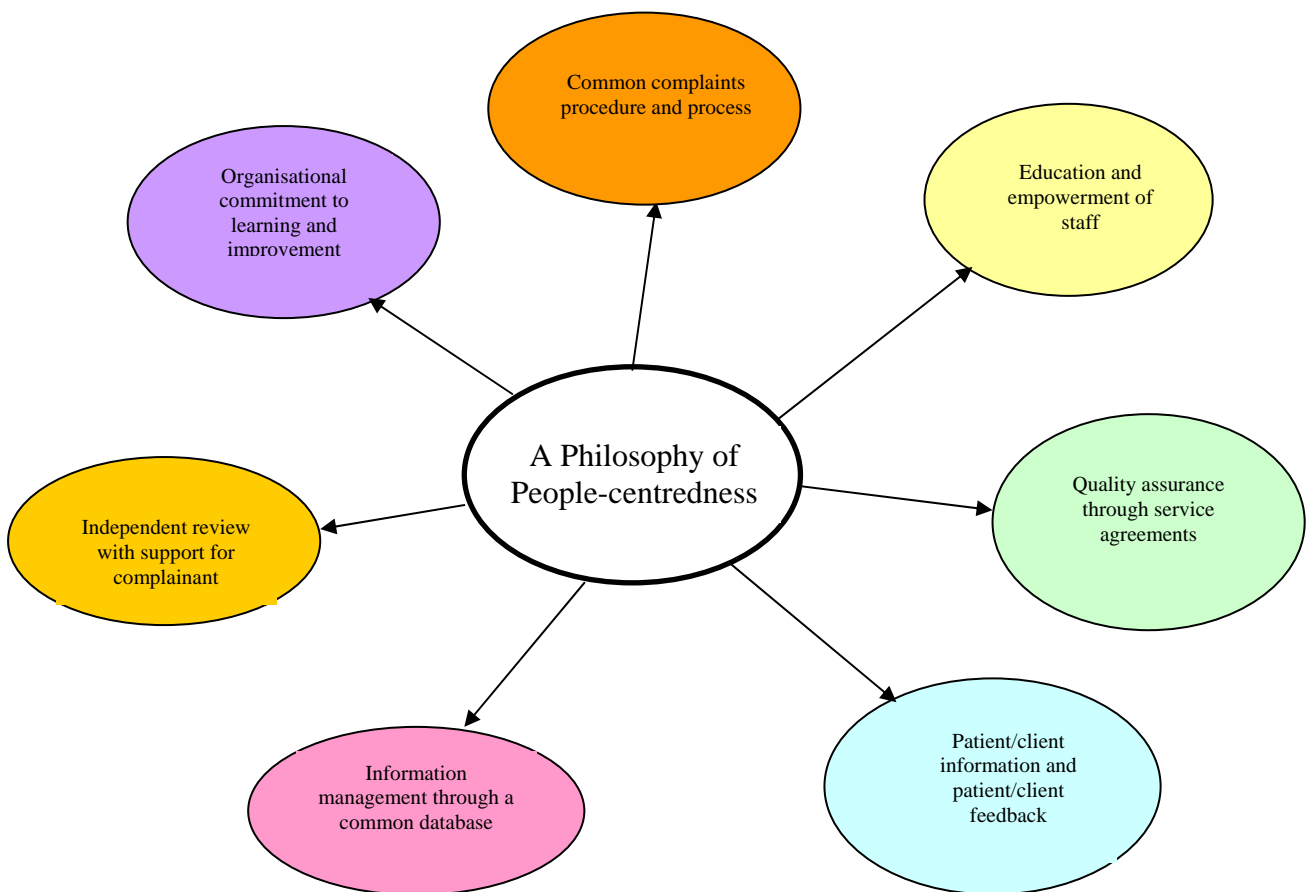
- *Keeping people informed of progress*

Long periods where there is no communication from the organisation to the complainant and where the organisation makes it difficult for the complainant to find out what is happening can be very frustrating for the complainant. Hence there is a need for regular communication to keep the complainant informed of progress.

- *Listening to people*  
Complainants on the whole do not find it easy to make a complaint about their care and treatment. It is important that we value their perspectives and take every complaint seriously.
- *Confidential*  
Confidentiality is a primary consideration both for the complainant and where relevant for the member of staff against whom a complaint is made.
- *Informative*  
A good complaints system should:
  - Provide the complainant with accurate information about what happened and a clear explanation for why this happened;
  - Provide staff with clear guidelines on how to improve the service.
- *Fair*  
The complaints handling process should be implemented without fear favour or prejudice towards the complainant, the person who is the subject of the complaint, or the service. Procedures and outcomes should be fair and be perceived as fair by both the complainant and, where relevant, staff who are the subject of a complaint.
- *Effective*  
The complaints procedure should be capable of thoroughly investigating complaints to the satisfaction of the complainant and should result in the resolution of the majority of complaints received.
- *Regularly monitored and audited to make sure it is effective and improved*  
Complaints provide opportunities for improvement. The system for handling complaints should also be subject to regular review and improvement and the feedback should improve the quality of services for the patient/clients.

Another important component of the framework is its emphasis on organisational learning and service improvement and its clear commitment to providing access to independent review to those complainants who may be dissatisfied with how their complaint was handled by the organisation. Figure 1 below sets out the components of the framework. Since the abolition of the ERHA and the establishment of the HSE, the HSE has built on the work that was undertaken by the ERHA and has published a revision of this framework. This framework and an accompanying set of guidelines for complaints managers have been the subjects of a widespread consultation undertaken in parallel to this consultation exercise. The recommendations contained in this report are fully consistent with the proposed framework.

**Figure 1: Framework Components**



**Source: A Framework for Complaints Handling in the Eastern Region, ERHA.**

## **4.2 Midland Area**

The system welcomes comments, enquiries, complaints and appeals. Complaints are acknowledged within 7 working days and the complaint is investigated and reported on within 42 days. In cases where this does not happen a progress report is sent after 42 days and again at every 42-day interval following that until the complaint has been fully investigated. If the patient is not satisfied with the outcome of the investigation he/she may appeal to an appeals officer who investigates the complaint, again responding within 42 days. If the complainant is unhappy with the response, the Chief executive officer will review the complaint. If the complainant is dissatisfied with the Chief executive officer's report, he/she is advised of the alternative courses of action open to him or her. The infrastructure for complaints is such that each acute hospital, each mental health hospital and each local community care area has a designated complaints officer. Additionally there are complaints officers assigned to Child Welfare Services, the Primary Care Unit, Central Services and Ambulance Services. There are 6 appeals officers in the area and these are primarily at the grade of general manager. The complaints function is closely linked with the Freedom of Information (FOI) function with copies of all reports going to FOI office.

## **4.3 North Western Area**

The North Western Area has a Staff Guide to the Complaints Procedure. Reference is made in this guide to a patient leaflet, but it is not clear whether this leaflet is in existence. The North Western Area invites people to communicate their concerns and suggestions on how the service can be further improved. It is acknowledged that some complaints are of such a serious nature that they require immediate action by management, such as complaints of a quasi-judicial or criminal nature, complaints where there is prima facie evidence of negligence, complaints that are likely to expose the North Western Area to litigation or adverse media coverage. In these cases line management is immediately informed. If a complaint is connected to a medico-legal claim, the medico-legal procedure supersedes the complaints procedure. All other complaints are acknowledged within 3 days and where possible a report of the investigation produced within 20 days. There is also a 7-day time frame within which staff should respond to the investigator of the complaint. In the case of complaints that are of a clinical nature, the officer investigating the complaint liaises directly with

the director of nursing, medical director or head of profession as appropriate. Any of these people can also be appointed to conduct the investigation into the complaint. If the complainant is dissatisfied with the outcome the complaint may be investigated by the Regional Complaints Officer who has the authority to investigate and conclude whether the written response answers the concerns raised in the original complaint. The complainant is advised of their right to pursue their complaint through the Ombudsman's office, regardless of the outcome of the local investigation.

The Complaints infrastructure is concentrated in each of the four General management areas. In each area Consumer Services Officers have been appointed to deal with FOI, complaints and appeals. "At each site arrangements will be made to co-ordinate the receipt of, instigate the investigation into and reply to the complaint. However it need not be the same member of staff who always investigates. Verbal complaints as well as written complaints are recorded.

#### **4.4 North Eastern Area**

The Complaints Procedure for the North Eastern Area emphasises that managing complaints is everybody's responsibility. It sets out a number of key principles of the policy and these include such aspects as responsiveness, accessibility, impartiality and confidentiality amongst others. This complaints procedure has a very detailed section on "who may make a complaint?" The service user, an immediate family member, a carer or a legal representative may make a complaint on behalf of the service user. Any other person making a complaint on the service user's behalf must have the written consent of the service user. This includes public representatives making complaints. Special conditions applying to psychiatric patients and persons with special needs are also cited.

There is a nominated complaints co-ordinator in each region, usually a senior administrative staff member, but these co-ordinators can also nominate others to investigate complaints.

The procedure is similar to that of the North West in how it deals with serious complaints requiring immediate action by management and medico-legal claims.

Verbal complaints are resolved locally where possible and all complaints must be recorded on a log form. Table 1 sets out the information required by the log form as an example of the detail required in recording complaints at local level.

Table 1. Details to be recorded in log form for Verbal complaints

<ul style="list-style-type: none"><li>a) Complainant's name and address</li><li>b) Service user's name and address (if different from above)</li><li>c) Contact telephone numbers</li><li>d) Brief description of the complaint with details of staff involved, time and date</li><li>e) Details of action taken</li><li>f) All forms should be signed and dated</li></ul>
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Source: Complaints Procedure North Eastern Area

The procedure also contains detailed guidelines for responding to written complaints, including pointers for documenting, investigating and responding to the complaint. The guidelines for communicating with staff members involved in an incident or complaint are worth replicating (see table 2), as this is one of the few policy/procedure documents that give guidance in this area.

Table 2. Communication with Staff Member involved in incident/complaint

<p>This communication should include:</p> <ul style="list-style-type: none"><li>➤ A statement indicating that a complaint has been received and giving the date and service areas referred to in the complaint</li><li>➤ Enclose details of complaint together with summary points the complainant wishes to have addressed</li><li>➤ Request a written report that addresses the key points raised</li><li>➤ Date by which report should normally be returned to the Complaints Co-ordinator (this should normally be two weeks)</li><li>➤ Invitation to contact you to discuss details</li><li>➤ Be given assurances re Confidentiality</li><li>➤ Provided with support, advice and help particularly where allegations of a serious nature are made</li><li>➤ When staff are interviewed they should be advised that they may be accompanied and represented by staff association/trade union</li><li>➤ Staff should always be kept informed and updated on progress of complaint investigation</li></ul>
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Source: Complaints Procedure North Eastern Area

The procedure states that if the complaint is not resolved the complainant can request a review by writing to the Chief executive officer of the Health Service Executive. The Chief executive officer may decide in consultation with the Regional Customer Services Co-ordinator if it is necessary to set up an independent review in relation to individual complaints. An independent review panel will be provided with all the documentation relevant to the complaint, will conduct the necessary investigation and report back to the complainant also informing the complainant of the right of referral of the complaint to the Office of the Ombudsman.

The timeframes for the various stages in the investigation are set out in the procedure as follows:

- Acknowledge complaint within 5 working days
- Outcome of investigation must be issued within 28 working days
- Response to review issued within 20 working days
- Independent review response within 30 working days.

The importance of monitoring complaints and comments is highlighted and the procedure states that these should be discussed at departmental meetings. The complaints co-ordinators are also required to submit monthly reports to the Regional Customer Services Department.

