The Scottish Parliament
Pàrlamaid na h-Alba

Official Report

HEALTH AND SPORT COMMITTEE

Thursday 11 February 2016

Session 4

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HEALTH AND SPORT COMMITTEE
10th Meeting 2016, Session 4

CONVENER

*Duncan McNeil (Greenock and Inverclyde) (Lab)

DEPUTY CONVENER

*Fiona McLeod (Strathkelvin and Bearsden) (SNP)

COMMITTEE MEMBERS

*Malcolm Chisholm (Edinburgh Northern and Leith) (Lab)
Rhoda Grant (Highlands and Islands) (Lab)
Colin Keir (Edinburgh Western) (SNP)
*Richard Lyle (Central Scotland) (SNP)
*Mike MacKenzie (Highlands and Islands) (SNP)
*Nanette Milne (North East Scotland) (Con)
*Dennis Robertson (Aberdeenshire West) (SNP)

*attended

THE FOLLOWING ALSO PARTICIPATED:

Brett Collins (Save Face)
Kevin Freeman-Ferguson (Healthcare Improvement Scotland)
Pat Kilpatrick (British Dental Association Scotland)
David Moulsdale (Optical Express)
Robbie Pearson (Healthcare Improvement Scotland)
Simon Withey (British Association of Aesthetic Plastic Surgeons)

CLERK TO THE COMMITTEE

Jane Williams

LOCATION

The James Clerk Maxwell Room (CR4)

Scottish Parliament

Health and Sport Committee

Thursday 11 February 2016

[The Convener opened the meeting at 12:47]

Decision on Taking Business in Private

The Convener (Duncan McNeil): Good afternoon and welcome to the 10th meeting in 2016 of the Health and Sport Committee. As usual, I ask everyone to switch off mobile phones, which can interfere with the sound system and the running of the meeting. I also ask people to note that colleagues are using tablets and other devices instead of hard copies of papers. We have received apologies this afternoon from Rhoda Grant, who cannot be with us, for good reason.

Our first item is a decision on whether the committee will consider in private agenda item 3, which is consideration of the main themes that arise from today's evidence. Does the committee agree?

Members *indicated agreement.*

Subordinate Legislation

National Health Service (Scotland) Act 1978 (Independent Clinic) Amendment Order 2016 [Draft]

Healthcare Improvement Scotland (Fees) Regulations 2016 (SSI 2016/26)

Protection of Vulnerable Groups (Scotland) Act 2007 (Prescribed Purposes for Consideration of Suitability) Regulations 2016 (SSI 2016/27)

Public Services Reform (Scotland) Act 2010 (Commencement No 7) Order 2016 (SSI 2016/22)

12:48

The Convener: As we normally do when taking oral evidence at a round-table discussion, I will introduce myself then we will work round the table, introducing ourselves and saying what organisations we come from. Then we will proceed to a general question to get us going.

My name is Duncan McNeil. I am the convener of the committee and the MSP for Greenock and Inverclyde.

Robbie Pearson (Healthcare Improvement Scotland): I am the director of scrutiny and assurance and also the deputy chief executive at Healthcare Improvement Scotland.

Fiona McLeod (Strathkelvin and Bearsden) (SNP): I am the deputy convener of the Health and Sport Committee and MSP for Strathkelvin and Bearsden.

Kevin Freeman-Ferguson (Healthcare Improvement Scotland): I am a senior inspector with Healthcare Improvement Scotland and I am currently responsible for leading the work that we do on regulating independent healthcare services.

Dennis Robertson (Aberdeenshire West) (SNP): I am the MSP for Aberdeenshire West.

Mike MacKenzie (Highlands and Islands) (SNP): I am an MSP for the Highlands and Islands.

David Moulsdale (Optical Express): I am the chairman and chief executive of Optical Express.

Pat Kilpatrick (British Dental Association Scotland): I am national director of the British Dental Association Scotland.

Nanette Milne (North East Scotland) (Con): I am an MSP for North East Scotland.

Brett Collins (Save Face): I am a director of Save Face.

Richard Lyle (Central Scotland) (SNP): I am an MSP for Central Scotland.

Simon Withey (British Association of Aesthetic Plastic Surgeons): I am a consultant plastic surgeon and am representing the British Association of Aesthetic Plastic Surgeons, and I sat on Bruce Keogh's United Kingdom review.

Malcolm Chisholm (Edinburgh Northern and Leith) (Lab): I am the MSP for Edinburgh Northern and Leith.

