EXECUTIVE NOTE

THE HEALTHCARE IMPROVEMENT SCOTLAND (APPLICATIONS AND REGISTRATION) REGULATIONS 2011

SSI 2011/35

The above instrument was made in exercise of the powers conferred by sections 10P, 10Y and 10Z6 of the National Health Service (Scotland) Act 1978 ("the Act"). The instrument is subject to negative resolution procedure.

Policy Objectives

The purpose of the instrument is to set out provisions relating to the applications made to Healthcare Improvement Scotland (HIS) to register a independent health care service, and to the information which an applicant will be required to provide. "Independent health care services" are defined in section 10(F) of the Act and will be regulated by HIS from 1 April 2011. Independent health care services which are currently registered with the Scottish Commission for the Regulation of Care ('the Care Commission') will be deemed registered with HIS and will not need to go through the application process again.

Anyone who wishes to provide an independent health care service will be required to apply to HIS for registration. The policy objective is to ensure that the application and registration process for independent health care services is clear and proportionate. The regulations leave much of the day-to-day running of independent health care regulation to HIS. They are therefore less prescriptive than the current Care Commission regulations.

Applicants are required to provide the information set out in schedule 1 of the regulations. Once registered HIS must inform providers what records they are required to keep, which matters HIS must be notified of and what is required in an annual or periodic return. The regulations also prescribe who is disqualified from applying to provide an independent health care service.

The regulations also set out the process for registered independent health care services to apply for a variation, removal or addition of a condition, or for cancellation of their registration.

HIS are required to maintain a register of independent healthcare services and make this publicly available. HIS will remove the address of an independent health care service from the register if they consider disclosure of the address would expose any person to danger.

Consultation

A public consultation was carried out on a draft of the Regulations between 10 September 2010 and 5 November 2010. The consultation exercise was web-based. A number of emails were also sent out to a wide range of stakeholders, including independent healthcare providers and umbrella organisations with direct involvement and/or an interest in healthcare services in Scotland. The consultation paper was sent to relevant

Committees of the Scottish Parliament, including Health and Sport, Justice and Education Lifelong Learning and Culture.

Minor changes have been made to the regulations which were consulted on.

Financial Effects

A Business and Regulatory Impact Assessment has been completed in relation to these regulations and is attached. These regulations are similar to those that exist at present. They impose no additional requirements on independent health care services and there are therefore no additional costs associated with them.

Scottish Government
Directorate for Health and Healthcare Improvement
January 2011

BUSINESS AND REGULATORY IMPACT ASSESSMENT

INTRODUCTION

1. This Business and Regulatory Impact Assessment (BRIA) provides information on the impact on the care and healthcare sectors of the regulations relating to the establishment of two new scrutiny bodies, Healthcare Improvement Scotland and Social Care and Social Work Improvement Scotland.

TITLE OF THE PROPOSAL

2. Public Services Reform (Scotland) Regulations**:**

- The Social Work and Social Care Improvement (Requirements for Reports) Regulations 2011
- The Healthcare Improvement Scotland (Requirements for Reports) Regulations 2011
- The Social Care and Social Work Improvement (Fees) Order 2011
- The Healthcare Improvement Scotland (Fees) Regulations 2011
- The Healthcare Improvement Scotland (Applications and Registration) Regulations 2011
- The Social Care and Social Work Improvement Scotland (Registration) Regulations 2011
- The Social Care and Social Work Improvement Scotland (Applications) Order 2011
- The Social Care and Social Work Improvement Scotland (Requirements for Care Services) Regulations 2011
- The Healthcare Improvement Scotland (Requirements as to Independent Healthcare Services) Regulations 2011
- The Healthcare Improvement Scotland (Inspections) Regulations 2011
- The Public Services Reform (Social Services Inspections) (Scotland) 2011
- The Public Services Reform (Joint Inspections) (Scotland) 2011

PURPOSE AND INTENDED EFFECT OF REGULATION

Objectives

3. The Public Services Reform (Scotland) Act 2010 (PSR Act) established two new scrutiny bodies, Social Care and Social Work Improvement Scotland (SCSWIS) and Healthcare Improvement Scotland (HIS). The bodies are responsible for improving the quality of social services and healthcare in Scotland and will become operational from 1st April 2011. With the establishment of these bodies the Government expects to bring about a number of improvements in the approach to scrutiny of social care, social work, children's services and healthcare services.

