

PUBLIC SERVICES REFORM (SCOTLAND) ACT 2010

EXPLANATORY NOTES

THE ACT

Part 6 – Health Care: Scrutiny and Improvement

Section 108 – Healthcare Improvement Scotland

189. This section amends the [National Health Service \(Scotland\) Act 1978 \(c. 29\)](#) by inserting the following sections into the Act.

Healthcare Improvement Scotland

Section 10A – Healthcare Improvement Scotland

190. Subsection (1) creates Healthcare Improvement Scotland, which is referred to in the Act and in these notes as HIS. It will be a statutory body corporate which will exercise the functions given to it by or under the Act or other relevant legislation. Subsection (1) (b) provides that as part of its function, HIS will be expected to promote improvements in healthcare provided in Scotland.
191. Subsection (2) defines what is meant by healthcare in subsection (1)(b) as services for, or in connection with, the prevention, diagnosis or treatment of illness provided under the health service or by people providing independent health care services
192. Subsection (3) and (4) places HIS under an obligation to act subject to and in accordance with directions given by the Scottish Ministers and enables the Scottish Ministers to vary or revoke such directions.
193. Subsections (5) gives effect to schedule 5A of The National Health Service (Scotland) Act 1978 (contained in schedule 16 to this Act) which sets out the constitutional arrangements and general provisions for the establishment and operation of HIS.

Principles

Section 10B – Principles

194. This section sets out the principles in accordance with which HIS will be required to exercise their functions. These prioritise the safety and welfare of persons, and the promotion of good practice.

Functions related to the health service

Section 10C – Health service functions

195. Subsections (1)(a) to (c) require HIS to exercise the functions of supporting, ensuring and monitoring the quality of health care provided by the NHS in Scotland (including quality assurance, and accreditation) the promotion of user involvement in the planning and development of health services by Health Boards, Special Health Boards and the Common Services Agency; and the discharge of those bodies' functions in a

way that encourages equal opportunities. Subsection (2) confers certain functions exercisable by the Scottish Ministers under particular provisions of the 1978 Act on HIS. Subsection (3)(a) provides that HIS must make available to the public information on the availability and quality of health service services which under subsection (3)(b) should be made available in any format that may reasonably be requested. Information provided might include details about the location and types of services available as well as the results of HIS's inspections of services provided under the health service.

196. Subsections (5) to (7) provide a definition for health service functions which HIS may exercise.
197. Subsection (3)(c) requires HIS to provide advice to Scottish Ministers when requested, and subsection (3)(d) allows it to do so at any time even without a request by Scottish Ministers. Subsection (3)(e) requires HIS to provide advice to service users and persons representing carers of such users, local authorities, health boards, special health boards and the Common Services Agency, health service providers or prospective providers, and any other bodies set out in regulations, about any aspect of its functions. For example, HIS might offer advice to service providers on how to meet any standards and outcomes. Subsection (3)(f) provides a power for HIS to publish information arising out of its inspection and other work such as good practice guidance. Subsection (4) allows HIS to charge a reasonable fee for any advice, forms or documents it provides in connection with its obligations under subsection (3)(e).

Section 10D – Health service functions: further provision

198. This section permits Scottish Ministers to delegate by order to HIS such of their functions in relation to the NHS as they think is appropriate. This might include, for example, conducting an investigation into serious failure in NHS care.
199. Under subsection (2), HIS is required to carry out tasks for bodies associated with the NHS that Scottish Ministers and the other health bodies agree they should undertake and in the manner that is agreed. When carrying out such tasks or exercising functions on behalf of the Scottish Ministers, HIS may enforce any rights acquired and will incur any liabilities and be fully responsible for those tasks and the exercise of those functions.

Section 10E – Independent health care functions

200. Subsections (1) and (2) create functions for HIS in relation to information on the availability and quality of independent health care services similar to those for NHS services described above for section 10C.
201. Subsection (3) provides a list of the sections which confer functions on HIS to be known as independent health care functions. These functions include the registration, regulation and inspection of independent healthcare services and conditions attached to those functions and the designation of authorised persons who may inspect independent health care services. Subsection (4) further explains what is meant by the independent health care functions of HIS for the purposes of the Act.

