PATIENTS FIRST
AN AGREED AGENDA ON A PATIENT SAFETY AUTHORITY.
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FINE GAEL AND THE LABOUR PARTY

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PROPOSAL FOR A PATIENT SAFETY AUTHORITY

Why a Patient Safety Authority?

The Lourdes Hospital Inquiry Report, the report on the death of Pat Joe Walsh, the Peter McKenna case, the death in Heatherside Hospital, Buttevant, Co Cork and the failures in regard to Leas Cross, individual cases of child abuse or neglect, together with the many other cases of concern regarding patient safety which have emerged in recent times clearly demonstrate the need for a new approach to the monitoring and regulation of standards of patient care. The creation of one single employer (HSE) for a majority of the staff who work in the health services also supports the case for the establishment of an independent body with a strong legislative base.

Professional regulatory bodies fulfil a very important, but limited, role in patient safety. The complexity of much of the current health service provision; the growth in multi-disciplinary teams and the greater sharing of responsibility for patient care has diminished the impact which individual professional bodies, such as The Medical Council and An Bord Altranais, can play in the effective policing of patient safety. Under the proposal to establish the Patient Safety Authority these bodies will continue to have an independent role in regulating the conduct of their members.

The proposed Patient Safety Authority brings together all of the regulatory bodies, other than professional bodies, which are charged with regulating standards of patient care. This includes the roles currently undertaken by the Social Services Inspectorate, Mental Health Commission and the Health Service Executive. Its remit will be entirely patient focussed.

It will be required to work in conjunction with other statutory regulatory bodies including the Irish Medicines Board, Food Safety Authority and the Health and Safety Authority as well as other bodies with regulatory functions, including professional bodies. The legislation will provide for the acceptance and recognition by these agencies of reports on inspections carried out by each other, where this is appropriate. It will provide that they co-ordinate their work so that their inspection regimes do not place an inordinate burden on services which are inspected by more than one of them.

In summary the legislation will recognise that there are other regulatory bodies whose responsibilities impact on peoples’ health and safety, whether as patients or in general terms.

In the context of the Patient Safety Authority (PSA) the term “patient” includes a person who is receiving, or who has received treatment, directly from, or under the auspices of, a member of a designated health professional body. This includes persons receiving such treatment in prisons or places of detention. It also includes a “dependant person” who requires assistance with the activities of daily living by reason of a physical infirmity or a physical injury, defect or disease, or cognitive impairment, whether the need for assistance is temporary or enduring. It includes a vulnerable child particularly one who is in residential care, and/or in the care of the HSE.

Our healthcare system treats hundreds of thousands of patients each year and carries out thousands of medical and surgical procedures. Patients put their lives in the hands of doctors and other healthcare professionals each day yet there is no hospital inspectorate for acute hospitals, no body to set and enforce hospital standards, no statutory body dedicated to ensuring patient safety in healthcare facilities and there are limited avenues through which patients can seek redress for substandard care.
The PSA will be the patient’s watchdog in Ireland. It will independently review, inspect and assess the management, provision and quality of healthcare and social care. It will be the registration authority for all health and social services and their facilities. It will be a driving force for continuous improvement in health and social care services. The rationalisation and expansion of the inspection system will amount to a transformation of health and social care inspection regimes. It will provide a long overdue and much needed integration and streamlining of the system of regulating the standards of health and social care services in Ireland.

The general public expects and demands such a system. Among service providers, including private nursing homes, there is an appetite for better coordination and cooperation to improve inspections while allowing staff to concentrate on delivering services. There is a need for one body to take the lead in coordinating and managing this activity. The Patient Safety Authority will spearhead the move to more integrated and effective arrangements for inspection.

It will be required to take active steps to promote respect for human rights and equality of opportunity for all service recipients. It will be responsible for protecting the rights of those involuntarily detained under the Mental Health Act 2001.

When established the Patient Safety Authority (PSA) will:

1. **Oversee the registration and Accreditation of Hospitals and Inpatient Facilities**
   - Register and accredit all hospitals, inpatient, and residential, facilities providing care and/or treatment for persons who are ill, in need of care or who have a disability.

2. **Set and monitor standards of patient safety in all registered health and social care facilities**
   - Set National Minimum Standards for health facilities.
   - Audit and monitor the standard of care provided in hospitals, nursing homes and residential centres.
   - Carry out inspections and publish inspection reports annually.

3. **Advise on patient safety**
   - Review and advise on obstacles to the efficient running of registered centres and opportunities for greater efficiencies.
   - Monitor and advise on the personal social services provided by, or on behalf, of the HSE in respect of services for children, elderly people or people with disabilities.
   - Advise the public, the HSE, agencies operating health and residential facilities and the Minister for Health on patient safety.

