EXECUTIVE COUNCIL

PUBLIC

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Report Author:	DHSS and Attorney General
Portfolio Holder:	MLA Mike Summers OBE
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List of Documents:	Appendix 1 - Regulated Activities: Private General Practice Appendix 2 - Standards for Private Medical Services Appendix 3 – Self Assessment Dashboard Appendix 4 – Worked Example of CMO Assessment Framework

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1. Recommendations

Honourable Members are recommended to:

(a) Agree the proposed activities to be included in the scope of regulation;

(b) Agree the standards that private medical practitioners must achieve and sustain, and develop further standards for other procedures;

(c) Note that the role and legal responsibilities of the Chief Medical Officer under the current legislation will not change pending a review of the law;

(d) Approve the relationship between the publically funded health services and private medical services as described in the paperwork to further develop proposals;

(e) Agree that in accordance with section 3(c) of the Public Health Ordinance, the Health and Medical Services Committee is required to discharge two additional functions, namely to advise Executive Council:

(i) on the regulation of Private Medical Practitioners (Surgeons, Doctors Dentists Midwives and nurses for example) and providers of invasive cosmetic procedures (such as tattoos, body piercing or Botox or collagen injections, for example).

(ii) On the policy principles for the development of new law for the regulation of medical services and public and environmental health, to replace or amend as necessary the current Public Health Ordinance and the Medical Practitioners Midwives and Dentists Ordinance and other law of the Falkland Islands, for the better protection of the public in these areas;

(f) Note the need to review and confirm the governance relationship between the Health and Medical Services Committee, the Chief Medical Officer, the Director of Health and Social Services and the role and composition of the Health and Medical Services Committee; ~~and the proposed Regulatory Committee of the Health and Social Services Directorate;~~

(g) Agree the principle of cost recovery through administration of fees; and

(h) ~~Mandate further work on redefining DHSS and CMO roles and use of a new regulatory committee for governance of additional functions.~~

2. Additional Budgetary Implications

None

3. Executive Summary

3.1 The need for regulation of Private Medical Practitioners under a modern arrangement is needed to encourage choice and variety of provision for the community and to encourage future business investors, while also safeguarding people and ensuring high standards of care and provision.

3.2 A system proportionate and sufficient for the Falklands' needs and which fits efficiently with existing frameworks and responsibilities is required.

3.3 Therefore an interim approach is suggested, since there is also a further and more extensive detailed review of legal frameworks, committee responsibilities and the respective roles of DHSS and CMO that may be planned in the future.

3.4 The current proposal is that the CMO considers and approves (if appropriate) potential providers on the basis of clear standards, a self-assessment, and further enquiry (where needed) plus the advice of a separate committee with a regulatory over-view. The regulatory committee responsibilities may be either vested in a separate committee for

that purpose or could be a sub group of the HMSC.

3.5 There will be further legal work involved both to underpin such a proposed interim arrangement and also in advising the DHSS and CMO in reviewing more extensively the possible extension of powers and responsibilities to cover environmental and public health. This would be a matter for future submissions.

4. Background and Links to Islands Plan and Directorate Business Plan/s

Private Medical Services

4.1 Private medical services have been provided for some time now on the Falkland Islands. A need was identified to design and develop a proportionate risk based approach to the regulation of these services that mirror the best of the approach offered through the publically funded health and care service.

4.2 Patients have a right to choose between a publically funded health and care service and private services. The Government has an obligation to ensure the quality and safety of all services including any private medical services.

4.3 The model sets out the relationship between the private medical service provider and the publically funded health services that makes clear what the patient can expect should they choose to use both services or if the private medical service provider needs to refer the patient to the publically funded health service.

4.4 The proposed regulatory model sets out an approach that is proportionate, risk based and easy to deliver as it builds off the back of existing duties and legal responsibilities of the Chief Medical Officer for all health care services on the Falkland Islands. The regulatory approach also sets the oversight and governance arrangements.

Current Governance of Health

4.5 The existing arrangements for the governance of health principally arise from the Public Health Ordinance and the Medical Practitioners, Midwives and Dentists Ordinance.