#### **4.5 South Eastern Area**

This area has in place a policy entitled “We’re listening to you” which incorporates compliments, comments and complaints. A regional Appeals and Complaints Officer has responsibility for the overall organisation, effectiveness and accountability of the comment, compliments and complaints procedure. He is accountable to the CEO and the Management team for:

- setting up, resourcing and monitoring the procedure.
- directing and overseeing the arrangements for training and publicity
- collecting data about complaints from managers and staff and distributing data to CEO and management team
- investigating on appeal where a complainant remains dissatisfied.
- presenting recurrent, important issues to the management team for action,
- production of an annual report on comments, compliments and complaints.

Comment cards are available to service users. The complaints process in the Southeast has five stages. Stage one involving front line staff who receive a complaint assessing if it is resolvable at this level. Stage 2 - when not resolved at front line it is passed to the general manager or line manager. Stage 3 - complaint if not already resolved is passed to the general manager, who informs the Head of Department of the staff member complained about. Stage 4 - appeal which is conducted by the Regional Appeals and Complaints Officer. Stage 5 - the Ombudsman's office. In the case of clinical judgement complaints, they are referred directly to the general manager who informs the consultant in charge of the patient. The consultant and general manager together try to resolve the complaint and if necessary will meet the complainant and their family. In relation to complaints about professionals other than doctors the general manager works with the head of the profession to resolve the complaint. The general manager must also notify the clinical risk manager. If a clinical complaint is not resolved it goes to Regional Appeals and Complaints officer who must take appropriate clinical advice from staff not involved in complaint. In exceptional circumstances, the CEO may establish an investigation panel to investigate a particularly complex complaint. Complaints are logged on a "Take Action" database or manually in the case where staff do not have access to the database.

#### **4.6 Southern Area**

The Southern Area has a complaints policy that has the following principles: Responsiveness, accessibility, simplicity, impartiality, swift resolution, confidentiality, quality enhancement and accountability. All hospitals and community care offices have local complaints co-ordinators, but the policy clearly states that any staff member may accept a complaint. The policy sets out 3 steps in the resolution of verbal complaints. If staff fail to resolve the verbal complaint the complainant is advised that they can submit their complaint in writing to the local complaints co-ordinator. For some complainants this will be the first contact, as they may have chosen to make the initial complaint in writing rather than verbally. For written complaints the three step process is investigation by the local complaints co-ordinator, investigation by the general manager and if not resolved investigation by the CEO. The CEO may also request external individuals to undertake an investigation. The

staff guide to complaints management contains the positions and locations and contact numbers of all local co-ordinators.

In **Cork University Hospital** the complaints officer is a member of the Quality Risk Management and Clinical risk groups and these feedback to the organisation the learning from complaints and incidents.

#### **4.7 Dublin Academic Teaching Hospitals**

##### **4.7.1 Beaumont Hospital**

In Beaumont Hospital patient representatives are available to patients to: give support and assistance; listen to patients concerns; help in a crisis situation; respond to a complaint; give information about hospital policies, procedures and services. This is explained very clearly in a patient information leaflet. The Complaints policy has a set of general principles and operational procedures for both verbal and written complaints. Verbal complaints must be resolved by the person receiving the complaint where possible. All verbal complaints are registered and should be forwarded to the patient representative within 24 hours. Unresolved complaints are referred to the patient representative for resolution. He/she acknowledges complaints within 2 days and undertakes to find a resolution within 28 working days. In the event of a complaint being a “clinical matter”, the Patient Representative will investigate this with the appropriate clinicians and notify the Medical Administrator. If the complainant is dissatisfied with the response he/she may refer the matter to the Complaints Appeals Committee established under the terms of the Patients Charter. The policy document for Beaumont hospital sets out very clear and pertinent guidelines for the patient representative to follow in responding to a complaint. These are reproduced in Table 3 as an example of good practice in corresponding with complainants.

Table 3: Guidelines for the Patient Representative

When formulating a reply to a written complainant the following apply.

1. Have we offered the complainant the opportunity to come and discuss their concerns with the clinical staff and managers concerned?
2. Have all the issues/concerns raised by the complainant been addresses in an honest and open manner? (It is useful to list each concern and respond in order).
3. Is there a clean and unambiguous apology for actions which have clearly fallen short of acceptable standards?
4. Is there an account of the actions to be taken by the hospital to prevent a recurrence?
5. Has the person against whom the complaint was made been notified and have they verified the accuracy of the proposed response.
6. The Patient Representative will formulate the written response following consultation with the relevant Clinician/Department Head. Where a complaint involves more than one Clinician/Department the Patient Representative will arrange to co-ordinate the response, again in consultation with the relevant staff.
7. The Patient Representative must liase closely with the Insurance/Claims Manager.

Source: Beaumont Hospital Complaints Policy

#### **4.7.2 St. Vincent's University Hospital**

An important element in the handling of complaints at St. Vincent's University Hospital is early local resolution, this meaning that front line staff resolve most complaints. However, any complaints raised at ward/department level and not resolved are forwarded to the hospital's Complaints Officer. If complainants do not wish to discuss their complaint at local level they are directed to submit their complaint in writing to and/or to meet with the Complaints Officer. Posters containing this information are displayed throughout the hospital and the procedure is included in the patient information booklet and on the hospital's website.

One noteworthy aspect of the system in this hospital is the speed of response, with all complaints being acknowledged within 5 working days and all complaints being fully investigated with a response issuing to the complainant within 28 days. Also, within the process of complaints handling, complainants may be invited to meet with the Chief Executive Officer and appropriate senior representatives of staff, who can address their concerns.

#### **4.7.3 Mater Misericordiae University Hospital**

The Mater Hospital has developed a draft Complaints Policy that was awaiting executive approval at the time of this consultation. The policy takes an integrated approach to complaints management with clear guidelines on alerting the Claims Co-ordinator where the complaint reveals possible negligence that may lead to a claim. The investigation of complaints about “clinical matters” is also integrated and the Complaints Officer investigates such complaints “with the appropriate clinician(s)” and may also “discuss the complaint with officers of the Medical Executive”.

An additional strength of the policy is the attention that is given to supporting an employee against whom a complaint is made. It states that such an employee may be freed from other responsibilities for the time taken to respond to the complaint and that the employee is entitled to consult with his/her legal representative at any time during the process.

#### **4.8 Dublin Maternity Hospitals**

The Coombe Women’s Hospital and the National Maternity hospital have complaints systems where clinical and non-clinical aspects of complaints are investigated with clinical issues being channelled through nursing/medical management. The National Maternity hospital holds a weekly clinical governance meeting with a dedicated time slot for complaints. This feeds in to clinical governance decisions and actions. In the Rotunda complaints are investigated and managed by the Master and Director of Nursing. Verbal complaints are logged in the Rotunda, whereas the other two Dublin maternity hospitals do not log verbal complaints.

#### **4.9 Good Practice in Managing Complaints**

Current practice in the Southern area is to acknowledge within 48 hours, in the North East acknowledgement on the same day is the practice. Current practice in some hospitals is that the complaint is examined locally for the purposes of validation, following this it is either investigated locally or referred to the Medical Council or appropriate regulatory body if there are issues of malpractice.

Some complaints officers feel they have access to good advice from their own managers and from their HRM departments. There also seems to be some peer support amongst complaints officers.

In most organisations there is a strong emphasis on induction programmes for staff and customer care training. Also many organisations have conducted cultural diversity training for staff.

Support for staff against whom a complaint has been made is an important component of any complaints system. The Mater Hospital's policy for example supports staff by allowing them to be freed from responsibilities to respond to the complaint.

There is a general awareness of the need to learn from complaints. Some services have a quarterly Management review of complaints to ensure that service improvements result from complaints they have received.

Concern has been expressed by many about the negative image associated with complaints and the impact this may have on the staff and the services they provide. Many organisations have attempted to present more balance in their complaints management system by also inviting positive feedback. For example the Midland Area has a system that accepts comments, enquiries, complaints and appeals. Beaumont hospital has a Patient Representative (rather than a Complaints Officer) who performs a wide range of functions in relation to patients from giving support and assistance, listening to concerns, responding to complaints and giving information about hospital policies, procedures and services.

## **5. The Proposed Regulations**

This section of the report is based on the contributions during the consultation process that took place from May to September 2005, as well as a review of complaints handling arrangements in other sectors and in other jurisdictions.

### **5.1 Section 45: Definitions.**

The definitions as set out in section 45 of Part 9 of the Act were deemed appropriate. There was some discussion about the definitions of “complaint” and “close relative” and the implications of these definitions. The issues relating to the definition of “complaint “ are discussed under Section 48 - matters excluded from the right to complain” and the issues in relation to “close relative” are discussed in Section 46 (3) (a) - advocacy.

### **5.2 Section 46: Who may make complaints?**

Section 46 (3) (a) states that “If a person entitled under this section to make a complaint is unable to do so because of age, illness or disability, the complaint may be made on that person’s behalf by a close relative or carer of the person. During the consultation several people expressed concern about situations they had experienced where several relatives make complaints about the same action. A recommendation arising from this is that on first contact with the health services each person should be requested to designate a relative or carer as the primary liaison person between the service providers and the family. If the family wishes to make a complaint it would then agree to do so through this liaison person. The purpose of such an arrangement is to avoid duplication in the investigation process where more than one relative or carer has made complaints about the same action.

It was also suggested that advocacy services might appropriately be offered to marginalized, disadvantaged or disempowered users who wish to make a complaint. An additional concern was the use of the word “citizen” as conferring entitlement to complain, as there are many people resident in this country who are not citizens, but are equally entitled to make a complaint.

There was general agreement that it would be inappropriate for staff of the HSE to act as advocates for complainants. This complaints system is not an appropriate mechanism for staff to make complaints. The Trust in Care (2005) policy allows for staff to make complaints about *abuse* of patients or clients by staff members. However it is acknowledged that a system or mechanism needs to be put in place to support staff who wish to make complaints about actions taken in relation to patients or clients that may adversely affect them. This is particularly important in the case of children where staff may be the only possible advocates for them.

Additionally, children should be entitled and supported to make complaints in their own right. The HSE complaints system needs to acknowledge this and build child-friendly supportive processes into the complaints system.

An additional recommendation was that service providers should be flexible in receiving complaints allowing complaints to be made by letter, by e-mail or verbally in face-to-face or telephone communication. However, where a complaint is made against a named staff member, it should be made in writing giving specific details such as dates and locations in order to allow the complaints officer to check the veracity of the complaint. It is important for staff members to be sensitive to complainants who may have poor literacy skills when requesting a written submission of the complaint.

#### **5.2.1 Section 46(3)(e) - Advocacy.**

A person appointed to act as an advocate should have obtained (where possible) the consent of the person on whose behalf the complaint is being made. The Act recognises that a person may be unable to make a complaint because of age, illness or disability, but it is also possible that a person may choose not to make the complaint him/herself for other reasons and may instead choose an advocate. In such cases informed consent to act as an advocate is essential. The complaints officer should make available a simple consent form that should be signed and dated by both the complainant and the advocate.

The Comhairle (Amendment) Bill 2004 introduces personal advocacy services specific to people with disabilities. The new service will be administered by

Comhairle and envisages the provision of advocates to persons with a disability who have difficulty in obtaining a social service without assistance. The main function of the personal advocate in this particular service is to assist, support and represent the person with a disability in applying for and obtaining a social service and also in pursuing any right of review or appeal in connection with that service. The DOHC strongly recommended that the HSE and its service providers seek to avail of this Comhairle administered, regionally based advocacy service in meeting the requirements of S.46(3)(4) of the Act and that this arrangement be reflected in the Regulations. This was considered appropriate by those who attended the consultation workshops. However, it was felt important that advocacy on behalf of people with a disability should not be restricted solely to the Comhairle administered service. The Irish Advocacy Network was considered a good source of locally based advocacy organisations, of which there are several.

A strong recommendation emerged that the HSE should develop a framework and guidelines for accrediting advocacy services and that this work should involve consumer representation. In the absence of some regulatory mechanism, there was some concern about the potential for groups to establish advocacy services and exploit complainants. It is important therefore to ensure that all those eligible to act as advocates receive appropriate training.