The Convener: I put on the record that this is an opportunity for the committee to discuss with witnesses the four statutory instruments that are before us. I could read their titles out, but in the interests of time I will not, as it is clear that that is the context in which we are working. We have read written evidence that we have gratefully received from you. The first stage is to explore the consultation that took place and to ask for your views on Scotland's approach to regulating independent clinics, including taking a phased approach, and how that fits in with what is happening in the rest of the United Kingdom and across Europe.

Who wants to take that first question? Come on, now. I see that David Moulsdale has just beaten Robbie Pearson to it, but we will hear from Robbie after him.

David Moulsdale: Fundamentally, we broadly support further regulation—or new regulations—as set out. Further regulation is necessary for patient confidence and, like many of our colleagues, Optical Express has fairly extensive experience of dealing with the Care Quality Commission. Although I understand that Healthcare Improvement Scotland is different, it has similar principles. We think that regulation is good for the sector and we totally support the proposals.

Robbie Pearson: I echo that point about the position of Healthcare Improvement Scotland. We are obviously responding on this secondary legislation that has been introduced to Parliament in direct response to the Scottish cosmetic interventions expert group, and what we see here is an opportunity for us in Healthcare Improvement Scotland to introduce a regulatory framework that builds on the work that HIS has already been doing since 2011 in regulating independent providers—hospitals, for instance.

What we have set out in our proposals and in the consultation is recognition that 2016-17 will be a year of transition—that is probably the best way to describe it. The point that was made in the national expert advisory group report was that the market is quite opaque, so in the year ahead we will be establishing what the market looks like and trying to understand it better from a regulatory standpoint. We see 2016-17 very much as a year of transition, as was reflected in the consultation exercise.

Pat Kilpatrick: On behalf of the dental profession in Scotland, the BDA Scotland welcomes the legislation, which has been needed for a long time because purely private practices in Scotland have been totally unregulated. That has been a source of concern to the profession on the whole, so we welcome the legislation whole-heartedly.

The Convener: I think that Brett Collins takes a slightly different view.

Brett Collins: Ultimately, there is an anomaly in the proposed legislation, and it sits within the non-surgical cosmetic procedures. That anomaly exists because that is an industry sector that includes a wide spectrum of people who provide services in Scotland and the rest of the UK. In that landscape you will find everyone from doctors, nurses and surgeons to beauticians and completely untrained individuals providing treatments. Fundamentally, therefore, within the current proposed regulation and the method for regulation, there are some significant flaws and contradictions. Although I take on board what Robbie Pearson said about a learning process in 2016-17, you do not need a crystal ball to predict a lot of the challenges that we will face because of the manner in which the proposals are to be implemented.

As well, we have a number of concerns in that, ultimately, as our submission says, the Department of Health says that

"any regulated activity or treatment must meet the following criteria:

there is fair playing ... the requirement to register must be based on risk to people who use services and the extent to which statutory system regulation of providers can mitigate that risk ... all types of provider must meet the same requirements."

Fundamentally, the suggestion that all providers

"must meet the same requirements"

must be one of the biggest flaws because, specifically for non-surgical cosmetic treatment, the proposals do not get anywhere near to holding all providers to meeting the same requirements, because they do not include all providers. For that to be achieved, all providers should be accountable to the same body and to the same standards of regulation. Ultimately, the proposals fail to achieve that.

Surely, for any form of regulation to be successful, it must define who is suitable to provide the treatments. In its response to being asked whether regulation should be based on

whether an independent clinic provides the service rather than on specific procedures or cosmetic treatments, HIS said that, because of the fact that treatments and methods of delivery change, the regulation could quickly go out of date if it were based on procedures and treatments. Ultimately, what causes risk to the public are the procedures and treatments; they are what cause damage to health and appearance. If you are not going to look specifically at the procedures and treatments—the cause of the risk—because you feel that, ultimately, you would not be able to safeguard the public's safety, how on earth will regulation safeguard public safety?

When I read the response from HIS, I thought that it was saying that regulation of the industry cannot be done. It can. Certain interpretations could be changed and what treatments broadly do in terms of injecting skin, skin healing and so on could be examined in a different way.

To me, the catalyst has been non-surgical treatments. In the report that was published, non-surgical treatments are referenced consistently, but we are told that the proposals are not supposed to regulate non-surgical cosmetic treatments. That does not seem to make sense. Nurses, doctors and dental professionals are singled out and some medical professionals—for example, prescribing pharmacists—are excluded, as are non-healthcare professionals, including beauty therapists. I know that a phased approach is being taken, but the phased approach does not incorporate everyone in the same regulation. Eventually, there might be a licensing scheme run by several authorities: in London, where borough councils have licensing schemes, the situation is not consistent across the board.