4.6 Section 3 of the Public Health Ordinance creates to Health and Medical Services Committee (formerly the Board of Health). The Committee has responsibilities and powers under the ordinance and can be given additional responsibilities by the Executive Council, in addition to these responsibilities, the Committee exists:

"*to advise the Governor, the Chief Medical Officer and other public officers in relation to policy matters arising in relation to the administration and operation of the King Edward VII Memorial Hospital, Stanley, the medical and dental services provided by the Government of the Falkland Islands, the physical and mental health of the people of the Falkland Islands (including without prejudice to the generality of the foregoing, community health service and the health and welfare of children and the elderly) or environmental health matters advise*."

4.7 As the Ordinance does not envisage medical practitioners outside Government Service, Executive Council is recommended to immediately exercise its powers under section 4(c) of the ordinance to ask the Committee to advise Executive Council on the regulation of Private Medical Practitioners (Surgeons, Doctors Dentists Midwives and nurses for example) and providers of invasive cosmetic procedures (such as tattoos, body piercing, Botox or collagen injections, for example). This fits with the current remit of the committee which already spans Medical practice, Public Health and Environmental Health within the definition of responsibilities quoted above.

4.8 In relation to Environmental and Public Health, the Ordinance sets out a number of Offences (expressed in financial values which have been eroded by inflation over time). As an interim step the financial penalties could usefully be amended to a more modern scale of fines. However, fundamentally the focus of the Public Health Ordinance is quite narrow – primarily concerned with premises that produce food, the quality of housing, and infectious disease control.

4.9 The regime anticipates that health inspectors are appointed to identify potential offences and, by extension, to refer case files to the Attorney General for prosecution.

4.10 The Committee is intended to take a proactive role in relation to Environmental Health Issues – such as premises creating a nuisance (such as leaking a contaminant onto adjacent land or creating smoke, etc.). The committee can make bylaws about these subjects. The current Board of Health By-Laws were created in 1937 and cover both public health and environmental health matters. The By-laws have been amended from time to time, but might usefully be reviewed to ensure they are adequate for modern purposes. The Committee is responsible for serving 'abatement' notices on potential 'offenders' and a failure to comply with such a notice is an offence with the court able to impose a fine –again suggesting that inspectors on behalf of the committee should take action and if necessary refer files to the Attorney General for prosecution.

4.11 As discussed in paper 25/15 (8th April 2015), the regulation of medical practitioners arises from the Medical Practitioners, Midwives and Dentists Ordinance. The earlier paper identifies a number of deficiencies with the Ordinance and recommends both interim legislative amendments and a full review (with a target date of December 2018). As highlighted in the earlier paper, the scope of regulation could usefully be extended to include other limbs of the medical profession, such as nurses and, envisaged by the regime proposed, potentially those providing invasive cosmetic treatment.

4.12 The 2009 reorganisation and the ultimate creation of the post of Director of Health and Social Services has clearly altered prior assumptions regarding responsibilities. The post of Chief Medical Officer has of course been in existence for much longer. Accordingly, it is useful within the review of the two ordinances (whether or not the definitions appear in the legislation – which is unlikely to be advantageous) to very clearly record the role of these key posts in the leadership, governance and assurance processes in relation to all aspects of health. Similarly, the role of the committee must be clear in this context.

The Proposed Model

4.13 The proposed model sets out the range of regulated activities that will be permitted as part of private medical services. Providers of these services will need to register the services that they want to deliver with the CMO.

4.14 The CMO, advised by a regulatory committee (or the HMSC if it is decided that it can discharge the new duties), will assess and adjudge annually the safety of the services provided (Appendix 1 details proposed Regulated activities in General Practice and Appendices 3 and 4 give examples of an assessment via "dashboard" framework to structure the CMO's approach). These judgements will be made through a self-assessment submitted by the provider against an agreed set of standards (see Appendix 2) covering quality and safety of care. Those that satisfy the Committee and the CMO will continue to be registered to practice in the Falkland Islands.

4.15 Private Medical Practitioners' registrations will be published in the gazette and this and supporting information will be made available to those citizens who use private medical services.

4.16 The model sets out mechanisms and the approach that will be needed if private medical services fail to meet the agreed set of standards for quality and safety of care. A draft handbook has been developed to organise the approach. Once Honourable Members have considered the proposals, this can be finalised.