4. The proposed subordinate legislation will underpin the operation of the new bodies and the regulation of services providing care and healthcare by the new

scrutiny bodies. Regulation of these services by SCSWIS and HIS will provide protection to those who use the services and encourage further improvement in the quality and standards of services provided.

5. The regulations have been drafted to give SCSWIS and HIS the flexibility to take a proportionate, evidence and risk-based approach to scrutiny under the new regulatory regime introduced by the PSR Act. The general thrust of the regulations is to leave as much as possible of the day-to-day operation of SCSWIS and HIS to their discretion and not to be overly-prescriptive. The regulations have drawn extensively from the operational experience of SCSWIS and HIS predecessor bodies (Care Commission, SWIA, HMIE and NHS QIS) as well as the regulations used by these bodies when carrying out their functions. They are also in line with the independent Crerar Review of Regulation, Audit, Inspection and Complaints handling of public services in Scotland which recommended simplifying the scrutiny landscape and having more risk-based and proportionate scrutiny.

6. In order to carry out their regulatory role the new scrutiny bodies will make use of the proposed secondary legislation in relation to:

- Applications and registrations;
- Fees;
- Inspections and Joint Inspections;
- Reports; and
- Requirements.

Background

7. The PSR Act requires any person seeking to provide a care service, or independent healthcare service as defined in the PSR Act (and the NHS (Scotland) Act 1978 as amended by the PSR Act) to apply to SCSWIS and/or HIS for registration of that service. This range of the services are currently regulated by SCSWIS' and HIS' predecessor bodies.

Rationale for government intervention

8. The policy on regulating care and healthcare services is well established. Under the PSR Act the focus on regulation will be on continuous improvement in the quality and standards of services and an intelligence-based, risk-based and proportionate approach to scrutiny.

9. The proposed regulations set out the powers and responsibilities of the new bodies in relation to the regulation of care and healthcare services, which will enable them to deliver the functions set out in the PSR Act. The regulations will allow the new bodies to tailor their regulatory activities as well as the programme and methodology of inspections to the category of providers and take into account the features of each individual provider. Without Government intervention, the simplification of scrutiny sought by the Parliament, service providers and the public will not be achievable and the emphasis on making and sustaining improvements is likely to be less than desired. This proposal ensures that measures are taken to bring about a more proportionate and risk-based approach to scrutiny.

10. The proposed fees regulations will, however, leave the current fee regime unchanged at least in the first year of SCSWIS and HIS operation. This is because of recent developments that have impacted on the scrutiny landscape and how regulators should operate, including the Crerar Review Report and the Independent Budget Review. Other factors that may affect any future decision on fees include the financing position of SCSWIS and HIS, albeit this will only be fully known when the new bodies will be operational. Any change to fees will need to take into account these developments.

11. In the meantime, the Scottish Government will continue to work closely with the new bodies in their first year of operation and beyond. This will include analysing the evidence that SCSWIS and HIS will gather on the activity levels required to regulate the various care and healthcare services within each sector, the overall funding position of SCSWIS and HIS and the implications of that for the fees across all services. This means that any change to the fees is unlikely to be implemented before year 2012/13. Any new fee arrangement and the rationale for change will be subject to consultation.

CONSULTATION

Within Government

12. The draft consultation was made available internally to: Positive Futures; Community Care Division; Community Justice Division; Housing Access and Support; Options and Partnerships (Learning); Care and Justice (CYPSC); Adult Care and Support; Workforce and Capacity Issues; Scrutiny Bodies Project Team – Health and Care; Quality Division and Branch 1 - Solicitors HCC Division.

Public consultation

13. The full public consultation document with the proposed draft regulations was made available on the Scottish Government's website, http://www.scotland.gov.uk/Publications/2010/09/09155722/20, between 10 September 2010 and 5 November 2010. 45 responses were received on the consultation from a wide range of stakeholders from the care and health sectors. The analysis of the consultation indicated that providers generally welcomed the new regulatory regime. There were also queries about how new arrangements would operate in practice and how the new bodies, once established, would address these with the service providers.

14. A short questionnaire on the impact of the proposed changes on the business sector was issued to a number of care and independent health care providers. However, many other comments pertinent to the BRIA were also made by respondents to the main consultation exercise.

OPTIONS

15. The options are:

- Do nothing (**Option 1**);
- Replicate the provisions of the current regulations (**Option 2**); or
- Introduce more streamlined regulations (**Option 3**).