### **5.3 Section 47: The time limit for making complaints.**

The specified period of 12 months from the date the action occurred or the date the person became aware of the action as set out in Section 47 (2) (a) & (b) was considered reasonable as it falls well within the statute of limitations, thus allowing time for the investigation to be completed and subsequently pursue a legal course of action if this is the complainants wish.

Section 47 (3) states that “A complaints officer may extend the time limit for making a complaint if in the opinion of the complaints officer special circumstances make it appropriate to do so.” There was general agreement that the regulations should not specify these special circumstances but should leave it to the discretion of each individual complaints officer to make this decision. It was however considered appropriate that the HSE might give some guidance to complaints officers on this,

recognising that it would not be possible to delineate all possible circumstances where an extension of the time limit would be appropriate. The following is a list of some of the circumstances that were considered appropriate (inserted here not to inform the regulations but to assist the HSE in developing guidelines for its complaints officers):

- If the complainant is ill or bereaved
- If new information relating to the action becomes available to the complainant
- If the complainant was living abroad and unable to make complaint within the 12 month timeframe
- If it is considered in the public interest to investigate the complaint
- If the complainant didn't have courage to complain at the time
- If the complainant felt coerced into not making a complaint or if he/she feared repercussions would arise from making a complaint.

The consensus from the workshops was that it is better to be lenient in allowing complainants to exceed the time limit, particularly where the only alternative for the complainant is to pursue his/her complaint through the legal system. In cases where a complaint has been made against a named staff member, the complaints officer should also consider the implications for the staff member and come to a reasonable decision in extending the time limit for the complainant.

### **5.3.1 Time limits for responding to complaints**

An additional recommendation relating to time limits was that the regulations should specify time limits for responding to and investigating complaints. The variation in practice in this regard throughout the HSE is considered to be a problem. There was not absolute agreement in regard to specific timeframes and service providers tended towards longer timeframes, whilst consumer and advocacy groups tended towards shorter timeframes. Giving due consideration to all opinions, the following timeframes are being recommended as a workable solution:

**Response to complaint:** This should issue in writing within 5 working days of receiving the complaint. In the case of a verbal complaint made whilst on the premises of a health facility a verbal response should issue as soon as is practically possible and definitely within a 24 hour period.

**Investigation of complaint:** The regulations should also specify 10 working days as the limit within which staff must respond to requests from a complaints officer for clarification or explanation of events related to the complaint. (This is currently perceived to be the area where most time delays occur in complaints investigation and complaints officers feel they have limited powers to ensure that staff will comply with their requests).

**Communication of the outcome of investigation:** The complaints officer should communicate the outcome of the investigation to the complainant within 20 working days of the acknowledgement of the complaint. There may on occasion be circumstances where the investigation cannot be completed within this timeframe, e.g. where the complaint is complex and involved several incidents over a period of time or requires responses from several groups of staff or staff who are no longer employed by the HSE. In circumstances where this occurs the complaints officer must communicate this to the complainant within 20 working days of acknowledging the complaint and give some indication of the time it will take to complete the investigation. The complaints officer should communicate progress on the investigation every 10 days following the initial 20-day period until a final report on the investigation is issued. Regardless of the complexity of the complaint no investigation process should exceed 6 months. If this does occur the complaint should be forwarded for independent review.

#### **5.4 Section 48: Matters excluded from right to complain.**

##### **5.4.1 The exercise of clinical judgement**

This section of the act is the one that resulted in most debate and discussion amongst health service providers. Section 48 (1) (a) and (b) both refer to the exclusion of complaints that concern matters related to or arising from “the exercise of clinical judgement”. Section 2 (1) of the Act defines clinical judgment as “a decision made or opinion formed in connection with the diagnosis, care or treatment of a patient”. Some of the difficulties around its inclusion or exclusion in complaints procedures seem to arise because the different stakeholders are interpreting the meaning of clinical judgment differently. In a broad sense, clinical judgment can be understood as the decisions taken by a clinician that are based solely on clinical evidence and

clinical expertise. The difficulty that this poses is that in reality few clinical judgements are made on this basis. Other factors frequently play a part in the making of a clinical decision, for example the availability of resources, time factors etc.

The most serious issue that stems from disagreements about the definition of clinical judgement is the danger that some complaints may be excluded from consideration by this complaints procedure and may subsequently fail to meet the criteria for consideration by the pertinent regulatory body. A consideration of the position in relation to clinical judgement taken by some of the key agencies involved in the investigation of complaints has been set out below in an attempt to identify whether it is likely that complaints could be of a nature that might lead to their exclusion from all complaints investigations systems.

#### **5.4.1.1 Ombudsman's office and clinical judgment.**

The Ombudsman's office does not consider matters that concern clinical judgment because the staff in that office do not have clinical expertise and therefore do not feel competent to investigate complaints of this nature. The health boards were brought within the jurisdiction of the Ombudsman's Office by the Ombudsman Act (First Schedule) (Amendment) Order 1984. The SS1 332/1984 included the limitation that the reference to health board in the amended Schedule does not include:

- (a) persons when acting on behalf of health boards and (in the opinion of the Ombudsman) solely in the exercise of clinical judgment in connection with the diagnosis of illness or the care or treatment of a patient, whether formed by the person taking the action or by any other person, or
- (b) health boards when acting on the advice of persons acting as aforesaid, being actions of health boards that, in the opinion of the Ombudsman, were taken solely on such advice

Section 2 (2) of the Ombudsman's Act 1980 makes no reference to the exclusion of administrative functions performed by clinical staff. Therefore it would seem that it is within the powers of the Ombudsman's office to conduct investigation into an action taken in the performance of an administrative function that is the result of negligence or carelessness of a clinical practitioner. It is worth noting that a substantial proportion of complaints will have clinical as well as non-clinical aspects to them insofar as they refer to care and treatment of patients and therefore cannot be excluded

in their entirety from investigation by the Ombudsman's office. Indeed a recent example of such a case published by the Ombudsman's office is the Report by the Ombudsman in relation to a complaint about care and treatment of a patient at Sligo General Hospital (2005). The focus of that investigation was not on any aspect of clinical decision making, but on how the various incidents at issue could have happened and why measures were not in place designed to prevent such occurrences. This report makes reference to an intern's decision not to prescribe medication and his decision not to consult with a senior colleague when making a judgment/decision. The report also criticises the hospital for serious lapses in nursing standards. The report provides a good example of the difficulties a complaints officer may face in classifying individual complaints as pertaining to or not pertaining to clinical judgement.

The Ombudsman for Children's Act (Schedule 2) excludes from that office's investigation remit actions taken "solely" in the exercise of clinical judgement **in the opinion of the Ombudsman for Children**. The office takes a similar approach to the Ombudsman's office in dealing with referred complaints that contain both clinical and non-clinical aspects, in subjecting the non-clinical or administrative aspects to investigation

#### **5.4.1.2 Existing complaints systems and clinical judgement**

Several hospitals have complaints systems that do consider matters that relate to clinical judgment and report that staff are fully cooperative with such systems. For example in some of the maternity hospitals clinical and non-clinical aspects of complaints are investigated within the hospital, with clinical matters referred to nursing and medical management within the hospital.

In the South Eastern Area complaints concerning clinical judgement are also investigated locally. In the case of clinical judgement complaints, they are referred directly to the General Manager who informs the consultant in charge of the patient. The consultant and general manager together try to resolve the complaint and if necessary will meet the complainant and their family. In relation to complaints about professionals other than doctors the general manager works with the head of the profession to resolve the complaint.

Beaumont hospital's complaints guidelines states that in the event of a complaint being a "clinical matter", the Patient Representative will investigate this with the appropriate clinicians and will notify the Medical Administrator.

#### **5.4.1.3 The Medical Council and clinical judgement**

The Medical Council is charged with protecting the public by ensuring that all registered medical practitioners reach required standards of education and training before being registered to practice. Additionally the Council has a duty to consider complaints against medical practitioners to determine if there is evidence of professional misconduct or whether the doctor is unfit to practice medicine. Professional misconduct is defined as "conduct which doctors of experience, competence and good repute consider disgraceful or dishonourable and/or conduct connected with his or her profession in which the doctor concerned has seriously fallen short by omission or commission of the standards of conduct expected among doctors" (Medical council's guide to ethical conduct and behaviour). Additional tests of professional misconduct that are drawn upon in legal proceedings in this jurisdiction are those set out by Mr. Justice Keane in *O Laoire v The Medical Council* 1995. The five tests are set out in Appendix C. In a recent Position Paper on *Negligence vs. Misconduct*, Kennedy (2004) highlighted the difficulties of defining the term medical negligence and furthermore the difficulty in establishing a case for negligence before a court. Kennedy points out that in order to establish a case for negligence before a court a plaintiff or claimant must establish:

- the existence of a "duty of care"
- a failure to attain the standard required by that duty of care
- loss or damage occurring to the person affected by the failure to take care
- the loss or damage must have been caused by the failure to conform to the required standards.

If any one of these elements are missing it is difficult to maintain an allegation of negligence. Kennedy whilst acknowledging that there is some overlap in the tests for professional negligence and professional misconduct summaries the tests for each as follows:

Table 4: Negligence vs. Misconduct

	Professional Negligence	Professional Misconduct
The Purpose	the purpose of a negligence action is to put the wronged party back in the position they would have been in but for the negligent act	the purpose of disciplinary proceedings in a regulatory professional body is to preserve the public interest
The Case	the damage suffered by the claimant/patient/client and the courts assessment of that damage in the form of compensation	the conduct of a particular practitioner and the imposition of a penalty by the Council having regard to the public interest
The Burden of Proof	is on the balance of probabilities	beyond all reasonable doubt
Role of the Client	Claimant in the proceedings	Witness to the proceedings

Adapted from: Kennedy, W (2004) Position Paper: Negligence vs. Misconduct

His advice to the Fitness to Practice Committee when considering complaints is to have regard to the definition of professional conduct in the Guide to Ethical Conduct and Behaviour, to the definitions set out by Mr. Justice Keane in the O Laoire case, to whether the practitioner in question knew or ought to have known that the conduct he or she had embarked upon was improper; and whether or not the public interest is at risk.

#### **5.4.1.4 An Bord Altranais and clinical judgement**

An Bord Altranais or any person may apply to An Bord Altranais' Fitness to Practice Committee for "an inquiry into the fitness of a nurse to practice nursing on the grounds of alleged unfitness to engage in such practice by reason of physical or mental disability". Similarly to the Medical Council, if the Fitness to Practice Committee is of the opinion that there is a prima facie case for holding an inquiry it will do so.

#### **5.4.1.5 The Health and Social Care Professionals and clinical judgement**

Concern was expressed by a number of Health and Social Care professionals about Section 48 (1) (a) and (b) excluding clinical judgment. In the absence of a Council similar to the Medical Council or An Bord Altranais, there is currently no regulatory mechanism to protect the public in receipt of care from these professionals. However

the Health and Social Care Professionals Bill 2004 when enacted will make provision for this. Section 50 (1) states that the Council shall establish a) a preliminary hearings committee, b) a professional conduct committee, and c) a health committee. The Bill in Section 51 (1) states that a complaint may be made to the Council concerning a registrant on the grounds of - a) professional misconduct; b) poor professional performance; c) impairment in ability to practice because of a physical or mental ailment, an emotional disturbance or an addiction to alcohol or drugs; d) a failure to comply with a term or condition of registration; e) failure to comply with a committee of inquiry; f) a contravention of the Act; g) a conviction in the State for an offence triable on indictment or a conviction outside the State for an offence consisting of acts or omissions that, if done or made in the State would constitute an offence triable on indictment.