4.17 There are legislative requirements for the regulated activities, the standards for quality and safety and for enforcement actions. It is clear that a wholesale review of the Public Health and the Medical practitioners Midwives and Dentists Ordinances is long overdue. The existing regime will support the regulation of private medical practice in the manner currently envisaged as a short-term temporary measure but work to make a more robust legal framework is quite urgent.

4.18 It is proposed that the Health and Medical Services Committee is charged with the responsibility of developing policy principles for the development of new law in this area. It is correct that this work is led by the Director of Health and the Chief Medical Officer, to support the work of the Committee and of course the Attorney General and Government Legal Services will provide all appropriate support.

4.19 Based on the current analysis, the key roles of Director of Health and Social Services and the Chief Medical Officer appear to broadly be as follows:

- The Director of Health and Social Services is responsible for the strategic direction of health and the provision of health services by the Government, This would include the strategic direction of the Government's initiatives relating to health services, environmental and public health. They are responsible for budgets, operational leadership and other related matters.

- The Chief Medical Officer provides a vital assurance check to Government. They must exercise an independent view on the state of medical services, as well as environmental and public health. It is considered important that the Chief Medical Officer is sufficiently independent to exercise dispassionate scrutiny and be able to alert Executive Council to contrary views or matters of concern.

Accordingly, in accordance with the remit across medical, public and environmental health, the Chief Medical Officer's view should be expressly sought and given in any matter relating to these issues. This may include papers on such things as sanitation, Government housing policy or provision, the provision of utilities such as drinking water, and environmental health issues such as new restaurants, food production or storage facilities or premises for doctors or those providing invasive cosmetic procedures for example. It would be good assurance for advice from both the Director and CMO to be side by side on any advice to Executive Council and the Health and Medical Services Committee.

4.20 Under the model proposed in this paper, it is suggested that the Director of Health and Social Services will chair a new regulatory committee to advise the CMO. If it were not merely an advisory role, this link could be seen to potentially undermine the independence of these two key positions and it is a matter that could usefully be kept under review by the Health and Medical Services Committee to ensure suitable governance and assurance relationships are maintained.

4.21 If the new structures for a regulatory committee (either within the functions of the HMSC or as a separate body) are agreed, then this also presents an opportunity to consider at a later date whether the committee could also support an efficient governance mechanism to encompass Public and Environmental Health. At the same time further work could develop proposals clearly defining the relationship of responsibilities between the Director of Health and Social Services and the Chief Medical Officer (as discussed above) and support the procedures for separate comment from the various roles represented. Members are asked to mandate such further work.

Connections with Island Plan and Directorate Business Plan

4.22 The Falkland Island Government Island Plan (2014-2018) includes an objective to '*plan for the needs of the Islands' growing elderly population" and* indeed refers to the aim of creating a sustainable community with excellent health services for all age groups.

4.23 The H&SS Directorate Business Plan refers to the work-stream that had already begun on the regulation for private medical practitioners.

5. Options and Reasons for Recommending Relevant Option

5.1 The proposed option for regulation is a system proportionate to the Falkland Island circumstances, to safeguard the public and ensure delivery of high quality medical services in our particular setting.

5.2 This avoids the option and expense of a full regulatory system with an independent regulator such as the Care Quality Commission in the UK. It also provides the quality assurance and safeguards needed which a "do nothing" option would not deliver.

5.3 The proposed model would deliver a workable and appropriate system at negligible cost (becoming no cost once more providers emerge in years to come). This avoids

additional complexity and there are no requests for additional ongoing funding involved.

6. Resource Implications

6.1 Financial Implications;- The principles of good Government are that the costs of regulation should be recovered. The costs of regulation however, should not hinder or act as a disincentive to the provision of private medical services.

6.2 To date the annual cost of regulating private medical services has been set at £2,000. The rationale for this fee is linked to the time and commitments of those who would provide oversight and approvals to the private provision.

6.3 The costs are a reasonable assessment based on activity and unit costs associated with that activity. It is proposed that these are reviewed and if possible the fees reduced once a steady state is reached and with new providers competing in the market. Comparable regulatory costs in other jurisdictions for community based medical services are around £1,700.

6.4 The previous ExCo paper of 8th April 2015 identified that after the costs for setting up regulation, ongoing annual costs to FIG would be £5,000 p.a. which would initially be partially offset by £2,000 revenue if one provider is involved. As further providers emerge in the future the intention is to reach a break-even point where costs and revenue were as balanced as possible.