Section 10F – Meaning of “independent health care services”

202. Subsections (1) and (2) lists and provides detailed definitions for the services which are to be considered independent health care services for the purposes of the Act namely any independent hospital or clinic, any private psychiatric clinic or any independent medical agency, and any independent ambulance service.

Section 10G – Power to modify definitions

203. This section gives Scottish Ministers a power, following consultation, to amend by affirmative order the definition of an independent health care service. The power may be used to add to or remove from the range of defined services or to amend the definitions themselves.

Standards and outcomes

Section 10H – Standards and outcomes

204. This section gives Scottish Ministers a power to prepare and publish standards and outcomes applicable to services provided under the health service and independent health care services; and to keep any published standards under review. Under subsection (4) any published standards must be taken into account by HIS when making any decisions related to registration, inspection and enforcement in respect of services provided under the health service and independent health care services. This section also ensures that consultation must be undertaken prior to initial publication and consequent amendment of the standards and outcomes.

Inspections

Section 10I – Inspections of services provided under the health service

205. As part of the duty of furthering improvement in the quality of healthcare in Scotland, conferred by section 10A under this section, HIS may inspect any service provided under the health service. Such inspections are to be subject to a plan prepared in accordance with section 10L and which is approved by Scottish Ministers.

Section 10J – Inspections of independent health care services

206. HIS may inspect any independent health care service. The purposes of an inspection of independent health care services are to review and evaluate their effectiveness, to investigate particular aspects of a service and to encourage continuous improvement in the provision of those services. Subsection (3) provides that any service or combination of services in any part or all of Scotland may be inspected. This would enable for instance a themed inspection of independent health care services provided to older people. Such inspections are to be subject to a plan prepared in accordance with section 10L and which is approved by Scottish Ministers.

207. Subsection (5) provides that HIS may require a person who provides an independent health care service registered under the Act to supply it with any information to enable HIS to discharge its functions. This may include such aspects as pre-inspection questionnaires or other information. Subsection (7) makes provision for HIS to decide the form which any inspection will take, subject to any regulations made under section 10O. This will enable HIS to conduct inspections in a manner appropriate for the type of service being inspected.

Section 10K – Authorised persons

208. This section provides that any inspection must be carried out by a person authorised by HIS – an “authorised person” - and that such a person may carry out inspections of any or all independent health care services.
209. Subsection (3) provides powers for an authorised person to enter and inspect any premises being used to provide an independent health care service. Subsection (4) provides that any confidential information that person acquires during such an inspection may not be used or disclosed by that person other than for the purposes of the inspection, or if required under law or a court order or disclosed to the extent that is necessary for the purpose of protecting the welfare of a child or adult at risk or the prevention or detection of crime or prosecution of offenders. Confidential information for the purposes of the Act is information which can identify an individual and in respect of which a duty of confidentiality is owed to the individual in question.

Section 10L – Inspections: best regulatory practice

210. Subsections (1), (2) and (3) require HIS to develop a plan for carrying out inspections, including inspection of services which are subject to self evaluation, in accordance with best regulatory practice, that is, in a way which is transparent, accountable, proportionate and consistent. Subsection (4) requires HIS to have regard to any guidance issued by Scottish Ministers for the plan. Subsections (5) and (6) require HIS to review the plan, obtain Scottish Ministers’ approval for any revision of the plan and consult as appropriate when preparing or revising the plan.

Section 10M – Inspections at request of Scottish Ministers

211. This section provides that HIS must undertake an inspection of any service provided under the health service and any independent health care service at the request of the Scottish Ministers. Subsection (3) provides that an inspection or investigation is to be conducted in accordance with a timetable approved by the Scottish Ministers. Under this provision, for example, Scottish Ministers might request HIS to undertake an inspection of the services provided to people with mental illness across both NHS and private providers.

Section 10N – Inspections: reports

212. Subsection (1) requires HIS to prepare a report after carrying out an inspection of NHS or independent health care services and send a copy of the report to the person (or body) providing the service(s). Subsection (2) provides that HIS should give that person (or body) an opportunity to comment on a draft of that report. Subsection (3) provides that HIS must make the report available to the public and subsection (4) makes provision for regulation to make further provisions about the preparation, content and effect of reports and, in particular, makes provision specifying the circumstances in which HIS inspection reports may be subject to restricted access or withheld.