4. **Establish an Adverse Incident Reporting and Risk Management System**
   - Receive reports of adverse incidents or potentially adverse incidents.
   - Receive reports of all unexplained deaths in residential centres and investigate where this is considered necessary.
   - Establish a clinical/medical incident register.
5. **Investigate complaints**
   - Investigate complaints at the request of the Minister, the HSE or on its own initiative.
   - Investigate complaints from members of the public, when it has not been possible to resolve them under Part 9 of the Health Act 2004.

6. **Provide an Advocacy service for vulnerable complainants**

7. **Oversee the operation of regulatory bodies for health professionals**

8. **Act as the Commissioner for Mental Health Services**

9. **Facilitate “Whistleblowers”**

10. **Carry out Quality Reviews**

**How it will work:**

1. **Oversee the Registration and Accreditation of Hospitals and Residential Facilities**

   **Registration/Accreditation:** Fine Gael and the Labour Party will ensure that all providers of hospital and inpatient healthcare and social care facilities will be registered with the Patient Safety Authority (PSA).

   To ensure successful registration, health and social care providers will be expected to demonstrate that they comply with a set of National Minimum Standards, which will be established by way of regulations made by the Minister for Health upon the advice of the PSA. No health or social care facility which comes under the remit of the PSA will be allowed to treat patients, or to provide residential care, unless it is registered and fully compliant with the standards set or legislated for by the Minister.

   Inpatient/residential facilities catering for the following will be registered:
   
   (i) Acute hospitals – voluntary, public and private
   (ii) District hospitals
   (iii) Nursing homes—both private and public
   (iv) Centres for people with intellectual disability
   (v) Inpatient and residential Mental Health Centres
   (vi) Centres for people with a physical or sensory disability
   (vii) Residential Child Protection centres
2. Set and monitor standards of patient safety in all registered health facilities

The PSA will advise the Minister for Health on National Minimum Standards for all hospitals and residential facilities: A set of National Minimum Standards will be introduced by the Minister for Health on the advice of the PSA and will cover the following in each health and social care facility:

- **Safety** - does the establishment provide treatment and care safely?
- **Clinical and cost effectiveness** - is the best possible treatment provided?
- **Governance** - is the establishment well-run?
- **Patient focus** - does the establishment put the patient first?
- **Accessible and responsive care** - is care organised around patients’ needs?
- **Care environment and amenities** - are the premises and the environment where patients are being treated well designed, equipped, staffed and maintained, and is it suitable for their needs?
- **Service specific standards** for the type of establishment inspected

**Inspections:** Once the Patient Safety Authority is well established it will test providers’ compliance by assessing each registered establishment against a set of National Minimum Standards. All inspection reports and subsequent recommendations will be published and made available on the PSA website. The regulations will specify the minimum frequency of inspections for each type of hospital, home or residential facility. More frequent inspections may be carried out as the PSA considers appropriate.

Residential centres for children, elderly people and people with disabilities must be inspected not less often than once in each six months period.

**Hygiene audit:** The Labour Party and Fine Gael believe that the responsibility of carrying out regular external hygiene audits should be given to the PSA. The standards for such audits would come under the “care environment and amenities” standards of the National Minimum Standards (see above).

Most Hospital Acquired Infections have one thing in common. They are spread through poor hygiene and the failure to implement proper cleaning and sterilising practices. They are largely preventable. Effective cleaning procedures and good hygiene practices can eliminate the spread of almost all of them.

The Patient Safety Authority will give particular attention to hospital hygiene. It will require hospitals to demonstrate that they have effective cleaning and hygiene procedures in place and that these are monitored by senior, and accountable, managers. In addition to receiving regular reports on the incidence of MRSA and other Hospital Acquired Infections the PSA will carry out regular inspections and investigations into the standard of hygiene in all hospitals. Apart from the threat to the lives and health of patients there is a significant financial cost to treating those who acquire infections in our hospitals.
The traditional approach where the “Matron” managed by walking about had, and still does have, much to commend it. It is proposed that the key position in regard to hygiene on a hospital ward, or unit, be that of the Nurse who is the manager on the ward/unit and that the Matrons/Directors of Nursing be required to spend more of their time out and about around the hospital in support of their ward/unit managers. The Nurse Manager on the ward/unit, and her/his superiors, must be made fully responsible and accountable for all aspects of hygiene on the ward/unit. They must have the unqualified support of the entire hospitals staff, including managers and medical staff, in the discharge of this responsibility.