6.5 Human Resource Implications
None.

6.6 Other Resource Implications
None.

7. Legal Implications

7.1 The registered activities, standards for quality and safety of care and enforcement powers will have to be set out in legislation. As discussed in the paper, a full legislative review is recommended under policy direction provided by the Health and Medical Services Committee, who, as part of that work will make recommendations about their own role and remit.

7.2 For the regulatory oversight to be extended to nurses, health and physical therapists and other allied health professions, as well as invasive cosmetic services, this policy would need to be agreed and reflected in new legislation. As set out in paper 25/15 in relation to the Medical Practitioners Midwives and Dentists Ordinance, and as set out above in relation to the Public Health Ordinance, there may be value in carrying out interim amendments to the legislation, pending the outcomes of the wholesale review to provide better regulation in the interim period.

8. Environmental & Sustainability Implications

8.1 None

9. Significant Risks

9.1 The risks of not progressing the private regulation of medical practice are that a private sector is not encouraged to develop to provide choice and variety of services to the community and future business investors.

10. Consultation

10.1 Consultation has taken place with a current approved private provider of medical services.

10.2 The consultant contracted to develop proposals for the model met with the Older People and Vulnerable Adults reference group to discuss issues, views and possible ways forward.

11. Communication

11.1 If the new proposed (interim) arrangements are agreed, then not only will the paper be published but those involved in 13.1 and 13.2 above will be given feedback and clarification of practical steps involved.

Appendix 1

Regulated Activities

Private General Practice

Assessment for treatment of disease, disorder or injury

1. This is where a private General Practitioner offers an assessment and treatment for any disease, disorder or injury and they have affiliation to a professional regulatory body in the United Kingdom or equivalent and they are on the Falkland Islands list of registered Medical Practitioners.

2. The activities to be included in the scope of regulation are:

   - Diagnostic and screening procedures.
   - The provision of treatment by means of surgical procedures.
   - Services in slimming clinics.

Diagnostic and screening procedures

3. These are diagnostic and screening procedures involving the following activities:

   - The use of X-rays and other methods in order to examine the body by the use of radiation, ultrasound or magnetic resonance imaging.

   - The use of instruments or equipment which are inserted into the body to:

     (i) view its internal parts, or

     (ii) gather physiological data.

   - The removal of tissues, cells or fluids from the body for the purposes of discovering the presence, cause or extent of disease, disorder or injury,

   - The use of equipment in order to examine cells, tissues and other bodily fluids for the purposes of:

     (i) obtaining information on the causes and extent of a disease, disorder or injury, and
     (ii) for the purposes of obtaining information on the causes and extent of a disease, disorder or injury, or
     (iii) the response to a therapeutic intervention, where such information is needed for the purposes of the planning and delivery of care or treatment.

- The use of equipment to measure or monitor physiological data in relation to the:

    (i) audio-vestibular system,

    (ii) vision system,

    (iii) neurological system,

    (iv) cardiovascular system,

    (v) respiratory system,

    (vi) gastro-intestinal system, or

    (vii) urinary system.

4. The following procedures are excepted.

    - The taking of blood samples where:

        (i) the procedure is carried out by means of a pin prick or from a vein, and

        (ii) it is not necessary to send such samples for analysis to a place which is established for the purposes of carrying out tests or research in relation to samples of bodily cells, tissues or fluids,

    - The taking of urine samples where it is not necessary to send such samples for analysis to a place which is established for the purposes of carrying out tests or research in relation to samples of bodily cells, tissues or fluids.

    - The taking and analysing of wound swabs, hair samples or nail clippings;

    - The non-ambulatory recording of blood pressure,

    - The use of 12-lead electrocardiography,

    - The use of a peak flow meter to measure peak expiratory flow,

    - Pulse oximetry when used for the purpose of spot recording,

    - Spirometry when carried out for screening, non-diagnostic or monitoring purposes.