#### **5.4.2 Professional negligence**

Section 46 (2) (c) of the Health Act indicates that a complaint can be made about an action that is the result of negligence or carelessness, as such an action would be considered not to accord with fair and sound administrative practice. Malpractice is a term used to describe negligence by a person in a professional occupation. Medical malpractice is negligence committed by a medical professional. Medical malpractice and medical negligence therefore have the same meaning.

Negligence may be defined simply as:

“Failure to exercise the degree of care expected of a person of ordinary prudence in like circumstances in protecting others from a foreseeable and unreasonable risk of harm in a particular situation”.

Merrum-Webster Legal Dictionary

The legal definition of the term negligence is

“negligence, in law, especially tort law, the breach of an obligation (duty) to act with care, or the failure to act as a reasonable and prudent person would under similar circumstances. For a plaintiff to recover damages, this action or failure must be the “proximate cause” of an injury, and actual loss must occur. Among possible defences to a negligence action are that the plaintiff assumed

the risk of injury (e.g., of being hit by a batted ball at a baseball game), or that the plaintiff brought on the injury by his or her own negligence. Most negligent acts are inadvertent; between them and fully intentional acts lie forms of conduct variously termed wilful, wanton, or reckless. Deliberate judgments that are dangerously careless (e.g., faulty building design) may, however, be considered acts of negligence.”

Columbia University Press.

The obligation to act with care may arise out of a relationship established by contract, as in the duty assumed by a common carrier (e.g., a railroad) in preserving goods and passengers from damage or injury. But the law also supposes that all persons in the ordinary course of conduct have a duty to avoid inflicting injuries on others. In all non-contractual situations this duty is to act as a “reasonable, prudent person” would act.

#### **5.4.2.1 Inclusion of Negligence in Complaints Systems**

It would seem therefore that there is the potential for a health professional to be negligent as an ordinary citizen (in their administrative and interpersonal interactions) and also as a professional (in diagnosis, treatment and care of a patient). In the US the determination of whether a medical professional was negligent “is made by measuring the person’s conduct against an objective standard of reasonable care under the circumstance”. It is worth noting that the term medical professional includes “ a physician, osteopathic physician, dentist, registered or licensed practical nurse, optometrist, podiatrist chiropractor, physical therapist and psychologist, as listed under the definition of Healthcare Provider”. As the standard of care for health professionals are set by other health professionals it is reasonable to assume that the standard of care itself and the claimed failure to meet it, must be established by expert testimony.

Current practice in the professional regulatory bodies is that all complaints are considered by the Fitness to Practice Committees and are primarily judged against the profession’s ethical guide. Only complaints that involve serious case of negligence or persistent negligence over a period of time constituting misconduct are likely to

warrant the holding of an inquiry, which is similar to a hearing before a court or a tribunal. It is likely therefore that, apart from the healthcare providers who currently include complaints of a clinical nature, most complaints where there are claims of negligence are likely to be pursued through the legal system. Given this situation it seems sensible to allow complaints that concern claims of negligence to be appropriately dealt with by this complaints system. This would require the involvement of the appropriate health professionals in determining if there has been a breach of standards. This could be achieved by ensuring a formal link between complaints officers and Healthcare Governance Committees with complaints officers utilising the expertise of the Committee to determine whether:

- a) the complaint is one that involves negligence and can be dealt with by the complaints system; or
- b) the complaint is concerned with professional misconduct or Fitness to Practice and should be referred to the appropriate regulatory body for investigation.

As each clinical profession has its own set of standards it could become very complex to assess adherence to such standards. Additionally the potential for overlap between the investigation of compliance with standards in a case of professional misconduct and a case of professional negligence may create difficulties for regulatory bodies investigating professionals. In order to ensure a comprehensive complaints process that is capable of dealing with issues of negligence it is therefore recommended that:

(a) a Patients' Bill of Rights and Responsibilities be incorporated into the regulations that accompany the Health Act. The proposed Bill of Rights and Responsibilities would not be based on the controversial "right to health" concept but rather on the rights of patients in relation to provider patient interaction and duty of care. This Bill of Rights and Responsibilities would then form the set of standards against which complaints can be assessed and all healthcare providers would be expected to comply with this set of standards. An example of such a Bill of Rights taken from the New Zealand system is included in appendix D. An additional advantage of a Bill of Rights and Responsibilities is that it makes explicit the expectations of patients and consumers. It is therefore strongly recommended that patient representatives and advocacy groups be centrally involved in developing an appropriate Bill of Rights and Responsibilities for the Irish healthcare consumer. This should also include reference

to children and the standards of interaction and duty of care that are appropriate when dealing with child complainants.

(b) Healthcare Governance Committees take on the role of agreeing with the regulatory bodies and other agencies involved in the investigation of complaints a comprehensive set of guidelines on the referral of complaints from the HSE to other agencies. Such guidelines should form the basis of standardising practice throughout all HSE healthcare facilities and HSE-funded healthcare facilities in relation to the inclusion and exclusion criteria for the investigation of complaints.

In summary, it is recognised that it is possible that complaints about poor administrative practice may have clinical components (that cannot be said to relate *solely* to matters of *clinical judgement*) that do not come within the realm of professional misconduct or Fitness to Practice (as these terms are defined by the regulatory bodies). These may involve professional or clinical negligence or may comply with the broader definition of negligence i.e. “failure to exercise the degree of care expected of a person of ordinary prudence in like circumstances in protecting others from a foreseeable and unreasonable risk of harm in a particular situation”. Such complaints can be dealt with appropriately by the complaints system as set out in Part 9 of the Health Act, with a Patients’ Bill of Rights and Responsibilities setting out standards against which complaints can be assessed and with the expertise of a Healthcare Governance Committee assisting the complaints officer.

## **5.5 Sections 49 and 53: Complaints and review procedures to be established.**

There is acceptance that a three-stage complaints procedure is necessary and appropriate with an emphasis on early resolution of complaints at local level where possible. This section of the report will deal with the infrastructure and procedures that are pertinent to each of the three stages, namely local resolution, independent review and the Ombudsman.

### **5.5.1 Stage 1: Local Resolution**

This consultation exercise has highlighted that service providers at the point of service delivery are currently successfully resolving many complaints informally. This practice needs to be encouraged and supported by raising awareness amongst staff

that each individual service provider is accountable to the patient/client and has a responsibility to respond to concerns that they raise and where possible provide an apology and/or explanation. The HSE must ensure that all employees are made aware of the complaints policy and are sufficiently familiar with the complaints procedures to explain them to the client or service user. The HSE must also ensure that all employees have access to detailed guidelines on the receipt and management of complaints and their role in the resolution of complaints at local level.

Additionally there needs to be a dedicated member of staff whose responsibility is to liaise with complainants, investigate complaints, maintain a complaints database and provide regular feedback to the management of the service on complaints trends and issues pertaining to service quality (arising out of complaints).

Local resolution needs to be accessible, simple and speedy. The current situation is far too complex in some organisations, with some having a review by the CEO and others having an internal appeals procedure following on from the initial attempt to resolve the complaint. Many complaints officers feel unsupported and ill prepared for the task. The complexity of the current practice can in part be attributed to the lack of authority and expertise invested in the role of complaints manager and the limited resources at their disposal. This results in far too many complaints remaining unresolved and therefore being referred to more senior managers and/or the complainant appealing the decision of the complaints officer.

The complaints handling system could be more effective and efficient if rather than dispersing resources through a number of internal investigations and reviews, resources are concentrated in one investigation process at senior level with a complaints officer having access to the advice of senior clinicians and managers where necessary. In organisations where the complaints officer is at a more senior level and there is more authority invested in the role the outcomes are more satisfactory e.g. in the South East, North East, Mid-west and Eastern regions. However in some of these regions there is another layer of complaints officers at a lower level of the organisation resulting in unnecessary complexity in the investigation and resolution of complaints.

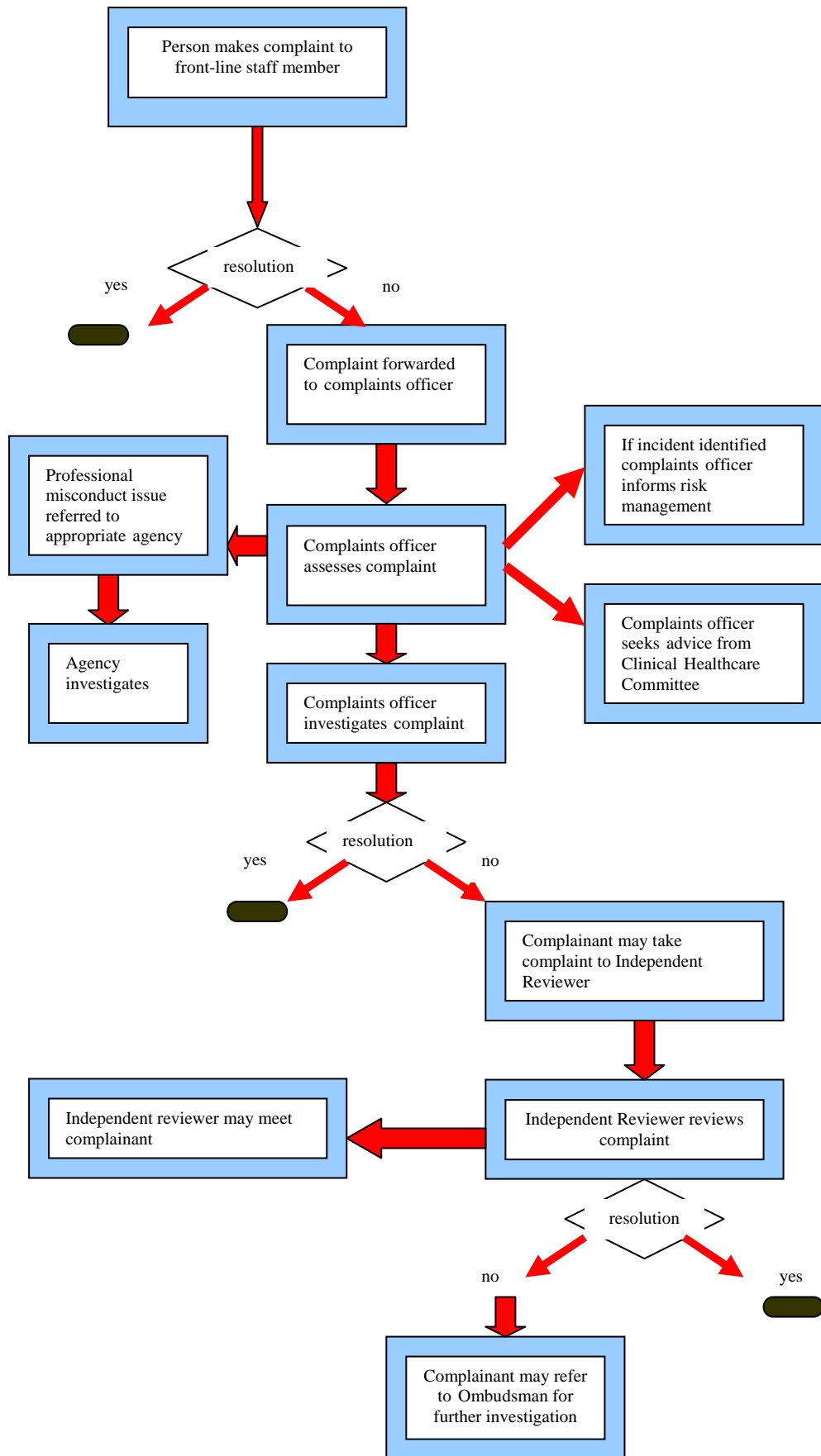
The complaint-handling system also needs to differentiate clearly between complaints and review of decisions. Complaints about the manner in which a service is provided or the standard of the service need to be clearly distinguished from the questions of a person's entitlement to a service. If a person's complaint is that they are entitled to a different service, the real issue may be with the HSE's (or contracted service provider's) decision about their entitlements. In this situation the person needs to have that decision reviewed by the HSE's appeals system. Care needs to be taken by complaints officers to ensure that persons with issues about their entitlements are identified at an early stage and redirected into the appropriate appeals process.