The idea is to enhance public safety and lower the risk. Therefore, decisions must be made about whether procedures are medical procedures that need to be provided by medically trained individuals, whether they need to be provided in an medical environment and whether they need to be regulated by a medically led regulator. If the answer to those questions is yes, the Government needs to state who can provide the treatments. If it is no, we do not need the presence of a state-run, medically led regulator to deal with non-surgical treatments.

I would like to make one final point—

The Convener: I will give you the opportunity to come back in, but you have raised a number of points, and I would not like them to be missed. I will ask for some responses from people around the table in order to see whether we can get a discussion going.

Simon Withey: I agree with some of the concerns, but I also agree with Robbie Pearson that the industry is opaque and no one really knows what is going on. There must be a degree of pragmatism and an attempt to try to understand what is going on out there. The Government's proposal is a pragmatic approach that will enable understanding of what is going on, but that has to be done in conjunction with strong public education about how to find a safe regulated practitioner, and in conjunction with an understanding of how the sector is going to be managed, which otherwise will not be regulated, even if that is introduced in phase 3. It has to be quite clear to everyone, especially the public, whether there will ultimately be differences between the responsibilities and regulation of the group that is regulated and those of the group that is partially regulated.

13:00

Pat Kilpatrick: There is an issue in relation to beauty therapists and dentistry. The BDAS is very concerned—we raised the issue in the general consultation—about the number of beauty therapists who are doing teeth whitening and bleaching, which can cause considerable harm to people's teeth. You just made the point that the public do not understand the situation. It is already in legislation that such processes can be carried out only by properly trained and qualified dentists. However, there is a back-street industry that is springing up everywhere. You can search on the internet and get a supplier locally. The procedure can cause significant damage to people's teeth, to the point at which, in the worst-case scenario, their dentine is completely destroyed and they have to have their teeth removed. That touches on the issues that Pat Cochrane has just raised about non-surgical cosmetic treatment. There is an industry out there. It is much cheaper to go to a beauty therapist who has no qualifications and is using a kit that they bought on the internet. The difficulty is where does the regulation start and stop? That is the dilemma. We are very unhappy about that.

Malcolm Chisholm: I picked up that example in the BDA submission. I want to be clear about what you are saying. You say that such activity is already against the law, so are you saying that that sector should be regulated so that beauticians can carry out such work under certain circumstances and subject to inspection, or are you saying that they should not be doing it at all? In a way, it is not a matter of regulating that sector but—as far as you are concerned—of ensuring that such activity does not happen. Is that not a different issue?

Pat Kilpatrick: It is—but it is perfectly legitimate for people to do it at the moment. They might be doing a range of other things on which they are

regulated. It goes back to the point about the procedures and the treatments. You can regulate the professional—the person—but if you regulate the procedures and the treatments, you are saying that there are certain things that a beauty therapist cannot do.

We have rules that are clearly laid out about dental care professionals and about what dental therapists can do. They cannot, for example, go around taking people's teeth out, but they can do shallow fillings and a lot of periodontal work. The General Dental Council has tried to regulate both the procedures and the professionals. It is a more robust approach. That is part of the difficulty here.

The Convener: How will the proposed legislation make a difference in that area? Will it make a difference?

Robbie Pearson: We need to be clear about the statutory instruments. They relate to phase 1 in terms of non-surgical procedures that are set out in the regulations and the healthcare practitioners who carry out the procedures. In the expert advisory group report, there was a recommendation for a phase 2 of further regulation, which may involve local authority licensing.

I want to go back to an earlier point that was made by the British Association of Aesthetic Plastic Surgeons. The fact that procedures may evolve and change over time is important; there is already a difficulty in defining and describing procedures and there is in our submission an example of that in relation to chemical peels. The important point is that to make the legislation pragmatic and so that, in the course of 2016, we can better understand the market, regulation should be based on individual healthcare practitioners.

Fiona McLeod: I want to ask about the phasing. I notice that phase 2 is for the likes of beauticians and that phase 3 is for other allied health professionals. Is there a logic to that order, in as much as other allied health professionals are already regulated by professional bodies and so we can wait until phase 3, but we need to tackle the beauticians earlier, in phase 2?