The provision of treatment by means of surgical procedures

5. Surgical procedures including all pre-operative and post-operative care associated with such procedures carried on by a General Practitioner for:
    a) the purpose of treating disease, disorder or injury,
    b) cosmetic purposes, where the procedure involves the use of instruments or equipment which are inserted into the body, or
    c) the purpose of religious observance.
6. The following procedures are excepted from a) above and where there is no use of anesthesia or use of only local anesthesia:
    - nail surgery and nail bed procedures carried out by a health care professional on any area of the foot, and
    - surgical procedures involving the curettage, cautery or cryocautery of warts, verrucae or other skin lesions.
7. The following cosmetic procedures are also included:
    - the piercing of any part of the human body,
    - the subcutaneous injection of a substance or substances for the purpose of enhancing a person's appearance, and
    - the removal of hair roots or small blemishes on the skin by the application of heat using an electric current.

Services in slimming clinics

8. Services provided in a slimming clinic consisting of the provision of advice or treatment by, or under the supervision of, a General Practitioner, including the prescribing of medicines for the purposes of weight reduction.

Appendix 2

Standards for Private Medical Services

Standard 1: Requirements where the medical provider is an individual or a partnership

1. The purpose of this standard is to ensure that patients have their needs met because suitably qualified practitioners provide the service.

2. The provider must demonstrate that they are:
   - Of good character.
   - Be registered with the General Medical Council or equivalent professional regulatory body in other nations.
   - Listed on the Falklands Island Government register of Medical Practitioners.
   - Demonstrably have the necessary skills and qualifications to carry out the services they intend to provide.
   - Provide details of continuing professional development, revalidation and license to practice.
   - Evidence of professional indemnity insurance with a reputable insurer for at least £1million.
   - Evidence of an enhanced CRB check.
   - Provide all the necessary documentation required to meet this standard.

3. The Chief Medical Officer cannot register any service if these conditions are not met at the time of application or if subsequently the provider cannot continue to meet this standard.

Standard 2: Patient centred care

4. The purpose of this standard is to ensure that patients have care and treatment that is personalised to meet their needs and reflects their preferences. Providers must work in partnership with the patients to assess those needs and preferences and set out an agreed plan to meet their requirements.

Standard 3: Consent

5. The purpose of this standard is to ensure that patients or those acting lawfully on their behalf have given consent before treatment is delivered. The provider must make sure that they have obtained consent lawfully and that the patient understands the care and treatment they are being asked to consent for.

Standard 4: Safe care and treatment

6. The purpose of this standard is to ensure that patients are protected from avoidable risk and harm. The provider must demonstrate that they have the required skills, capability and experience to keep patients safe. The provider must prevent and control any spread of infection.

7. The provider must protect patients against the risks associated with the safe management of medicines, by means of the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines used for the purposes of the regulated activity.

8. Providers must be able to demonstrate how they will mitigate risks that may arise during care and treatment given that some procedures and interventions are not without risk.

Standard 5: Premises and equipment

9. The purpose of this standard is to ensure that premises where care and treatment are provided are clean, suitable for the purpose intended, maintained appropriately and that all relevant equipment is maintained and stored securely.

10. Premises must also be appropriately located for the purpose for which they are being used.

Standard 6: Receiving and acting on complaints

11. The purpose of this standard is to ensure that patients can make a complaint and that they know how to do so. Providers must have an effective, open and transparent system for handling and responding to complaints. The complaints policy must allow for stage two complaints to be made to the Chief Medical Officer. All complaints must be investigated and any relevant and appropriate action taken where failures have been identified.

Standard 7: Good governance

12. The purpose of this standard is to ensure that providers audit their work as part of the science of improvement. Providers should systematically seek feedback from patients on their experiences to help drive improvements.

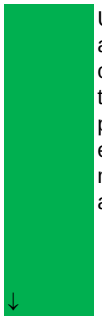
13. The provider must ensure that patients are protected against the risks of unsafe or inappropriate care and treatment arising from a lack of proper information about them. They must maintain an accurate record of each patients care and treatment. These records must be kept securely and located when required. They must be kept for an appropriate period of time and securely destroyed when appropriate to do so.

14. Information sharing with the publically funded service when appropriate should be done so through existing information governance arrangements.