It is therefore strongly recommended that existing practice be changed to having only one internal investigation of the complaint within the organisation. This requires substantial changes to the role and level of seniority of the complaints officers. Consumers and advocates placed importance on the visibility and accessibility of the complaints officer. It is therefore important that each local health office and each hospital have a designated complaints officer. In the case of voluntary organisations who do not have the resources to appoint a complaints officer at a senior level, the CEO of the organisation may take on this function or he/she may appoint a person who reports directly to the CEO and has a strong working relationship and support and advice from the HSE local health office complaints officer.

The complaints officer should hold responsibility for the complaint from the time it is referred from a front line staff member to the time the HSE has finalised the investigation and reported back to the complainant. This means that all staff involved in the investigation and resolution of the complaint, whether they are senior clinicians, senior managers or the CEO of the organisation, should work through the complaints officer's office. This should significantly reduce the time delays that are created by the current common practice of referring the complaint up the hierarchical chain of the organisation. The effectiveness of this system is dependent on having complaints officers who have a good understanding of the complaints investigation roles of all health agencies, who have been well-trained for their role and who have been vested with the authority to operate effectively in this role. There should also be a designated Complaints Monitoring Committee located within Consumer Affairs at HSE headquarters and each of the complaints officers should be required to submit

quarterly reports to this Committee. This monitoring committee should have patient representation in its membership. The HSE framework for Handling Complaints, which arises from the work of the former ERHA, needs to be modified to reflect these changes. Whilst this framework was appropriate for a health system that was made up of several providers, it is no longer appropriate to one large organisation with an integrated set of providers. Figure 2 sets out a modified Complaints Pathway that takes account of the proposed changes arising from this consultation.

**Figure 2: Complaints Pathway: Steps in Complaints Handling**



### **5.5.1.1 Link with Healthcare governance**

Many of those who took part in this consultation exercise expressed serious concerns about fragmentation, duplication and unnecessary complexity in how the system deals with adverse events, whether they are complaints, incidents, errors, negligence or misconduct cases. This not only makes it very difficult for complainants to obtain a satisfactory response but it also inhibits organisational learning and reduces the potential for complaints to lead to service improvement.

The establishment of the Clinical Indemnity Scheme has resulted in a standardised system for reporting and managing incidents. The use of a common methodology of investigation i.e. root cause analysis, will further strengthen the risk management system. This is a model that could usefully inform a standardised HSE approach to managing complaints. Regardless of whether or not a similar methodology is used for investigating incidents and complaints, it is important that there is close linkage and good understanding of the functions of each. The complaints officer needs to know when to alert the risk management system to the occurrence of an incident that may be identified within a complaint.

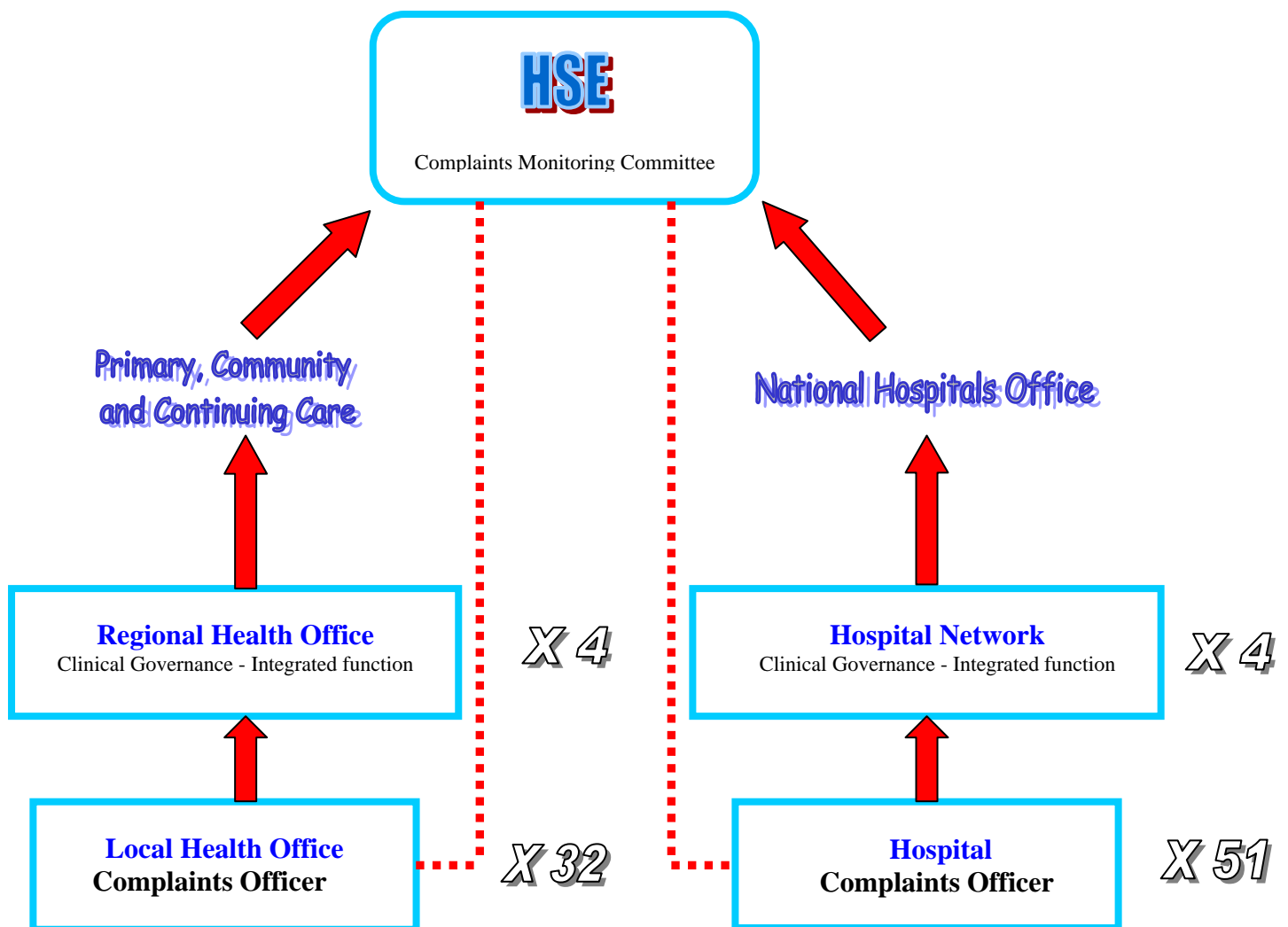
Both risk management and complaints management fall within the remit of good healthcare governance. Indeed, the function of healthcare governance provides a natural forum for complaints, risk management, quality and audit to exchange information and contribute to improvements in patient care. Where Healthcare Governance Committees are already in place it would be strongly advisable that the complaints officer should be a member of this committee. His/her role within the committee should not simply be a reporting one. The Healthcare Governance Committee should also serve as an important source of advice and assistance for the complaints officer in classifying, directing and investigating complaints. Equally important is the inclusion of patient representation on Healthcare Governance Committees. Such committees should establish clear lines of communication and forge a positive working relationship with the regulatory bodies and other agencies that may be involved in the investigation of complaints. The Committee should be

the primary source from which the complaints officer seeks any advice or clinical expertise he/she may require in classifying, directing or investigating a complaint. It is very much hoped that all HSE healthcare facilities will shortly have Healthcare Governance Committees in place.

### 5.5.2 Regional Level Integration

There is anecdotal evidence that having collaboration and some degree of integration between the Freedom of Information (FOI) function, the Risk Management function and the Complaints Function leads to improved responsiveness to the public. It would therefore seem important to have some mechanism for the integration of these functions at regional and hospital network level (see figure 3).

**Figure 3: Integrating Complaints Officers within HSE**



### 5.5.3 Role and Functions of the Complaints Officer

Each local health office and each hospital should have a designated post of Complaints Officer. There has been some suggestion that the HSE might consider changing the title of such posts to Patient Representative or Patient Liaison Officer to reflect a more open and welcoming approach to feedback from users. However there are others who feel this would cause unnecessary confusion. It also needs to be borne in mind that the term “patient” does not apply to all persons eligible to make complaints.

The primary functions of the Complaints Officer should be as follows:

- to ensure complaints systems are widely advertised in the healthcare facility and that all staff have been made aware of the complaints policy
- to support and advise staff on dealing with informal complaints
- to liaise with complainants
- to decide if a complaint should be investigated or referred elsewhere for investigation

(this necessitates that the complaints officer have a full understanding of the investigative criteria, powers and procedures of all the agencies that have a role in investigating healthcare complaints)

- to refer a complaint for investigation to professional regulatory bodies if deemed necessary and to inform the complainant that he has done so
- to inform risk managers when complaints indicate incidents that may have occurred
- to fully investigate complaints,
- to inform and request a written response from staff members about whom a complaint has been made
- to ensure that fair procedures are followed and full details of the complaint are provided in cases where a complaint is made against a staff member
- to provide a detailed report to the complainant on the outcome of the investigation of their complaint and any proposed changes or improvements to the service that will result from the concerns they may have raised
- to inform complainants of their right to independent review and to refer their complaint to the Ombudsman or the Ombudsman for Children.

- to maintain a complaints database and provide regular feedback to the management of the service on complaints trends and issues pertaining to service quality (arising out of complaints)
- to provide quarterly reports to regional and national complaints monitoring functions
- to make recommendations to senior management on changes that should be made to prevent the reoccurrence of a complaint

#### **5.5.4 Stage 2: Independent Review**

Independent review is a practice that is in place in many other health systems procedures for dealing with complaints. For the purposes of clarity it may be helpful to have a definition of independence as it pertains to stage 2 of the procedure.

*Independence* requires that apart from the contract to perform the function of independent review, there is no contractual or financial relationship between the independent reviewer and the organisation against whom the complaint is made and that there is no contractual or financial relationship between the independent reviewer and the complainant. In the case of a complaint against a health professional it is important that the independent reviewer is not a colleague of the person about whom the complaint is made and that he or she has no professional or personal relationship with the complainant or the person or organisation about whom the complaint is made. It follows therefore that the independent reviewer cannot be a practicing healthcare professional.

Independent review serves three important functions:

- It provides an impartial means of checking on the quality of Local resolution or Stage 1 of the complaints procedure
- It serves as reassurance to the complainant that any intentional or unintentional bias in the internal investigation of their complaint will be highlighted

- Through its recommendations it provides opportunity for continuous improvement both in service delivery and in the operation of the complaints system.

In order to fulfil these functions the review process must be *independent* and it must have the *authority* to ensure that recommendations are enforced.

There is acceptance of the right of the complainant to have a review of how their complaint was handled and the necessity to have a degree of independence attached to this review. Some are of the view that the Ombudsman's office provides this independence at stage 3 of the process and that stage 2 i.e. the review, can be conducted internally within the organisation as is currently the practice in some provider organisations. However, the consumer and advocacy groups were of the strong opinion that a review cannot be fair and impartial if it is conducted by employees of the organisation (about which the complaint has been made). Many of the staff who contributed their views during this consultation, particularly those complaints officers who already have a system for external independent review in place within their existing complaints system, are of the opinion that independent review is valuable to the organisation in terms of providing feedback on the complaints procedure and process.