I also have a question for Pat Kilpatrick, because I am not quite sure about the teeth whitening. Is it the case that, under current legislation, beauticians cannot do that but are just doing it anyway?

Pat Kilpatrick: Yes.

Fiona McLeod: Right. That is not about changing regulations, but about enforcing them.

Pat Kilpatrick: Yes.

Fiona McLeod: Right. Is there phasing because you will catch certain professions under their own professional regulation?

Robbie Pearson: Mr Freeman-Ferguson might want to deal with the phasing, but I think we have to distinguish between existing professional regulation and the proposed regulation. People are registered with their professional bodies, and as registrants they are required to be competent and professional in their behaviour. What is proposed is in respect of regulation of a set of procedures that are currently unregulated. Professionalism and the regulation of the quality of care are two different things.

Kevin Freeman-Ferguson: The expert group recommended the phasing approach so that we could capture in a timely manner in phase 1 a wide range of services that are potentially quite high risk and currently unregulated. By commencing the regulation of independent clinics and adjusting the definition, we can efficiently capture quite a lot of procedures and practitioners who are doing some significant high-risk interventions. We can do that using the existing regulatory framework and can commence it using Scottish statutory instruments. It can be done quite quickly.

The work to set up the licensing scheme will take longer because it will need primary legislation, which will require a bit more work and a bit more debate through the parliamentary and statutory process. We will have phasing so that we can start regulating and quickly capture some of the most high-risk procedures. It is appreciated that that will still leave some procedures and practitioners unregulated; that will take longer but will be brought on in the second phase. The third phase will be for the other practitioners. As has been said, that area is considered to be the lowest risk, so we will look at that at the end.

Fiona McLeod: Thank you.

The Convener: Are we agreed that we are doing the high-risk ones first? Many people are already regulated under professional regulation, are they not? Or am I getting that wrong?

Robbie Pearson: Individual practising doctors and nurses are regulated by the General Medical Council and the Nursing and Midwifery Council respectively. That is a professional issue of their professional competence to practise. As Mr Freeman-Ferguson said, we are, in the first instance, talking about regulating the procedures that are currently unregulated but that we believe to be at the higher end of risk and need to be regulated. The phasing proposal seeks to be pragmatic in that regard.

The Convener: Paper 2 has a list of what needs to be regulated, including

"Cosmetic clinics ... Private GPs ... Private dentists ... Mobile clinics ... Dental professionals".

Is it only dental professionals in the private sector that need to be regulated? What regime other than professional standards is there? Is there any inspection of dental professionals?

Robbie Pearson: The BDA will be able to comment on that, but there are triennial inspections of national health service dentistry—a long-standing review process that examines the quality of dental practices in Scotland.

The Convener: Are they subject to unannounced visits and inspection?

Robbie Pearson: I am not sure that they are unannounced, but Healthcare Improvement Scotland does not carry out the NHS part.

Pat Kilpatrick: The inspections are carried out by NHS boards, which send teams of inspectors who are practising dentists into practices to examine them. The process is very robust and detailed and it takes a lot of preparation time and a lot of time to go through.

The Convener: But why would the inspections not be done by Healthcare Improvement Scotland?

Pat Kilpatrick: Inspection is done by the local NHS board, which gives the dentists in the practice their list number, so the contractual relationship is really with, for example, NHS Lothian or NHS Greater Glasgow and Clyde. There are NHS Greater Glasgow and Clyde list number dentists who are responsible for the inspection and regulation of the practice.

We are pleased that the issue has come to the fore. A considerable number of dental practices in Scotland—approximately 30, although Robbie Pearson and his team might know the exact number—are wholly private and do no NHS work, so are therefore totally unregulated.

I understand how the phasing will work, and it is important that practices are properly regulated. Although the GDC requires dentists to adhere to its professional standards, they do not cover the infrastructure of a practice. In Scotland, we are fortunate to have the highest decontamination standards in the UK and some of the highest in Europe. That is great and to be commended, and we fully support such regulation. However, a totally private practitioner does not need to comply with those standards, which are important for good-quality services and the safety of patients and the public.

The Convener: I was just making a point about consistency.

I have a number of bids for questions, if none of the panel members wants to come in on that point.

Richard Lyle: My question is on an entirely separate issue.

Dennis Robertson: My question is a supplementary, convener.

The Convener: I will take Dennis Robertson's supplementary first.

Dennis Robertson: I could be wrong, but my understanding from reading the submissions is that, if a private clinic had one NHS patient, it would not have to undergo regulation because it would be inspected through the procedure to which NHS dentists are subject. Is that right?