Many senior hospital staff are now in receipt of performance related pay (PRP). We support this concept and the financial rewards which hospital staff receive for their efforts. One of the criteria for annual PRP awards for relevant staff, including General Managers and Nurse Managers must be the achievement of high standards of hygiene in all areas of our hospitals.

**Monitor and advise on the personal social services:** In fulfilling this function the PSA will be responsible for monitoring the Social Services provided by the HSE and the services provided, by others, on its behalf. The intention is that services for the elderly, people with disabilities and vulnerable children would be audited on an ongoing basis. The audits may be carried out on individual services or for all services in a geographic area (e.g. all services in a Local Health Office area).

3. **Advise on patient safety**

**Advise the Minister for Health:** A set of National Minimum Standards will be introduced by the Minister for Health, on the advice of the PSA, for the registration and accreditation of specified health and social care facilities.

The PSA’s advisory role will include advising and making recommendations to the Minister for Health on patient safety following a review of findings from the inspections it carries out. It will focus as far as possible on “outcomes” for health and social care. It will contribute to the development and delivery of policy. Relevant information from inspections will be used in the development of policy and the evaluation of its delivery.

There is no point in making recommendations if they are not acted upon. Power to enforce recommendations of the PSA will rest with the Minister for Health. Those affected by its recommendations will be allowed to make submissions to the Minister before a final decision is made. This will not prevent voluntary agreement between service providers and the PSA on the implementation of any of its recommendations. To ensure Ministerial accountability, the Minister for Health must respond to PSA recommendations within six months of receipt of these or of the publication of its annual report. The Minister’s response, outlining the steps that s/he has taken or intends to take, including the timelines for future actions, must be laid before the Oireachtas Health Committee.

**Advise the public and health sector:** PSA advice on patient safety will also be made available to the public/patients, the HSE, and agencies operating health and residential facilities. The PSA will disseminate information on good practice, encourage innovation and assist service providers to learn from experiences. It will ensure that information about the best and/or most innovative practices which are identified during inspections is communicated to relevant agencies.

Where appropriate the PSA will support health and social care bodies and their staff to develop tools for self assessment which can contribute to the continuous measurement and improvement of the standard of their services.
4. Establish an adverse incident and risk management system

Healthcare and social care services rely on a range of complex interactions of people, knowledge, skills, and technologies, including drugs. While thousands of people are treated successfully in our hospitals and health facilities each year, adverse incidents do occur.

We propose that the Patient Safety Authority be charged with taking steps to reduce and, as far as possible, eliminate clinical and medical errors and other adverse incidents, by identifying problems and recommending solutions that promote patient safety in hospitals and other residential and social care facilities.

This can be done with the introduction of a mandatory national reporting scheme for serious medical/clinical events and incidents, including near misses. Under the reporting scheme, all registered health facilities must submit reports of 'serious events' and 'incidents' and the action taken to deal with them. In turn, the PSA will analyse the collected data to identify trends and recommend changes in health and social care practices and procedures that may be instituted to reduce the number and severity of future serious events and incidents i.e. it will be charged with learning from such incidents and recommending solutions. The totality of all such incidents, for each service, will be reviewed during routine inspections.

The scheme will be developed in such a way as to encourage an open and fair reporting culture.

5. Investigate complaints

The Patient Safety Authority will have the powers to investigate complaints regarding patient safety and adverse incidents at the request of the Minister for Health, the HSE or on its own initiative.

Giving the PSA the power to investigate complaints on its own initiative is a radical move as currently many complaints cannot be, or at least are not, investigated unless someone makes a formal complaint. To avoid the investigation of frivolous complaints the decision to investigate on its own initiative will be left to the discretion of the PSA. It will be required to give reasons for its decision to initiate any such investigation on its own initiative.

The PSA will also be responsible for investigating complaints about hospitals, social care and residential facilities that have not been resolved locally and/or for members of the public who were unable to resolve their complaints under Part 9 of the Health Act 2004 within 6 months of the complaint being made.

6. Advocacy service for vulnerable complainants

When formulating, making or pursuing a complaint, complainants may find themselves in a vulnerable position. They may be seriously ill, elderly or feel lost, or helpless, in what is often a very daunting process.

While there are many channels of supports for health agencies and staff against whom complaints are being made, they are not matched by supports for complainants.

To ensure greater balance in the complaints process, Fine Gael and Labour will support the provision of an advocacy service by the PSA for vulnerable complainants to support them through the complaints process and to accompany them to any relevant meetings.
We will support the establishment of a panel of volunteers, who will act on behalf of the PSA, to fulfil the role of advocates on behalf of people who request such support. The advocacy support system will be established in consultation with Comhairle.