There is considerable variation in the practice of reviewing complaints, with some organisations having the CEO conduct a review of the complaint investigation, some referring the complaint to an appeals officer for review and others referring to external consultants or establishing an external panel of experts to conduct review. There is also variation in terms of the perceived functions of the review and review procedures. For example, many of the reviewers were either asked or took it upon themselves to *re-investigate* rather than *review* the complaint and in so doing attempted to find a solution to it. In such cases it would not be unusual for the reviewer or review team to meet with the complainant and with members of staff implicated in the complaint. In other cases the review started from the perspective that the complainant is appealing the decision of the complaints officer and the procedure followed has been the same procedure that applies to appeals relating to entitlements under the Social Welfare Acts. Other reviewers clearly saw their remit as pertaining to a review of the documentation relating to the complaint with the

purpose of establishing whether the investigation was fair and impartial and whether proper protocols and procedures had been adhered to.

In defining the review function it is important to bear in mind the role of the Ombudsman and the Ombudsman for Children, which is to provide an independent re-investigation of the complaint. The distinction between review and re-investigation is an important one. A review is conducted to determine if correct procedure has been followed and if the complainant has been treated fairly in the process of the investigation of the complaint. The primary purpose of the review is to ensure the complainant has been fairly treated. The purpose is not to find a solution to the original complaint, that is the role of the Complaints Officer and/or the Ombudsman's office or Ombudsman for Children's office at a later stage. Stage 2 Independent Review should therefore be standardised and focused on the task of reviewing the documentation relating to the complaint to determine if procedures and guidelines have been followed. The Bill of Rights and Responsibilities referred to in the earlier section should serve as the standard against which to measure whether the complaint was dealt with in a fair and impartial manner. As the reviewer is not investigating the clinical practice of clinicians it should not be necessary for him/her to have clinical expertise, though he/she may seek clinical, legal or administrative advice in relation to particular aspects of the complaint.

The regulations to accompany Part 9 of the Health Act need to make provision for the establishment of the post of Independent Reviewer. The regulations should ensure that the following issues are facilitated:

- The HSE should establish, maintain and fund the Independent Review function.
- The duration and terms and conditions of employment of the Independent Reviewer should be agreed between the HSE and the Reviewer. (The volume of complaints requiring independent review should provide an indication as to whether this should be a part time or full time post.)
- The contract should be subject to review every two years.

- The person appointed to the post should not be a practicing healthcare professional, should not be an employee of the HSE and should have no other financial or contractual relationship with the HSE.

All complainants who have had their complaint investigated through local resolution should have the right to seek an independent review, provided they do so within 28 days of receiving the final report on their complaint from a complaints officer. Additionally, complainants whose complaint has been under investigation through local resolution for a period of more than six months may request an independent review.

The Independent reviewer should not examine or review a complaint received by him in any of the following circumstances:

- If the complaint is excluded under Section 48 (1) of part 9 of the Health Act
- If having completed his review of the complaint he has directed the HSE to re-investigate the complaint
- If he has directed the HSE to forward the complaint to a professional regulatory body or Fitness to Practice Committee for consideration of an inquiry into the alleged misconduct of a clinician implicated in the complaint.
- If the complaint is under investigation by the Ombudsman's office or the Ombudsman for Children's office.

The Independent Reviewer, having reviewed a complaint, may:

- Take no further action because local resolution has been carried out satisfactorily;
- Refer the case or part of the case back to local resolution recommending actions that might resolve the complaint;
- May make recommendation about improving systems to avoid future problems or to give redress.

The Independent Reviewer will give the complainant full reasons for his decision and will inform the complainant of his right to complain to the Ombudsman.

The Independent reviewer should be empowered:

- To receive and review any complaint made to him by or on behalf of a complainant concerning the handling by the HSE of a related complaint made to the HSE by or on behalf of the complainant.
- To review any complaint referred to him that has been under investigation by the HSE for a period of more than 6 months.
- To require the production of documentation in the possession of the HSE in connection with his/her review of the complaint
- To issue a written report to the complainant and to the HSE stating his/her conclusions and recommendations (if any) consequent on his review of the complaint
- To review generally the procedures of the HSE in relation to the receipt and the investigation by the HSE of complaints under part 9 of the Health Act 2004; and to make such recommendations to the HSE in relation thereto as he deems appropriate<sup>1</sup>
- to review the implementation by the HSE of complaints officers recommendations;
- To submit annually to the HSE a report on his activities during the year, which may also contain recommendations for change in the HSE's procedures for receiving and investigating complaints, the HSE in turn being required to forward this report to the Minister for Health.
- To seek the resolution by the HSE of a complaint in such a manner as he deems appropriate and reasonable in the circumstances.

The HSE should be required to comply with the recommendations of the Independent Reviewer.

### **5.5.5 Stage 3: The Ombudsman and the Ombudsman for Children**

Complainants whose complaint remains unresolved following local resolution are entitled to take their complaint to the Ombudsman or the Ombudsman for Children as appropriate. Whilst there was some support for the appointment of a Health Ombudsman, in place of independent review, this was not a widely held view. It is

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<sup>1</sup> This could be achieved by randomly selecting complaints files from service providers for review. This practice would be similar to that of the Independent Adjudicator in the Legal System who randomly selects approximately 50 files for review each year from the Law Society's internal complaints system.

important to note that the introduction of an Independent Review stage in the Complaints handling process does not impinge on the rights of any individual to take their complaint to the Ombudsman for re-investigation. Neither should it impinge on the Ombudsman for Children's power to intervene in the investigation of a complaint involving a child at any stage.

It is important that the Ombudsman's office takes an approach consistent to that of the HSE in terms of inclusion and exclusion criteria and the rights of complainants. At the time of writing, the Ombudsman's office is preparing a themed report that includes a proposal to introduce rights for complainants. This lends support to the concept of a Bill of Rights and Responsibilities for patients, as outlined earlier in this report.

#### **5.6 Section 51: Restriction on type of recommendations complaints officers may make and power to suspend implementation of recommendations.**

This section of the Health Act places restrictions on the complaints officer in terms of recommendations that might have resource implications for the service plan. During the consultation concern was expressed about the lack of power of complaints officers in terms of recommending improvements to services. Many complainants cite their main reason for making a complaint as being to ensure that their experience will not be repeated for other patients. If complaints are to be genuinely perceived as an opportunity to make improvements to services, it is important that this opportunity is not compromised through restrictive guidelines on complaints officers. Complaints officers in their quarterly reports should be required to raise issues such as recurring patterns of poor service and these should be taken cognisance of at regional and national level. One suggestion, which should be given serious consideration, is that a contingency fund should be made available by HSE headquarters to allow the implementation of priority recommendations arising from complaints investigations.

#### **5.7 Section 52: Adherence to complaint and review procedures to be condition of arrangements with service providers.**

There was strong consensus that there should be a standardised approach to managing complaints throughout the HSE. The effective management of complaints should form part of the contractual agreement between the HSE and its contracted service

providers. These service providers should be subject to review of their complaints procedures by the Independent Reviewer in the same manner as HSE providers.

**5.8 Section 54: Referral of complaint to Ombudsman for Children.**

The proposals set out in this report do not in any way impinge on the rights of individuals to refer complaints to the Ombudsman or the Ombudsman for Children. Complaints officers need to be familiar with the role of the Ombudsman and the Ombudsman for Children and need to inform complainants of their right to refer their complaint if dissatisfied with the outcome of the complaints officer's investigation.

**5.9 Section 55: Annual Report to include report on complaints and reviews.**

The value of detailed annual reports on complaints was recognised by the contributors to this consultation process. Openness and transparency in reporting on complaints activity is a necessary prerequisite to organisational learning and service improvement. Complaints officers will be required to submit quarterly reports on complaints activity to the HSE Complaints Monitoring Committee. These should form the basis for the HSE's annual report to the Minister. This annual report should be accompanied by the Independent Reviewer's annual report.

## **6. Conclusions**

There are many examples of good practice in complaints handling within our health system. This report has attempted to highlight some of these practices. Together with the contributions during the consultation process, they form the basis for much of what is recommended in this report.

The main problems with existing practice are the variability across the system, the significant time delays that can occur in the investigation of some complaints, the complexity of the internal investigation processes, and the expressed consumer need for greater transparency and independence.

These problems can be addressed by adopting a standard system across all HSE providers and HSE contracted providers. This system needs to operate standard time frames (that reflect best practice) for responding to and investigating complaints. It is strongly recommended that the local resolution stage of investigation be simplified, with more resources being channelled to improving a single internal investigation step. Complaints officers need to be appointed at a more senior level to ensure they have the expertise and authority as well as the support to fully investigate complex complaints.

The integration of the complaints system with other HSE and regulatory bodies complaints systems is important in simplifying the process for complainants. There needs to be an acceptance that the distinction between clinical and non-clinical complaints is to some extent artificial and that the system must respond to complaints that do not come within the powers or remit for investigation by the regulatory bodies. This requires greater collaboration between the regulatory bodies and the HSE in the matter of the investigation of complaints.

An independent review function that is independent of the HSE should be established and all complainants should be entitled to have their complaint reviewed. A key function of the Independent Reviewer is to encourage organisational learning and improvement in the HSE complaints system.

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## **Appendix A: Consultation Document on Part 9 of the Health Act, 2004 - Complaints.**

### **PART ONE**

#### **Scope and Focus**

This consultation document proposes an examination of the provisions of Part 9 of the Health Act, 2004, Sections 45 to 55, dealing with “Complaints”. It is essential that we establish a shared understanding of the requirements and priorities attaching to this particular part of the Act in advance of the introduction of Regulations which will specify how the HSE will establish **a statutory framework** for dealing with complaints received under Part 9 of the Health Act, 2004.

The Department of Health and Children is seeking to consult and obtain the views of the Health Service Executive (HSE) and other relevant service providers on this particular matter and intends initiating a facilitated consultation with the HSE, via the Complaints Officer Network and other service providers.

These Regulations will be introduced in the form of secondary legislation, a Statutory Instrument (S.I.) which will take its authority from the specific power laid down in the Act (Part 9). The Act, primary legislation, sets out the general law and authorises the Minister to make Regulations dealing with details of the operational framework to be regulated for.

It is important to note, for the purpose of the consultation process, that the S.I. cannot deviate in any way from what is laid down in the Act and to do so may result in the Regulations being regarded as “ultra vires” i.e. the Minister does not have the power, under the Act, to do what she is purporting to do by Regulation.

In keeping with the requirements of “Regulating Better” and bearing in mind the citizens rights and customer service aspect of these Regulations, it is essential that the consultation process in considering the framework and procedures for the complaints process bear in mind the issue of proportionality. The complexity of the process, its operating procedures and framework, while needing to be robust in a statutory sense, must not outweigh the accessibility, efficiency and transparency of the service being offered to the complainant.

#### **Complaints Procedures - a Citizens Right**

Any citizen wishing to make a complaint to the HSE about any action of the executive or a service provided under Part 9 of the Health Act, 2004 has the right to have the complaint handled properly, openly, impartially, fairly and within a reasonable timeframe. The citizen has a right to clear transparent customer friendly procedures

and the task of facilitating citizens in this regard should be carried out as close to the citizen as possible.

Each citizen must have confidence in the administration of the complaints process, must feel that it is inclusive of them, allowing them the right to appeal and access to the Ombudsman. The HSE must provide the citizen with a statutory complaints process based on effective mechanisms capable of demonstrating adherence to the law coupled with fair and consistent decision making.

The HSE in establishing this statutory complaints process will be facilitating the citizen in exercising his or her right to have a complaint investigated but will also be putting in place an effective mechanism not only to resolve individual complaints but also to improve the overall quality of health care for the citizen. This quality improving function will form an integral and underlying element of the complaints process, improving the standards of care delivered to the citizen across the service and informing the governance / risk management procedures being developed by the HSE.

Part 9 of the Health Act 2004 in making provision for the introduction of a statutory complaints process is also honouring a commitment made to each Irish citizen in **The Health Strategy “Quality and Fairness - A Health System For You”** which calls for the development of a statutory framework for complaints to achieve greater clarity and uniformity of approach in dealing with complaints, structured local resolution and processes as well as an opportunity for independent review.