Pat Kilpatrick: Yes.

Dennis Robertson: A practice would require to have only one NHS patient and it would not then have to undergo regulation.

Pat Kilpatrick: It would have to register as an NHS practice even if it had only one patient. It is considerably advantageous for dentists if they have some NHS patients, which is why the number of wholly private practices is relatively small.

Dennis Robertson: Those 30 or so clinics could register with the NHS and have one patient, and they would not then have to go through the regulation process that we are talking about.

Pat Kilpatrick: We have not discussed the detail of that with Healthcare Improvement Scotland, but we assume that it will involve the same combined practice inspection regime that the NHS undertakes. We are bringing the rest of the dental profession up to the standards of NHS Scotland. That is why the legislation is important.

Dennis Robertson: It would also save the practices £3,500. Is that right?

Pat Kilpatrick: Not really. With the combined practice inspection, they might not be paying the cash up front, but it can take anything between 60 to 80 hours of dental time for the teams to prepare. In addition, the practice has to make the investments and do all the staff training. The process is not easy; it is robust and detailed. The money issue is largely irrelevant, to be honest.

The Convener: It is interesting that those practices sit outside all the other inspection regimes, but there is a hybrid scheme for dentists—

Pat Kilpatrick: No. NHS dentists are all inspected by their NHS boards. There are more than 1,000 NHS practices in Scotland, and they are all inspected, regulated and robustly controlled.

The Convener: But not as robustly as this legislation would provide for.

Pat Kilpatrick: No—that has always been the problem.

The Convener: They are not subject to unannounced visits or the same measures for complaints, are they?

Pat Kilpatrick: To come back on the point about unannounced visits, legislation is currently being introduced to Parliament to put in place unannounced visits for NHS dental practices. They are not currently subject to such visits, but if the legislation progresses—as I believe it will—they will be subject to unannounced visits. That would give them parity with the private dentists who are in the scheme that we are discussing and who will be subject to unannounced visits.

The Convener: That is something that we can take up. I see that Mr Collins wants to come in.

Brett Collins: I have a question about the inspection, which currently takes place every three years. Does it include any element of looking at non-surgical treatments in the practice? If a dentist who is getting his third-year inspection is providing dermal fillers as a treatment, would the NHS inspection look at any aspect of that particular treatment or procedure set in that practice?

Pat Kilpatrick: No.

13:15

Brett Collins: I have another question, after which I will give back the floor. My question is for Robbie Pearson. I am little bit confused about the word “phasing”. To me, phasing is one entity working through a process of phases. When we write in documents that this will be regulation by phasing, we are forgetting that phase 2, and potentially phase 3, is not carried out by HIS. That is correct, is it not?

Robbie Pearson: The regulation of beauticians, for example, would not fall within Healthcare Improvements Scotland’s responsibility.

Brett Collins: It would not be the same regulation.

Robbie Pearson: It would be a different and more appropriate body to do that in the context of licensing within local authorities.

Brett Collins: We have not answered my—

The Convener: Mr Collins, I have given you a lot of latitude, and I do not want to put you off contributing, but I cannot allow you to have a direct question-and-answer session. You need to go through me, as convener, please.

Brett Collins: Can I ask a final question?

The Convener: Yes.

Brett Collins: I bring you back to the original question. The Department of Health states that the regulation must include all types of providers and that they must all meet the same requirements. Does the proposed regulation meet that requirement?

Robbie Pearson: That is a matter for the Scottish Government and the Scottish Parliament. The Department of Health may have said that in England, but England has a different regulatory regime that includes the role carried out by the Care Quality Commission. With the phasing and Healthcare Improvement Scotland’s role in and responsibility for looking at individual healthcare practitioners rather than procedures, we take a pragmatic approach. In Scotland, we register services; we do not register providers. That is another distinctive difference between Scotland and England.

Simon Withey: I take some of Mr Collins’s points. It would be interesting to understand what the licensing process would be like, because without that information it would be difficult to know whether the approach would ever be effective.

I do not know whether anyone has considered the possibility that those who are non-regulated could apply for clinic status and become regulated. If you drive the public information message clearly and strongly enough, it may be that the public are looking for regulated practitioners. Certainly, it is being proposed in England that there will be a strong public health message, and the intention is that patients will choose regulated practitioners rather than unregulated practitioners. There may be an opportunity for some of the unregulated group to choose to be regulated. I do not know whether the system would be in place to allow that.