Section 10O – Regulations relating to inspections

213. Subsections (1) and (2) provide a power for regulations to make further provision on the detail of inspections at sections 10I, 10J and 10M - and for different types of inspection to be carried out for such services.
214. Subsection (3) provides a list, which is not exhaustive, of the issues which the regulations may address in relation to those inspections such as the frequency of such inspections, the persons who are authorised to conduct such inspection, the interviews and examinations which may be carried out in relation to such inspections, requiring information produced to be held and further disclosed in accordance with prescribed conditions and the creation of offences.
215. Subsection (4) provides a definition for “health records” as referred to in subsection (3) (e).

Registration

Section 10P – Registration of independent health care service

216. This section sets out the framework for applications for registration of an independent health care service and specifies that such applications must be made to HIS and in addition to information that may be prescribed in regulations, the identity of the manager of the service must be included as well as any information HIS may reasonably require from the applicant.

Section 10Q – Grant or refusal of registration

217. Registration will only be granted if HIS is satisfied that the applicant has demonstrated that they have complied with or will comply with the relevant standards and other relevant requirements. The burden of proof is with the applicant rather than HIS.
218. Subsections (1) and (2) provide that an application can be granted either unconditionally or subject to any conditions HIS sees fit to impose. Specific conditions may be required to take account of the circumstances in an individual service, for example, a condition that a particular door is kept locked to prevent children from wandering directly onto a busy road, or that a particular ratio or skill mix of staff is needed.
219. Subsection (3) provides that if HIS is satisfied that the applicant is complying with, or will comply with, all relevant requirements set out in regulations under section 10Z7, and the requirements of any other legislation that it considers relevant, it should give the applicant notice of its decision to grant registration either unconditionally under section 10Z(1)(a) or subject to conditions under section 10Z2. Otherwise, it will give notice of its refusal of registration under section 10Z(1)(b).

220. If HIS grants the application, it must issue a certificate of registration (subsection (4)), which the independent health care service provider must display in a prominent position (subsection (5)), in the premises where the independent health care service is operated from and, if there is a separate management office, in that office too.

Improvement notices

Section 10R – Improvement notices: independent health care services

221. This section gives HIS the power to serve an improvement notice on an independent health care service. Such a notice will specify the improvements required to bring an independent health care service up to the standards required and the timescale for meeting these standards. It also provides for the HIS to warn that if the necessary improvements are not made within the time allowed HIS intends to begin procedures under Section 10S.

Proposals and applications in relation to registered independent health care services

Section 10S – Cancellation of registration

222. This section gives HIS the power to cancel the registration of an independent health care service that, having been issued with an improvement notice, is still not meeting the relevant requirements. This could be concern about a condition of registration that has been breached or where a relevant offence has been committed. Further grounds for cancelling registration may be prescribed by regulations.
223. Subsection (2)(a) provides that relevant offences for the purpose of this section are:
- an offence under this group of sections;
 - any other offence which in HIS's view makes it appropriate to cancel a registration.
224. Registration can be formally cancelled even if a provider closes an independent health care service before the cancellation process is complete. This will ensure that the provider's record accurately reflects the situation and HIS will be aware of previous history in dealing with any future applications.
225. Cancellation of registration would not normally be the first step in a formal enforcement action. It is only likely to be used where the service has not met conditions of registration over time and has ignored the serving of an improvement notice. If an independent health care service provider is convicted of a relevant offence, such as obstructing an inspection and fails to remedy matters at fault, HIS will be able to cancel registration.

Section 10T – Emergency cancellation of registration

226. Subsections (1) to (3) enable HIS to apply to the sheriff for an order cancelling the registration of any independent health care service. The sheriff may make such an order where he considers that, unless the order is made there will be serious risk to the life, health or well-being of users of the service (or other persons). Subsections (4) and (5) require HIS to inform the appropriate authorities and the provider of the application where an order (or an interim order) is made. Subsection (6) allows the Sheriff to determine the application even where the service provider is not present.
227. Subsection (7) provides that the order can come into effect on the day it is made or on some later date decided by the sheriff. An order to cancel a service's registration would have the effect of closing the service. This provision therefore allows a delay before closure takes effect in order that the service may be closed down in a proper manner and for instance services users relocated.
228. Subsections (8) and (9) allow an appeal to be made to the sheriff within 14 days of an order being made and for the sheriff principal on hearing such an appeal to confirm, revoke or modify the order. The order remains in force when an appeal is made. No further appeal is allowed.