The Health Strategy sees the introduction of a statutory complaints process as a component part of the people centred health care system of the future. It sees the complaints process as empowering citizens to take an active part in decisions that relate to their own health. The complaints process will form part of a dynamic integrated structure capable of adapting to the diverse and changing needs of society generally and of its citizens.

As we can see from other jurisdictions, taking Western Australia as an example, their complaints management policy for public hospitals incorporates many citizens / consumer rights which could be reflected in an Irish context. These rights could also be regarded as governing principles. The right to :

Be treated with respect, dignity and consideration for their privacy ;

Have complaints treated as genuine and properly investigated;

Be given appropriate and easily understood information regarding the process of complaints;

Have their complaints issues adequately addressed;

Participate in decisions about the management of their complaint;

Have information about their complaint filed separately from their health record;

Have personal information remain confidential within the complaints management process;

Be able to comment on the complaints management process;

Not suffer negative impact as a result of making a complaint.

### **January 2005 - a HSE Conference for Complaints Managers**

The HSE organised a very successful Complaints Managers Conference in January, 2005 and put forward a number of very helpful suggestions to HSE management on improving existing complaints processes and working towards the introduction of new statutory Regulations under the Health Act, 2004. These suggestions, set out below, should be further developed in the context of this consultation / feedback process.

Progress discussions with the DOH&C on the regulations to accompany the statutory framework for the handling of complaints.

Develop initiatives to improve the effectiveness of local resolution and develop Independent Review.

Develop National Standards for complaints handling.

Support cultural and attitudinal change such that complaints are perceived as an opportunity to learn rather than blame.

Provide support and training for Complaints Managers.

Provide Advocacy Services for marginalized, disadvantaged or disempowered citizens wishing to make a complaint.

Provide accessible Public Information on the Complaints procedures.

Integrate Complaints Management and Risk Management.

Provide IT Support Systems to ensure effective recording and review of complaints.

Conduct regular reviews of complaints and utilise information to improve services.

## **Process :What does Part 9 of the 2004 Act provide us with in the context of introducing a statutory Complaints**

Part 9 of the Act sets out provisions governing the proposed complaints procedures under a number of key headings which are explored in greater detail in Part II of this document, in summary:

**Section 45:** Definitions.

**Section 46:** Who may make complaints.

**Section 47:** The time limit for making complaints.

**Section 48:** Matters excluded from right to complain.

**Section 49:** Complaints and review procedures to be established.

**Section 50:** Refusal to investigate or further investigate complaints.

**Section 51:** Restriction on type of recommendations complaints officers may make and power to suspend implementation of recommendations.

**Section 52:** Adherence to complaint and review procedures to be condition of arrangements with service providers.

**Section 53:** Minister to make Regulations for purpose of this Part.

**Section 54:** Referral of complaint to Ombudsman for Children.

**Section 55:** Annual Report to include report on complaints and reviews.

## **Format of Consultation Process**

The Department will engage directly with the HSE through its Corporate Governance Team (in association with Ms. Mary Culliton) and Complaints Officer Network/other service providers, in the first instance and has asked for the assistance of Ms. Eilish Mc Auliffe, Senior Lecturer in Health Policy and Management, TCD, to facilitate a series of consultation sessions with the HSE, service providers and any other relevant interested parties. Ms. Mc Auliffe has been chosen for her academic background and research expertise which includes a particular interest in change management and consumer participation in health care

## **Feedback**

The purpose of this consultation process is to assist in facilitating relevant stakeholders to inform the drafting of the Regulations to be introduced under Part 9 of

the Act. All comments will be collated by Ms. Mc Auliffe for feed back to the Legislation Unit, Department of Health and Children.

## **Part II**

### **Key Sections for consultation and feedback**

#### **Section 46(3)(e) - Advocacy.**

The Comhairle (Amendment) Bill 2004 introduces personal advocacy services specific to people with disabilities. The new service will be administered by Comhairle and envisages the provision of advocates to persons with a disability who have difficulty in obtaining a social service without assistance. The main function of the personal advocate in this particular service is to assist, support and represent the person with a disability in applying for and obtaining a social service and also in pursuing any right of review or appeal in connection with that service.

Definitions :

**“Disability”** in relation to a person, means a substantial restriction in the capacity of the person to carry on a profession, business or occupation in the State or to participate in social or cultural life in the State by reason of an enduring physical, sensory mental health or intellectual impairment.

**“Social Service”** means any service provided by a statutory body or voluntary body that is available or accessible to the public generally or a section of the public pursuant to statute or otherwise and includes but is not limited to, a service in relation to any of the following, namely, health, social welfare, education, family support, housing, taxation, citizenship, consumer matters, employment and training, equality, asylum and immigration.

It is strongly recommended that the HSE and its service providers seek to avail of this Comhairle administered, regionally based advocacy service in meeting the requirements of S.46(3)(4) of the Act and that this arrangement be reflected in the Regulations.

#### **Section 47 - time limits for making complaints**

The Act states that a complaint must be made within the specified period or any extension of that period allowed under subsection 47(3) which states “a complaints Officer may extend the time limit for making a complaint if in the opinion of the complaints officer special circumstances make it appropriate to do so”

The issue to be explored here is what time frame might be reasonable and workable to introduce as an integral part of the various stages that will apply throughout the complaints process, from receipt to acknowledgement of complaint to issue of findings in the matter. The issue should be considered in conjunction with matters raised for consideration in S.49 and S.53 below.

### **Section 48 - Matters excluded from right to complain**

The Act excludes complaints arising from matters relating solely to the exercise of clinical judgement by a person acting on behalf of either the executive or a service provider and this in turn excludes such complaints from the Regulations.

Section 54(1) of the Act provides for referral of a complaint to the Ombudsman for investigation, however, at present the Ombudsman's jurisdiction does not extend to clinical judgement and therefore it would be inappropriate and unworkable to provide for investigation into matters of clinical judgement in the Regulations. With regard to clinical matters, the Office of the Ombudsman considers that many complaints, which at first appear to relate to the exercise of clinical judgement, actually relate to administrative failures such as a lapse in communications or a failure to observe proper procedure.

It is acknowledged that individual Complaints Officers may have to make a judgement call on what is or is not a matter relating solely to clinical judgement and it is also acknowledged that it will take time for precedent and practice to be established in this matter.

The role of the Medical Council must also be taken into consideration. The Council, established by the Medical Practitioners Act, 1978, protects the interests of the public when dealing with registered medical practitioners. The Fitness to Practice Committee which consists of members of the Medical Council has a statutory duty under Part V of the Medical Practitioners Act, to consider complaints made by the Council or any person into the conduct of a registered medical practitioner on the grounds of :

His/her alleged professional misconduct and /or,

His/her fitness to engage in the practice of medicine by reason of physical or mental disability.

### **Complaints and Review Procedures to be established and Regulations required - Sections 49 and 53 taken together.**

Section 49(1) to (3) states "subject to subsection (2) and any regulations under Section 53, the executive shall establish procedures for.....dealing with complaints, reviewing recommendations made, approving existing /comparable complaints procedures of service providers and assigning review functions etc. to another body.

Section 53(1) and (2) provide for the making of Regulations governing requirements to be met by complainants, the appointment of Complaints Officers, procedures to be followed etc. These are two crucially important sections as they provide for the making of regulations establishing the key building blocks, operating procedures for the complaints process and the appointment of Complaints Officers.

The Regulations have to strike a fine balance between setting out a broad operational framework and being specific on actual time frames, procedures, criteria for approval of alternative complaints procedures and appeals bodies. They also have to provide for the appointment of Complaints Officers and how recommendations made by such officers are to be dealt with. The challenge here is to regulate for the introduction of an accessible, workable complaints process which functions relative to the size, location and nature of the service being provided by the HSE or a service provider.

Research shows that most complaints procedures have three stages - local investigation /resolution, independent Review and right of referral to an Ombudsman.

### **Procedures to be established within each region, under the auspices of the HSE :**

#### **A central point of -**

receipt and registration.

issue, within a specified number of working days (specify ?) of standardised acknowledgement with direct contact details and information on the complaints process.

#### **The appointment of Complaints Officers -**

the HSE and each service provider must appoint and resource (staffing, budget and IT) a sufficient number of Complaints Officers to ensure compliance with the arrangements made under these Regulations and that action is taken in line with the recommendation made on foot of any investigation.

The Complaints Officer will be responsible for the day to day effective and efficient investigation /local resolution stage of the complaints process.

#### **The investigation procedure should -**

ensure that the Complaints Officer investigates the complaint promptly and efficiently within a specified number of working days (specify ?) and to the extent necessary and in the manner which appears most appropriate and transparent to him.

allow for local conciliation, mediation and resolution where possible.

keep all parties informed of progress.

provide a written report outlining the investigation and findings.

provide an apology where a mistake has been made or a poor service delivered.

make recommendations directly to the CEO correcting matters where possible and /or preventing recurrence where appropriate.

advise the complainant of their right of review.

keep written and electronic records of the complaint and investigation

### **Implementing Recommendations / Independent Review Process**

The Complaints Officer will act independently in making written recommendations to the CEO. For the purpose of the annual report of the HSE to the Minister (Section 54 of the Act), the Complaints Officer will also be obliged to furnish the CEO with a yearly report on the number, detail and treatment of complaints received.

Section 49(1)(b) of the Act also entitles the complainant to seek a review of the recommendations of the Complaints Officer and the HSE is obliged to appoint independent Review Officers or under Section 49(4), to assign such review procedures to another body.

It is recommended that the HSE assign the review process under service agreement to an Independent Review Body. This body should be capable of convening a review panel composed of a small number of impartial people with sound judgement skills and the body, appointed under service agreement, should also be charged with drawing up comprehensive review procedures for approval by the HSE.

### **The Ombudsman**

If a complainant continues to be dissatisfied with the outcome of the investigation and independent review process governing their complaint, the complaint can refer the complaint to the Ombudsman or the Ombudsman for Children for investigation in accordance with Section 54 of the Act.

### **The establishment of Complaints Procedures by other service providers.**

Section 49, subsections (2) and (3) provide for the establishment by service providers of complaints procedures other than those of the HSE but any such procedures must be comparable with those of the HSE and approved by the HSE in the first instance.

This may be highly relevant in the context of service providers who already have an established complaints process or a service provider where the specialised nature or geographic location of the service being offered does not lend itself HSE statutory complaints procedures.

The consultation process should consider (i) the criteria for the approval, by the HSE, of other complaints procedures process and (ii) an audit of the number and type of complaints procedures currently in existence in the health arena.

### **Conclusion**

Translating a citizen's statutory right to complain into an effective regulatory lever for learning from experience and improving the quality of Irish health care and related services is a significant challenge. Regulating for an efficient and effective complaints procedure will offer transparency and protection to both the service provider and the complainant.

Stakeholder consultation is considered of paramount importance in advance of drafting the Regulations required to give effect to Part 9 of the Health Act, 2004 and your views /input will be extremely important in this regard.