Kevin Freeman-Ferguson: The current arrangements do not allow elective regulation. If premises do not meet the test for an independent clinic, we are not in a position to register them. If we ended up being required to take sanctions to drive improvement, and if the individual elected to be part of that process and did not meet the test for a clinic, the defence against the sanctions would be that the service did not need to be regulated in the first place. It therefore becomes difficult for us to accept voluntary registrations. However, that would not prevent a beauty salon service with no registered healthcare providers in the business from inviting a nurse or a doctor to join its team. That would make its premises and operation an independent clinic, and we could register that.

Richard Lyle: I have found the discussion interesting. Teeth were mentioned. I am sure that I have seen adverts, including on the television, in

which people other than dentists offer teeth whitening services.

Dennis Robertson touched on the issue that I want to raise. Healthcare Improvement Scotland's submission includes scenarios 1 to 11. I will pick two of them. Scenario 7 says:

"I am a doctor ... and I provide a range of consultations and treatments from a room or rooms in or attached to my home."

In response to that scenario, you say:

"we will only grant your registration if the environment you practice from meets the requirements".

The next scenario says:

"I am a nurse ... and I provide a range of consultations and treatments to my clients in their own homes."

You say that the nurse "must apply to register" to operate as a permanent, independent clinic. The comment was made earlier that the money is totally irrelevant but, with the greatest respect, I refer you to the costs. One of the responses to the frequently asked questions is:

"Yes, there will be a fee to pay. The registration fee for 2016/17 for independent clinics is £1,990."

You may correct me if I am wrong about that.

It then gets worse. You say, "If you apply and we don't regulate you, we don't give you your money back." I am all for regulation, and I want to encourage people to be regulated but, under the two scenarios that I gave you, the doctor could be charging his patients £100 an hour. The nurse may only be able to charge her patients £10 an hour. How do we get to the great figure of £1,990? Why will we not refund it for those who are not passed? Why do we not have a sliding scale that covers people who have a nice little earner in their service and people such as the nurse—with the greatest respect—who may earn only £10 to £20 an hour? That is the question that I want to pose.

The Convener: There are a couple of issues in there, about costs and who registers who—the business or the profession.

Robbie Pearson: I will deal with some of those points then ask Mr Freeman-Ferguson to deal with the refund of the fee.

At the beginning of the evidence session, my first point was that the market is opaque. We do not know who is out there doing what types of procedures in different environments.

Although we have a flat registration fee for 2016-17, in moving in future years into actual fees to operate with a licence to operate, we will be moving to a much more sophisticated and risk-based system that is about who is doing what and the regulatory burden on us to oversee procedures. There is quite a difference between a private GP having a face-to-face consultation with an individual in their own home and another, more technical, procedure being done that might have devastating and long-term consequences.

We have to better understand the differences within the market during 2016-17. That will lead to different pricing of the licence-to-operate fee and different risks, and it will require a considerable amount of work. Inevitably, for the forthcoming year of 2016-17, there is a flat registration fee. That has allowed people to come forward and be registered.

Mr Freeman-Ferguson might wish to deal with the issue of refunds, but a key point of principle is that of full-cost recovery for Healthcare Improvement Scotland. We have been clear, up-front and transparent in the programme board that I chair about how the costs have been calculated and apportioned in the construction of the fees.

The Convener: How would that apply to Optical Express? Would there be a fee for each location?

Robbie Pearson: If you mean for registering actual services, I will ask Mr Freeman-Ferguson to touch on how we do that.

The Convener: Yes—if you could address that, Kevin, that would be fine.

Kevin Freeman-Ferguson: The registration process is fairly well defined. It requires the examination of all the arrangements—the business and clinical governance arrangements—for the service. Our experience from registering hospitals is that that is a fairly defined process. The amount of work that is required to register a service is fairly fixed. It does not vary much, regardless of how big or small the service is.

If you consider the fees that are set out for an independent hospital, you will see that there is a fixed flat fee for the registration of a hospital, regardless of its size. As we move into the continuation fees for that hospital, the fee that we charge is per place. If a hospital has four places, it pays the amount of money times four. If it has 122 places—which is the largest independent hospital that we have—its annual continuation fee is obviously considerably bigger. We have looked at the work that we already do, and that process, combined with the fact that the market is very opaque, has led us to the conclusion that the most pragmatic approach is a fixed flat fee for registration.