Section 10U – Condition notices

229. This section enables HIS to notify the registered independent health care service, by a “condition notice” that a condition in force may be varied, removed or a new condition added.

Section 10V – Emergency Condition Notices

230. This section gives HIS the power to give immediate effect to any condition notice which it serves on a registered service. This will only be applied when, in HIS’ view, there is serious risk to life, health or wellbeing if the condition is not imposed. The service provider may make representations to HIS to vary or remove the emergency condition notice. HIS must consider any such representation and inform the provider of the action it proposed to take. Where HIS does not intend to vary or remove the condition the provider may appeal to the sheriff under section 10X(1).

Section 10W – Application of Act to condition notices following emergency condition notices

231. Section 10W disapplies the sections that outline that 14 days must elapse before a condition notice can be applied and thus provides that immediate effect of the emergency condition notices is allowed within the legislation.

Section 10X – Emergency Condition Notices: Appeals

232. This section gives a right of appeal to the sheriff to any person given an emergency condition notice within 14 days of the imposition of the condition, if they have made no appeal to HIS or have made an appeal and been informed by HIS that the condition notice stands. The sheriff may decide to direct that the condition continues, ceases, is varied or may impose additional conditions in relation to the registration.

Section 10Y – Applications in respect of conditions

233. Subsection (1) enables a provider of an independent health care service to apply for a change to their conditions of registration, to apply for the addition of a condition, for example, to limit the types of services which may be provided, or to apply voluntarily for the cancellation of registration, for example, if they plan to close or sell the business. Subsection (2) prevents a person voluntarily cancelling their registration if HIS has given notice of intention to, or decided to, cancel registration. Subsection (3) provides that an application shall be accompanied by the fee and that regulations shall say how the application is to be made and what particulars are to be stated in it. Subsection (4) provides that if HIS grants an application for a change of conditions it must give notice in writing and issue a new certificate of registration.

Section 10Z – Further provision as respects notice of proposals

234. Subsection (1) provides for HIS to give notice of decisions it intends to take, in respect of applications for registration made under Section 10P, if it intends to grant an application subject to conditions, or to refuse it. For example, in the case of a person applying for registration for the first time, the notice of proposal will state the conditions subject to which HIS proposes to grant the application.
235. Subsection (2) requires HIS to give notice if it intends to cancel a registration. Subsection (3) requires HIS to give notice if it decides to refuse an application for a variation of conditions made under Section 10Y. Such notice must set out the reasons (subsection (4)).

Section 10Z1 – Right to make representations to HIS as respects proposals

236. This section states that a notice given under Section 10Z must indicate that the recipient of the notice can, if they so wish, make written representations to HIS within a time limit of 14 days (subsection (1)). This ensures that that person has the opportunity to make their point of view known. Subsection (2) provides that HIS may not implement the terms of the notice until the 14 day period has ended unless they receive representations during the 14 day period or the person notifies HIS that they will not be making representations.

Notice of decision on application for registration

Section 10Z2 – Notice of HIS’s decisions

237. Subsections (1) and (2) provide that HIS should give notice when granting an application for registration unconditionally or subject to a condition that has been agreed in writing between HIS and the applicant.
238. Subsections (3) to (6) deal with situations where the representations stage has been completed, requiring HIS to serve a notice in writing of their decision on the applicant. The notice must explain the right of appeal conferred by section 10Z4 and in the case of a decision to grant an application subject to conditions or to vary conditions, set out those conditions. A decision to cancel registration, to grant an application subject to conditions which are not agreed, or to change conditions will take effect only after the outcome of any appeal has been determined, or after 14 days if no appeal is brought. In the case of a decision to grant an application subject to conditions which are not agreed, if the applicant decides not to pursue an appeal the decision will take effect immediately.

Conditions as to numbers

Section 10Z3 – Conditions as to numbers

239. This section provides that HIS can limit the number of people using certain services or to whom certain services are provided either on initial registration, or through a subsequent condition notice. For example, it may be appropriate for a new provider to be restricted on numbers until they get fully established, or where an independent health care provider is causing concern the power could be used as an alternative to enforcement action (i.e. withdrawing registration).