**Appendix B(i):  
List of Organisations Invited to Provider Consultation Workshops**

Adelaide & Meath Hospital inc NCH  
Amalgamated Engineering & Electrical Trade Union  
An Bord Altranais  
An Bord Uchtala  
Arvato Systems  
Beaumont Hospital  
Board for the Employment of the Blind  
Bord na Radharcmhastoiri (Opticians Board)  
Brothers of Charity Services  
Cappagh Orthopaedic Hospital  
Cavan General Hospital  
Central Remedial Clinic  
Cheeverstown House  
City of Dublin Skin & Cancer Hospital  
Clinical Indemnity Scheme  
Clonskeagh Hospital  
Comhairle na n-Ospideal  
Community Services - Dublin West  
Coombe Maternity Hospital  
Cork University Hospital  
Crisis Pregnancy Agency  
Daughters of Charity  
Dental Council  
Department of Health & Children  
Disability Federation of Ireland  
Drug Treatment Centre Board  
Dublin Dental Hospital  
Dublin Dental Hospital Board  
Food Safety Authority of Ireland  
Food Safety Promotion Board- Safefood  
General Medical Services (Payments) Board  
Health Research Board  
Health Service Employers Agency  
HSE - Corporate  
HSE - East Coast Area  
HSE - Eastern Region  
HSE - Mid Western Area  
HSE - Midland Area  
HSE - North Eastern Area  
HSE - North West Area  
HSE - Northern Area  
HSE - Shared Services Eastern Region  
HSE - South Eastern Area  
HSE - Southern Area  
HSE - Western Area  
IMPACT  
Incorporated Orthopaedic Hospital  
Irish Blood Transfusion Service  
Irish Dental Association  
Irish Health Services Accreditation Board  
Irish Hospital Consultants Association  
Irish Medical Council  
Irish Medical Organisation  
Irish Medicines Board  
Irish Nurses Organisation  
Irish Social Services Inspectorate  
Irish Society for Quality & Safety in Healthcare

James Connolly Memorial Hospital  
KARE  
Leopardstown Park Hospital  
Mater Hospital  
Medical Laboratory Scientists Association  
Mercy Hospital  
Merlin Park Hospital  
Midland Regional Hospital  
Naas General Hospital  
National Cancer Registry Board  
National Children's Hospital  
National Council for the Professional Development of Nursing and Midwifery  
National Council on Ageing and Older People  
National Disease Surveillance Centre  
National Federation of Voluntary Bodies  
National Hospital's Office  
National Maternity Hospital  
National Medical Rehabilitation Centre  
National Rehabilitation Hospital  
National Social Work Qualifications Board  
Office of the Ombudsman  
Office of Tobacco Control  
Our Lady of Lourdes Hospital  
Our Lady's Hospice  
Our Lady's Hospital for Sick Children  
Peamont Hospital  
Portiuncula Hospital  
Postgraduate Medical and Dental Board  
Pre-Hospital Emergency Care Council  
Psychiatric Nurses Association  
Regional Complaints & Appeals Office - HSE - South Western Area  
Rotunda Hospital  
Royal Hospital Donnybrook  
Royal Victoria Eye & Ear Hospital  
SIPTU  
Social and Market Research  
South Infirmary Victoria Hospital  
Special Residential Services Board  
Srs of Charity Jesus and Mary  
St Colmcilles Hospital  
St James Hospital  
St John of God Hospital  
St John's Hospital  
St Luke's & St Anne's  
St Mary's Hospital  
St Mary's Orthopaedic Hospital  
St Michael's House  
St Michael's Hospital  
St Patrick's Hospital  
St Vincent's University Hospital  
St Vincent's Hospital, Fairview  
Stewarts Hospital  
Sunbeam House  
Technical Engineering & Electrical Union  
The Amalgamated Transport & General Workers Union  
The Institute of Public Health in Ireland  
The Mental Health Association of Ireland  
The National Breast Screening Programme  
The National Children's Advisory Council  
The National Children's Office

The Not for Profit Business Association  
The Pharmaceutical Society of Ireland  
The Rotunda Hospital  
Union of Construction Allied Trade Unions  
University Dental School & Hospital  
Women's Health Council

## **Appendix B(ii): List of Organisations Invited to Consumer Consultation Workshop**

Representatives from the following list of organisations were invited to participate in the consumer workshop

Active Retirement  
Adelaide and Meath Hospital incorporating NCH  
ADHD  
Age & Opportunity  
Alzheimers Society  
Ballyfermot Information Centre  
Beaumont Hospital  
Brainwave  
Canal Communities Local Drugs force  
Cavan Drug Awareness  
Cheeverstown Hospital  
Children in Hospital  
Citizen Information  
Clondalkin Citizen's Information Centre  
Comhairle  
Consumer Carer Panel  
Consumer Panel Representatives  
Drug Task Force  
Drug Treatment Centre  
Equality Authority  
Gateway Women's Training Council  
HSE Carlow/ Kilkenny Area  
HSE ECA Community Care  
HSE Northern Area Community Services  
HSE Northern Area Community Services  
Irish Advocacy Network  
Irish Association for Older People  
Irish Patients Association  
Irish Senior Citizens Parliament  
Irish Society for Quality and Safety in Healthcare  
Letterkenny General Hospital  
Local Drugs Taskforce  
Mater Hospital  
Maternity Services North East  
Mayo Centre for Independent Living  
Muintir na Tire  
Muscular Dystrophy  
National Association for Mental Health in Ireland  
National Council for the Blind in Ireland  
National Women's Council  
Ombudsman for Children  
OPEN  
Orthopaedic Consumer Panel  
Orthopaedic Consumer Panel  
Our Lady's Hospital  
Patient Focus  
Patient Focus  
Patient Services Department  
Patient Support, Our Ladies Hospital  
Pavee Point  
Post Polio Support Group  
Representatives of the Homeless

Service User Group  
Social Inclusion  
Vergemount Hospital  
Waterford Regional Hospital  
West African Network  
Wexford Hospital  
Yvonne Keating Foundation

## **APPENDIX C:**

### **Tests of professional misconduct set out by Mr. Justice Keane in *O Laoire v The Medical Council* 1995**

The five tests are as follows:

1. Conduct which is “infamous” or “disgraceful” in a professional respect is “professional misconduct” within the meaning of S. 46 (1) of the act.
2. Conduct which would not be “infamous” or “disgraceful” in any other person, if done by a medical practitioner in relation to his profession, that is, with regard either to his patients or to his colleagues, may be considered as “infamous” or “disgraceful” conduct in a professional respect.
3. “Infamous” or “disgraceful” conduct is conduct involving some degree of moral turpitude, fraud or dishonesty.
4. The fact that a person wrongly but honestly forms a particular opinion cannot of itself amount to infamous or disgraceful conduct in a professional sense.
5. Conduct which could not properly be characterised as “infamous” or “disgraceful” and which does not involve any degree of moral turpitude, fraud or dishonesty may still constitute “professional misconduct” if it is conduct connected with his profession in which the medical practitioner concerned has seriously fallen short, by omission or commission, of the standards of conduct expected amongst medical practitioners.

Mr Justice Keane said that these five tests must always be read in the context of the definition of professional misconduct in the Medical Council’s Guide to Ethical conduct and Behaviour.

Source: Kennedy, W (2004) Position Paper: Negligence and Misconduct,  
Unpublished document: The Medical Council

## **Appendix D:**

### **Annex B: New Zealand Health and Disability Act 1994**

#### **Rights of Consumers and Duties of Providers**

##### **RIGHT 1: Right to be Treated with Respect**

1. Every consumer has the right to be treated with respect.
2. Every consumer has the right to have his or her privacy respected.
3. Every consumer has the right to be provided with services that take into account the needs, values, and beliefs of different cultural, religious, social, and ethnic groups, including the needs, values, and beliefs of Maori.

##### **RIGHT 2: Right to Freedom from Discrimination, Coercion, Harassment, and Exploitation**

Every consumer has the right to be free from discrimination, coercion, harassment, and sexual, financial or other exploitation.

##### **RIGHT 3: Right to Dignity and Independence**

Every consumer has the right to have services provided in a manner that respects the dignity and independence of the individual.

##### **RIGHT 4: Right to Services of An Appropriate Standard**

1. Every consumer has the right to have services provided with reasonable care and skill.
2. Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.
3. Every consumer has the right to have services provided in a manner consistent with his or her needs.
4. Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer.
5. Every consumer has the right to co-operation among providers to ensure quality and continuity of services.

##### **RIGHT 5: Right to Effective Communication**

1. Every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information provided. Where necessary and reasonably practicable, this includes the right to a competent interpreter.
2. Every consumer has the right to an environment which enables both consumer and provider to communicate openly, honestly, and effectively.

##### **RIGHT 6: Right to be Fully Informed**

1. Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including-
  - (a) an explanation of his or her condition; and
  - (b) the explanation of the options available, including an assessment of the expected risks, side effects, benefits and costs of each option; and
  - (c) advice of the estimated time within which the services will be provided; and
  - (d) notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval; and

- (e) any other information required by legal, professional, ethical, and other relevant standards; and
  - (f) the results of tests; and
  - (g) the results of procedures.
2. Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.
  3. Every consumer has the right to honest and accurate answers to questions relating to services, including questions about-
    - (a) the identity and the qualifications of the provider; and
    - (b) the recommendation of the provider; and
    - (c) how to obtain an opinion from another provider; and
    - (d) the results of research.
  4. Every consumer has the right to receive, on request, a written summary of information provided.

**RIGHT 7: Right to Make An Informed Choice and Give Informed Consent**

1. Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.
2. Every consumer must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the consumer is not competent.
3. Where the consumer has diminished competence, that consumer retains the right to make informed choices and give informed consent, to the extent appropriate to his or her level of competence.
4. Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where:-
  - (a) it is in the best interests of the consumer; and
  - (b) reasonable steps have been taken to ascertain the views of the consumer; and
  - (c) either,-
    - (i) if the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or
    - (ii) if the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.
5. Every consumer may use an advance directive in accordance with the common law.
6. Where informed consent to a health care procedure is required, it must be in writing if:-
  - (a) the consumer is to participate in any research; or
  - (b) the procedure is experimental; or
  - (c) the consumer will be under general anaesthetic; or
  - (d) there is a significant risk of adverse effects on the consumer.
7. Every consumer has the right to refuse services and to withdraw consent to services.
8. Every consumer has the right to express a preference as to who will provide services and have that preference met where practicable.
9. Every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure.

10. 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.

**RIGHT 8: Right to Support**

Every consumer has the right to have one or more support persons of his or her choice present, except where safety may be compromised or another consumer's rights may be unreasonably infringed.

**RIGHT 9: Rights in Respect of Teaching or Research**

The rights in this Code extend to those occasions when a consumer is participating in, or it is proposed that a consumer participate in, teaching or research.

**RIGHT 10: Right to Complain**

1. Every consumer has the right to complain about a provider in any form appropriate to the consumer.
2. Every consumer may make a complaint to:-
  - (a) the individual or individuals who provided the services complained of; and
  - (b) any person authorised to receive complaints about that provider; and
  - (c) any other appropriate person, including-
    - (i) an independent advocate provided under the Health and Disability Commissioner Act 1994; and
    - (ii) the Health and Disability Commissioner.
3. Every provider must facilitate the fair, simple, speedy, and efficient resolution of complaints.
4. Every provider must inform a consumer about the progress on the consumer's complaint at intervals of not more than 1 month.
5. Every provider must comply with all the other relevant rights in this Code when dealing with complaints.
6. Every provider, unless an employee of a provider, must have a complaints procedure that ensures that-
  - (a) the complaint is acknowledged in writing within 5 working days of receipt, unless it has been resolved to the satisfaction of the consumer within that period; and
  - (b) the consumer is informed of any relevant internal and external complaints procedures, including the availability of
  - (c) independent advocates provided under the Health and Disability Commissioner Act 1994; and
  - (d) the Health and Disability Commissioner; and
  - (e) the consumer's complaint and the actions of the provider regarding that complaint are documented; and
  - (f) the consumer receives all information held by the provider that is or may be relevant to the complaint.
7. Within 10 working days of giving written acknowledgement of a complaint, the provider must-
  - (a) decide whether the provider-
    - (i) accepts the complaint is justified; or
    - (ii) does not accept the complaint is justified; or
  - (b) if it decides that more time is needed to investigate the complaint,-
    - (i) determine how much additional time is needed; and

- (ii) if that additional time is more than 20 working days, inform the consumers of that determination and of the reasons for it.
- 8. As soon as practicable after a provider decides whether or not it accepts that a complaint is justified, the provider must inform the consumer of:-
  - (a) the reasons for the decision; and
  - (b) any actions the provider proposes to take; and
  - (c) any appeal procedure the provider has in place.