Option 1 – Do nothing

16. Given the full commencement of the provisions in the PSR Act that will establish SCSWIS and HIS on 1st April 2011 the regulations previously made under the Regulation of Care (Scotland) Act 2001 (RoC Act) and the relevant NHS regulations in relation to NHS QIS will fall. "Doing nothing" is therefore not a realistic option as without regulations SCSWIS and HIS could not effectively carry out their statutory obligations under the PSR Act. That is also likely to increase the risk for service users.

Option 2 – Replicate the provisions of the current regulations

17. Under this Option the regulations made under the PSR Act would replicate the provisions in the current regulations for care and independent healthcare services. The regulation of these services would continue to be prescriptive and narrow. This would not give the new scrutiny bodies, SCSWIS and HIS, flexibility on issues like methodology and programme for inspections. Further, the approach adopted in the PSR Act means that fresh regulations would be required to confer on the new bodies the powers they need to operate and function effectively.

Option 3 – New regulations to be used by SCSWIS and HIS

18. Under this Option the regulations made under the PSR Act give SCSWIS and HIS the flexibility to take more proportionate, intelligence-based and risk-based approaches to scrutiny and inspection by providing more flexible and broader powers. The proposed regulations would also encourage a more consistent approach, help reduce the scrutiny-related workload of service providers and promote a stronger emphasis on improvement. This approach would streamline and, to some extent, reduce the regulatory burden on social care and healthcare providers by affording SCSWIS and HIS flexibility as to what is required of providers.

SECTORS AND GROUPS AFFECTED

19. The principal impact of these proposals will be on SCSWIS and HIS, the range of service providers currently defined in section 47 of the PSR Act, section 10F of the National Health Service (Scotland) Act 1978 (as amended by the PSR Act) and any additional health or social care services that the Scottish Ministers decide it is necessary to regulate. The proposals will also impact on the general public and in particular those who use care and healthcare services.

BENEFITS AND COSTS OF THE OPTIONS

Option 1 – Do nothing

Benefits

20. Without a statutory framework the new bodies would not have all the necessary powers to properly discharge their functions. As a result the quality of services could be expected to fall considerably and the safety and well being of service users would be compromised. This could also result in a number of legal challenges against the new bodies for failing to discharge their statutory functions. The risk of catastrophic service failures may significantly increase. This approach would also limit SCSWIS development work on the improvement of the quality and standards of service offered by providers.

Costs

21. The administrative costs of regulation would fall to SCSWIS and HIS. These regulatory costs will be met from the fees charged to service providers to register their services as well as continuation fees. With this Option the new bodies could charge whatever they wanted for registration and continuation fees. However, the level of fees charged by SCSWIS and HIS could have a significant impact on the Scottish Government funded Grant-in-Aid to the new bodies because of the need to make up for the short fall resulting from low fee income. On the other hand, although higher fees would determine a higher fee income, hence a reduction of the subsidy from Scottish Government providers could be adversely affected from having to pay higher fees, especially in the current financial climate.

Option 2 – Replicate the provisions of the current regulations

Benefits

22. This approach would minimise the changes to the requirements on care and independent healthcare providers. There are non-monetary benefits to maintaining the current regulatory system as this would not require any legislative or administrative change to be made and would reduce any potential disruption. However, no financial value has been placed on the convenience of maintaining the current arrangements.

Costs

23. This Option entails replicating the provisions of the current regulations and there would be no additional costs associated with this approach. As with Option 1, the administrative costs of regulation will be borne to SCSWIS and HIS. These regulatory costs will be met from the fees charged to service providers to register their services as well as continuation fees. Any short fall in fee income would have to be funded by Scottish Government through the GIA. However, this approach – given the very prescriptive nature of the current regulations - will not provide SCSWIS and HIS enough flexibility to seek further efficiencies and savings.

24. As regards service providers, the costs associated with regulated services would be registration and continuation fees. These are a component part of the costs of delivering high quality services and also make up the total cost of providing a service. These costs should therefore fall to providers in the first instance, so that they can be taken into account in setting charges for using the service.

Option 3 – New regulations to be used by SCSWIS and HIS

Benefits

25. The proposed approach will ensure a proportionate, risk-based and evidence based approach to scrutiny. This means that the new scrutiny bodies would be able to better tailor their regulatory activities according to the category, type and performance of providers following a sound and rigorous assessment. This approach would enable SCSWIS and HIS to free up resources and focus their regulatory and inspection activities on failing providers or providers assessed as presenting a greater risk, hence offering enhanced reassurance to the public. In practice, this is likely to mean a reduced level of activities and reduced administrative burden for many low-risk and high performing providers. The new system will entail - over time - a reduction of the regulatory costs for the new bodies; however, many of the benefits associated with the new approach to the regulation of services are difficult to measure in monetary terms.