Appeal against decision to implement proposal

Section 10Z4 – Appeal against decision to implement proposal

240. This section provides for an appeal against a decision on registration made by HIS under section 10Z2(3). The appeal must be made to a sheriff within 14 days of the notice of decision. Subsection (2) provides for the sheriff's powers on considering an appeal.

Fees

Section 10Z5 – Registration Fees

241. This section sets powers in relation to the fees which are payable to HIS. Subsection (1) gives Scottish Ministers power to prescribe maximum levels of fees which may be imposed (following consultation with those who will or may be affected by the fees or their potential effect) and to determine whether or not a fee is payable by regulations. Subsection (2) sets out the activities for which the HIS is able to impose fees.
242. Subsection (3) requires HIS to have regard to its own expenses in setting particular fees within the maxima set by Scottish Ministers. This subsection also allows HIS to waive fees.

Regulations

Section 10Z6 – Regulations: registers and registration

243. Subsection (1)(a) provides for Scottish Ministers to make regulations about how HIS should maintain registers. Subsection (1)(b) allows regulations to be made about the information that should be provided in an application under Section 10P and what certificates of registration should include, for example the conditions of registration of an independent health care service. Subsection (1)(b)(iii) provides for regulations specifying types of applicants who cannot make certain kinds of applications.
244. Subsection (1)(c) and (d) allow regulations to be made that define the circumstances and conditions, including the payment of a fee, under which HIS should provide access to its

registers. Subsection (2) allows for regulations to be made setting out when fees should not be payable and provides that HIS can give access free of charge. These regulations would be, for example, to prevent unrestricted access to the names and addresses of services, such as children's services, where there might be a consequent risk to children. The regulations could contain a requirement for someone to show they had a legitimate interest before they could be granted access to certain registers.

245. Subsection (1)(e) gives Scottish Ministers the power to make regulations conferring additional functions on HIS in relation to registration under Section 10P.

Section 10Z7 – Regulations: independent health care services

246. This section gives Scottish Ministers the power to make regulations in respect of independent health care services. Such regulations would cover the normal day to day administrative matters required for well run independent health care services such as provision in relation to management, staffing, premises and the general way independent health care services are conducted.
247. Subsection (2) provides that regulations made under this section may make it an offence to fail to comply with specific provisions within the regulations, or with a condition of registration. Subsection (3) provides that a person guilty of such an offence would be liable to a fine not exceeding level 5 on the standard scale (£5,000 at present).
248. Subsection (4) requires the Scottish Ministers to consult such persons as they consider appropriate before making regulations under the powers in this section.

Complaints about independent health care services

Section 10Z8 – Complaints about independent health care services

249. Subsection (1) requires HIS to establish suitable procedures for dealing with any complaints made to it about independent health care services by users, their relatives or advocates or staff. Under subsection (3), before establishing such procedures, HIS will be required to consult SPSO and such other persons or groups of persons it considers appropriate. Any procedures developed must be kept under review by HIS and after consultation HIS may vary the procedure when appropriate to do so. While local resolution of complaints by the provider will be the norm, subsection (2) makes clear there is no requirement for a user of a service to go through the provider's own system before approaching HIS. HIS must also ensure that the established procedure is given the appropriate publicity.

Offences

Section 10Z9 – Offences in relation to registration

250. This section sets out offences in relation to registration under Section 10P (registration of independent health care services). Subsection (1) makes it an offence for a person to describe any service as an independent health care service for the purposes of this Act when it is not registered as such. If convicted of an offence under this subsection, the person would be liable to a fine not exceeding level 5 on the standard scale or up to three months imprisonment, or both.
251. Subsection (2) makes it an offence not to display a certificate of registration in a prominent place. The penalty on summary conviction is a fine not exceeding level 2 (£500) on the standard scale.

Section 10Z10 – False Statements in applications

252. This section creates an offence of knowingly giving information which is false or misleading in a material respect when making an application for registration, or for variation or removal of a condition. The penalty is a fine not exceeding level 4 on the standard scale.

Section 10Z11 – Offences by bodies corporate etc.