7. **Oversee the operation of regulatory bodies for health professionals**

While we recognise the many benefits of self-regulation there is a need for one group to make sure there is consistency and good practice among each of the regulators for the health professions.

To protect the public interest, promote best practice and achieve excellence in relation to regulating healthcare professionals, the Patient Safety Authority will be responsible for the following:

(a) promoting the interests of the public and patients in relation to regulating healthcare professions;
(b) advising on and promoting best practice in regulating healthcare professions;
(c) developing principles for good, professionally-led regulation of healthcare professions and
(d) promoting co-operation between the individual regulators and other similar organisations.

In carrying out its work the PSA will:

- Investigate and report on how regulators for the health professions carry out their work.
- Compare the performance of different regulators and, where necessary, recommend changes in the way they carry out their work in order to bring about improvements.
- Investigate, and/or seek a resolution to, complaints made by a patient against a regulator following an investigation by it e.g. concerning decisions made or the way a regulator handled a complaint.

8. **Act as the Commissioner for Mental Health Services**

The PSA will take on the functions currently under the remit of the Mental Health Commission. The purpose of bringing the Mental Health Commission within the remit of the PSA is twofold. Firstly many of the functions of the PSA are similar to those of the Mental Health Commission which currently registers centres and inspects services for persons with a mental illness. Secondly it will further help to integrate services for people with mental illness with those receiving care from other parts of the health services. In other words it will reduce the isolation of the Mental Health services and will allow each specialist area of health and social care to support and learn from one another in pursuit of the patient safety agenda.

9. **Whistleblowers**

Legislation will be introduced to protect health and social service employees who are worried about wrongdoing in their place of work and want to ‘blow the whistle’. The act will apply to all employees and includes all self employed professionals - doctors, dentists, and pharmacists.
To qualify for protection the disclosure must be made in good faith and the wrongdoing must involve:

- a crime or breach of legal obligation (regulatory, administrative or common law)
- miscarriage of justice
- danger to health and safety of a patient, staff member or member of the public
- attempts to cover-up such malpractice

The whistleblower will be encouraged to speak to their employer in the first instance and will be assisted and advised on how best this might be done.

A disclosure may be made to the Patient Safety Authority or to the Department of Health. A whistle blower will be deemed to be acting as a witness and not a complainant. S/he will only have to have reasonable suspicion and not irrefutable evidence to support their concerns.

In order to deal promptly and effectively with concerns the PSA will establish a helpline where employees, or contractors, can raise their concerns in confidence and receive advice.

The PSA will initiate a formal investigation, or arrange for an inspection to be carried out, where such action is deemed to be warranted.

The PSA will have no powers to discipline any health or social service employee or to bring criminal prosecutions against such individuals following the outcome of its investigations. Disciplinary action can only be taken by the relevant service management and/or any relevant professional bodies. Allegations or evidence of criminality will be referred to the Gardai.

Concerns about children, where there is deemed to be a current or serious risk, will normally be referred immediately to the Child Protection system of the HSE or in certain circumstances to the Gardaí.

Concerns about fraud or corruption within the HSE will be referred to the C&AG otherwise they will be referred to the relevant agency or to the Gardaí.

10. Quality Reviews

The PSA will carry out a number of quality reviews each year. A “Quality Review” is a review of a particular aspect of health and/or social care that is applied in every relevant organisation and its focus will come from the results of inspections. Its aim is to encourage each organisation taking part to improve the quality of the health or social care it provides to patients and the public. It will also allow the PSA to identify steps health and social care organisations can take to progress towards meeting higher standards and allows it to measure their progress.

Quality reviews will be carried out where an aspect of health, or social care, is of importance across the country and where there are opportunities for substantial improvements to be made locally by health or social care providers. Quality reviews can be applied in a variety of settings including along patient pathways, disease groups and to services provided to particular patient groups. They will follow a standardised approach and will rely on research based best practice guidelines. They will be tightly focussed and targeted.

The Authority may commission independent bodies to conduct these quality reviews on its behalf.
Examples of areas for quality reviews would be:

**Diabetes care**
- Mental Health Services for the Elderly
- Care of pressure areas in long stay centres for the elderly
- The impact of multiple visitors on patient care and safe practices in hospitals
- The circumstances of children under 10 in residential care
- Selective prescribing practices where they may be a cause of poor outcomes or poor standards of care

The PSA will also carry out, or arrange to have carried out, regular hygiene audits in hospitals. These will be additional to the regular audits carried out by individual hospitals. The results of all such internal hospital audits must be forwarded to the PSA.