Appendix 3

Self - assessment dashboard of private medical services - worked example

Standard 1 Requirements where the medical provider is an individual or a partnership	**Self rating*** ↑	**Supporting Evidence** FIG registration, CPD, revalidation and planned future training courses	**CMO Determination*** ↑
Standard 2 Patient centred care	**Self rating*** ↑	**Supporting Evidence** Assessment forms dated and signed and care information shared with patier	**CMO Determination*** ↑
Standard 3 Consent	**Self rating*** ↑	**Supporting Evidence** Consent forms signed and dated	**CMO Determination*** ↑
Standard 4 Safe care and treatment	**Self rating*** ↑	**Supporting Evidence** Medicines storage and management cannot be assured. There is no scope for systematically planning for requirements and ordering of stocks presents a challenge. Capacity for storing quantities of drugs is limited. Plan for community pharmacy to manage dispensing starting from xx	**CMO Determination*** ↑
Standard 5	**Self rating***	**Supporting Evidence**	**CMO Determination***

Premises and equipment		The capacity to dispose of Sharps containers is in place. Equipment for xx is tested and serviced as set out in the manufactures guidance	
Standard 6 Receiving and acting on complaints	**Self rating*** 	**Supporting Evidence** The complaints procedure is clear for stage 1 and 2 complaints	**CMO Determination*** 
Standard 7 Good governance	**Self rating*** 	**Supporting Evidence** Information sharing with the publically funded service has not always been timely but discussions are taking place to agree a set of thresholds for triggering information flows and exchange.	**CMO Determination***  Until there is agreement on the thresholds patient experience may be affected.

* A red, amber, green status is used to signify compliance along with direction of travel on future performance

Standard is not being met and is unlikely to be met
Standard is not being met and it is not clear if improvements will be effective
Standard is not being met and improvement is likely

Standard is being partially met but is unlikely to be sustained
Standard is being partially met and it is not clear if improvements will be effective
Standard is being partially met and improvement is likely

Standard is being met but declining
Standard is being met but it is not clear if improvements will be effective
Standard is being met and improvement is likely

Appendix 4

Regulation of Private General Practice

Chief Medical Officer Framework

Safe General Practice Services

By safe we mean patients are protected from harm and abuse

Standard	Prompts	Met	Partially met	Not met
Standard 1 Patients have their needs met because suitably qualified General Practitioners (GP) provide the service.	1. Have we seen the relevant documentation to support Falklands Island government register of Medical Practitioners?			
	2. Has the GP the relevant and specific qualifications, training and experience for the regulated activities they are providing?			
	3. Has the GP received GP with Special Interest (GPwSI) accreditation or equivalent?			
Standard 4 Safe care and treatment	1. Are the systems and processes in place to keep patients safe?			
	2. Do arrangements for managing medicines keep patients safe?			
	3. Are patient's individual records written and managed in a way that keeps them safe? This includes ensuring people's records are accurate, complete, legible, up to date, stored and shared appropriately.)			

Safe General Practice Services

By safe we mean patients are protected from harm and abuse

Standard	Prompts	Met	Partially met	Not met
Standard 5 Premises and equipment	1. Does the design, maintenance and use of facilities and premises keep patients safe?			
	2. Does the maintenance and use of equipment keep people safe?			
	3. Do the arrangements for managing waste and clinical specimens keep people safe?			

Effective General Practice Services

By effective we mean patients achieve good outcomes and treatment is based on best evidence

Standard	Prompts	Met	Partially met	Not met
Standard 2 Patient Centred care	1. Do patients have their needs assessed and their care planned and delivered in line with evidence-based guidance, standards and best practice, including during: - Assessment - Diagnosis - Referral to publically funded services.			
	2. How is this monitored?			
Standard 3 Consent	1. How are patients supported to make decisions?			
	2. How is the process for seeking consent monitored and improved to ensure it meets professional responsibilities and is in line with best practice on Human Rights?			

Positive patient experiences in General Practice Services

By positive patient experiences we mean services are organised to meet patients' needs and they learn from these experiences

Standard	Prompts	Met	Partially met	Not met
Standard 6 Receiving and acting on complaints	1. Do patients who use the service know how to make a complaint or raise concerns?			
	2. How easy is it for patients to use the system for complaining or raising concerns and a formal record kept?			
	3. How are lessons learned from concerns and complaints and is action taken as a result to improve the quality of care?			
Standard 7 Good governance	1. Is there a systematic programme of clinical and internal audit, which is used to monitor quality and systems to identify where action should be taken?			
	2. Are there robust arrangements for identifying, recording and managing risks, issues and mitigating actions?			