253. This section provides that if an offence under this group of sections is committed with the consent or connivance of individuals operating a body corporate, a partnership, or an unincorporated association, or if that person has been neglectful, then the person as well as the organisation is guilty of the offence. Individual officers of a body corporate, partners of a partnership, or persons managing or controlling an unincorporated association who are complicit in an offence under this group of sections will not be able to escape prosecution simply because the organisation is liable: both they and it may be liable to prosecution.

Inquiries

Section 10Z12 – Inquiries

254. Subsection (1) allows HIS to set up an inquiry on the exercise of its functions, or over the provision of an independent health care service or a service provided under the health service, giving HIS the authority to investigate issues of serious concern that may arise in respect of their functions or any particular independent health care service or a service provided under the health service.
255. Subsection (2) enables an inquiry to be held in private. This might be necessary to protect, for example, a victim of child abuse.
256. Subsections (3) and (4) provide for sections 210(2) to (6) of the Local Government (Scotland) Act 1973 to apply in relation to an inquiry. This will enable the person holding the inquiry to issue a summons requiring an individual to give evidence or produce any documents in their custody or under their control at a stated time and place. If that person fails to attend (for reasons other than not having the necessary expenses of their visit paid or tendered), they are liable to a fine or imprisonment.
257. Subsections (5) and (6) allow HIS to determine who should pay their expenses in relation to an inquiry. Subsection (7) allows HIS to award expenses to parties involved in an inquiry and to direct who should pay those expenses.
258. Scottish Ministers also have a power to ask HIS to set up an inquiry under section 76 of the [National Health Service \(Scotland\) Act 1978 \(c. 29\)](#).

Arrangements to provide independent health care services: registration

Section 10Z13 – Arrangements entered into by independent healthcare services: services to be registered

259. This section provides that, although a service commissioned by a local authority or health board need not exist as a registered independent health care service at the time the contract is entered into, the service must be a registered one by the time it is actually provided.

Duty of certain bodies to be aware of reports, etc.

Section 10Z14 – Local authorities and health bodies: awareness of HIS reports etc.

260. This section ensures that local authorities and health boards must, when providing an independent health care service, or when considering the commissioning of, or contracting for, the provision of such a service, take account of relevant information, where available, about the quality of the services, or the organisation or co-ordination of such services as assessed by HIS. (This might include, for example, the grading of a service inspection reports, and any other relevant information, such as condition notices produced by the regulator). In doing this the authorities must follow any guidance issued by Scottish Ministers.

Giving of notice

Section 10Z15– Giving of notice

246. This section deals with the serving of notice on an independent health care service provider or a person seeking to provide an independent health care service, and sets out when notice is deemed to have been delivered.

Scottish Health Council

Section 10Z16 – Establishment of Scottish Health Council

261. This section requires HIS to establish a committee of its board known as the Scottish Health Council and to delegate to the Council the functions, set out at 10C(1)(b) and (c), of supporting, ensuring and monitoring the duties under section 2B of the 1978 Act for Health Boards, Special Health Boards and the Commons Services Agency to encourage public involvement in the health services for which they are responsible; and of supporting, ensuring and monitoring the promotion under section 2D of that Act, equal opportunities in the delivery of all their functions.
262. This section also provides that Scottish Ministers may at some future time by order, modify the functions delegated or remove the requirement on HIS to delegate specific functions to SHC and then to dissolve the SHC. Any order dissolving SHC may be reversed at some future date.

Section 10Z17 – Transfer of staff

263. This section clarifies that section 12CA concerning transfer of staff amongst health service bodies is applicable to HIS and provides that the existing staff of NHS Quality Improvement Scotland will transfer to HIS on the date on which it is established as a new body.

Section 10Z18 – “Provide” in relation to independent health care services

264. This section provides a definition of the term “provide” in this Part of the Act which is to carry on or manage an independent healthcare service.

Consultation with Mental Welfare Commission for Scotland

Section 10Z19 – Duty of HIS to consult the Mental Welfare Commission for Scotland

265. This section provides that HIS must consult the Mental Welfare Commission for Scotland (MWCS) where HIS is exercising its functions in relation to the provision of guidance, advice or information and considers it appropriate to do so, having regard to the MWCS’ similar powers to promote best practice.