With regard to refunds of fees, it is not the case that a provider submits an application and we make an arbitrary decision as to whether they are registered. The registration process consists of quite an extensive dialogue that begins before the forms are submitted. We get an understanding of whether the kind of service and the arrangements

that the person or clinic has in place meet the requirements and, if we think that somebody who proposes to submit a registration form would not meet those requirements, we have a discussion with them about that in advance, so that we can ensure that they either do the work that they need to do to be more sure that they will get a registration, or that they decide that they do not want to register.

Once the registration form is submitted and that process begins, we are committed to doing quite a large piece of work to evaluate the information that is submitted and to make assessments about whether the provider and the service that they propose are appropriate, and whether the provider should be granted access to the market. We have to do that work. At the end of the day, we work towards granting everyone's registration; it is not our intent to not register anybody. Registration would be refused only in exceptional circumstances in which the provider could not demonstrate that they meet the necessary standards. If we find issues that need to be improved, there is a dialogue about that during the registration process, and we would work towards granting registrations.

Richard Lyle: The point that I was making is that there could be a nurse who may have only 10 clients, and there may be a doctor who has 20, 30 or 40 clients. I understand your point. I am pleased that your answer to the last question was basically that you will first have discussions with the person who is registering to ensure that they are going to pass, rather than taking their cheque, cashing it, and then turning round and saying, "Sorry, but you didn't pass." That has answered that question, and I am very pleased about that.

Why not have different fees to encourage people? I want to encourage people. I am concerned about what I have just been told about teeth whitening and about the back-street practices that may be going on. Why do we not encourage people to register? I can understand putting the process in place for big hospitals and for clinics in Harley Street or equivalent clinics in Scotland—it is fine for them. However, wee Mrs McShoogle who looks after local clients would have to pay £1,190, which I think is a bit over the top.

The Convener: What does this mean for bodies such as Optical Express? It does not see any burden, as it is a UK company and already complies with high standards. What happens in that situation? Would it have one registration, or would it register every premises?

Kevin Freeman-Ferguson: Optical Express would be required to register each of its treatment clinics that meet the test. Each clinic would have to register.

The Convener: Simon Withey wanted to get in.

Simon Withey: I support that pragmatic approach, but my sense is that it looks like we will end up with a registered sector and a licensed sector. At the moment, it is fairly clear what the regulation will look like for one of those—it will be pretty robust—but there is another system in which it remains very unclear. I am not convinced that you have exhausted the possibility, at phase 2, of having the same system to govern both sets of practitioners. However, it sounds as if you are saying that you cannot do that.

Robbie Pearson: The important point is that the expert advisory group report has been presented to ministers, and they have taken the view that there should be a two-step approach in relation to Healthcare Improvement Scotland. I think that that is more a matter for officials from the Scottish Government to comment on.

The Convener: We can raise that with them.

13:30

Pat Kilpatrick: In response to Richard Lyle's point about money, I am not saying that the fee is not big; it is big. That is really important and we have stated that. I agree with him about the fee. We do not represent DCPs or hygienists as a trade union or professional association but, if I was a dental nurse or a dental therapist, I could set up my own private practice. I could treat just periodontal disease and do lots of scaling, cleaning, polishing, minor fillings and preventative treatment for patients, and I would not earn anything like what a dentist would earn. I agree with Richard Lyle about a sliding scale.

In a year when the registration fees for individual dentists went up from about £450 to £980 per year, we are concerned that the cost of regulation is a considerable burden. A sliding scale that looked at income, turnover and maybe patient numbers and applied some sensitivity to the cost would be a good idea that I would support.

Malcolm Chisholm: Simon Withey's distinction between regulation and licensing was interesting. I wonder to what extent phase 1 is about what Healthcare Improvement Scotland is going to do and phase 2 will be about what somebody else is going to do, but that is just an opening thought.

I am surprised that we are where we are because, 15 years ago, I was the minister who took through the Regulation of Care (Scotland) Act 2001, which provides for the inspection of independent clinics. I understand that, at that time, the Care Commission developed standards for independent clinics, so I would be interested to know why none of those was ever implemented.

I would like Robbie Pearson to go into a bit more detail about what will be involved for the private clinics. For example, will standards be developed for them and will the inspection regime be similar to that for the other bodies that are inspected?

My final point is related to that. In his written submission, Simon Withey made the interesting point that the Care Quality Commission in England already inspects private clinics. It is always useful to compare what is happening in Scotland and in England. My general question is: in a couple of years' time, will the inspection of private clinics be the same in Scotland and in England, or will there be differences, which we could learn from?