Costs

26. The considerations made above under Options 2 and 3 on the administrative costs of regulation and costs to providers would also apply to this Option. However, this Option will afford SCSWIS and HIS the necessary flexibility so that over time they will endeavour to seek further efficiencies and savings. As a result, the regulatory costs of certain services will fall and the related fees will fall accordingly. With this Option it is therefore expected that the subsidy from the Scottish Government will also be reduced. The position on costs would be reviewed when SCSWIS and HIS are established.

SCOTTISH FIRMS IMPACT ASSESSMENT

27. There were no face-to-face meetings with stakeholders due to the limited time available to develop the policy following the full public consultation. However, a short BRIA questionnaire was sent to 10 service providers of varying scales which operate in care and health sectors. Four responses were received, with 75% of the respondents indicating that they would not be adversely affected by the proposals, whilst only 25% of the respondents indicated that there would be some impact from the proposals at a time where the sector is not well placed to deal with the changes.

28. Further, businesses and other stakeholders were regularly updated on the proposed changes during the development of and consultation on the PSR Act and the associated regulations. As a result of the feedback to the main consultation exercise, a number of changes were made to the draft regulations, including aspects relevant to the BRIA.

29. Under the new regulatory regime micro and small service providers will be subject to the same requirements and procedures as larger service providers so they will be on a level playing field when engaging with SCSWIS and HIS.

COMPETITION ASSESSMENT

30. The proposals are not expected to have an impact on competition. The proposed regulations will be applied consistently to services. In addition, the registration and continuation fees for health and care service providers will remain at current levels, which are set proportionally, taking account of the size of the organisation and potential impact.

TEST RUN OF BUSINESS FORMS

31. The new scrutiny bodies will develop the appropriate forms to administer regulation of services and will test these with services that have volunteered to take part in a pilot exercise. The forms will take on board the experience of previous regulators and working groups to ensure that no additional financial or administrative burden is placed on providers.

LEGAL AID IMPACT TEST

32. On the basis that the PSR Act and the related regulations will not introduce any new court process or right or appeal it is not expected that these proposals will have a significant impact on the use of the legal aid fund.

ENFORCEMENT, SANCTIONS AND MONITORING

33. Once regulation of services has commenced it will be illegal for a service to operate unless it is registered with the appropriate regulatory body. Existing services operating immediately before 1 April 2011 and registered with the Care Commission will be 'deemed' registered with SCSWIS or HIS from that date. They will then have a period of time to submit an application for registration along with the appropriate fee to the regulatory body. Services which are not operating immediately before 1 April 2011 are treated as new applications and must be registered before they can begin to provide the service. Operating a regulated service without being registered with SCSWIS and/or HIS is a criminal offence and anyone doing so will be liable on summary conviction to a fine not exceeding level 5 on the standard scale or to imprisonment for a term not exceeding 3 months or to both.

34. SCSWIS and HIS have statutory powers to register and inspect care services and to take enforcement action.

IMPLEMENTATION AND DELIVERY PLAN

35. SCSWIS and HIS will plan and manage the registration of those services that meet the definitions set out in the PSR Act and ensure that such services are registered within the timescale set out in the subordinate legislation here proposed.

POST IMPLEMENTATION REVIEW

36. Maximum fees for services will be reviewed by Scottish Ministers after the first year of operation of the new scrutiny bodies (see paragraphs 10-11).

SUMMARY AND RECOMMENDATIONS

37. The Options considered in this assessment are doing nothing (Option 1); replicating the current regulatory regime (Option 2); or introducing a more streamlined regulatory framework (Option 3). The Option being recommended is Option 3. Under the PSR Act the focus of scrutiny will be on the continuous improvement in the quality and standards of services. The benefits of regulating services relate to protecting vulnerable service users and ensuring that quality services are provided no matter who provides them or where they are provided. The costs of scrutiny must, however, be balanced against and proportionate to the outcomes being sought. The proposed regulations will promote a more proportionate and risk-based approach to regulation and inspections of services. The alternative approach would be doing nothing which could result into an ineffective regulatory system and expose users to potential risks or replicating the current statutory framework but this will fail to produce the simplification and improvement sought or the longer term savings. **As a result the approach recommended at Option 3 is recommended.**

DECLARATION AND PUBLICATION

38. I have read the Business and Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed by the Responsible Minister ……..

Date ……..

Contact

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