The Convener: You're het for that, Robbie.

Robbie Pearson: On the detail of how we will inspect and regulate the services, at the moment for independent hospitals and hospices we use the national care standards as a basis for inspection. The committee will be aware that those standards are under redevelopment, particularly in the context of human rights, and we are working on that closely with a range of stakeholders, including the Care Inspectorate. Kevin Freeman-Ferguson might be able to say what an inspection will look like on the ground.

The regulatory regime for the Care Quality Commission in England is quite different from the regime in Scotland. However, for private provision, we are converging and moving to regulation that is similar to that of the Care Quality Commission. The only distinctive difference will be that the commission regulates providers, while we regulate services. Kevin Freeman-Ferguson may be able to answer the question about standards and how we apply them.

Kevin Freeman-Ferguson: The national care standards are under review, but standards are in place for independent specialist clinics and GP practices. They were developed along with the suite of national care standards and we will continue to use them, along with the legislation, as the basis for our inspections of the relevant services until the new standards are developed. The independent healthcare team is involved in the development of the new national care standards to ensure that we get coverage for independent healthcare services.

On what an inspection of an independent clinic would look like, we are trying to achieve consistency across all independent healthcare services, so we will therefore endeavour to use the same self-assessment process and the same grading process, although inevitably there will be adjustments and tweaks. We are looking for consistency across the piece but with appropriate adjustments to ensure that, when we cross the threshold of a clinic, the intervention on a day-to-day level inside the premises is appropriate.

We currently spend around two days in a hospital or hospice, but I would not anticipate that we would spend two days in a clinic. We will adjust that but, in the broad scheme of things, we will be looking for consistency. Specifically with regard to dentists, we will also look to get consistency with the triennial health board practice inspections. We are working with colleagues who are involved in that work in order to ensure that those inspections marry up.

Malcolm Chisholm: I have a question for Robbie Pearson with regard to the first point that I raised earlier. Would it be right to say that everything in phase 1 will be your responsibility? Do you envisage that anything in phase 2 will be your responsibility as well, or do you assume that that will be somebody else's responsibility?

Robbie Pearson: Phase 1 is our responsibility, but phase 2 is entirely different. Kevin Freeman-Ferguson has experience of local government and local authority licensing, which I think would be the most appropriate vehicle for phase 2.

Kevin Freeman-Ferguson: There are a couple of options for phase 2, one of which is local government licensing. However, there is also a potential option to prescribe a number of treatments that should be delivered only in an independent clinic. If we can get to the point where we can prescribe or define specific treatments, there might be a list of prescribed treatments that should take place only in a clinic, which would obviously move the inspection to us.

The Convener: I have a quick supplementary question on the reason for including midwives in the proposed legislation. There are not many independent midwives working out there and some obvious questions arise around why they were included, how that sort of service would be inspected, what aspects of their work would be inspected, given that their service is delivered in people's homes, and the extent to which you have had consultation with midwives about the proposals.

Robbie Pearson: The inclusion of the midwives in the legislation was obviously a matter for officials in the Scottish Government. However, there is clearly a gap in that they are healthcare professionals who are not currently regulated, so there was a natural requirement and proposal to put their regulation in the legislation. We have been open and transparent in setting out through the consultation exercise what falls within the scope of the legislation. Obviously, we have received information from submissions on the views of the Royal College of Midwives and independent midwife practitioners. A very small

number of independent midwives operate in Scotland.

Kevin Freeman-Ferguson might have other points on that.

Kevin Freeman-Ferguson: We have engaged with the midwives as a group and we recognise that the majority of the services that they provide are provided in people's homes. Delivering services in people's homes is one of the areas that we are going to be looking at as we ramp up towards inspection. Currently, we regulate only hospitals, which deliver all their services within the bricks and mortar of the building. Private GPs, occupational health services, travel clinics and some cosmetic practitioners can all potentially deliver services in people's homes, which is something that we are very aware of. We are looking at how we can sensibly regulate that and what our approach might be.

The Convener: Before I call Mike MacKenzie, I will bring in Brett Collins, then Simon Withey, who both caught my eye.

Brett Collins: The objective of regulation is ultimately to reduce risk for members of the public who have the treatments concerned. I will give a few examples of how the landscape looks in terms of the effectiveness of regulation. I do not think that any budget has been put aside to raise awareness of the regulation and who it covers. In addition, there will not be a resource where a member of the public can go, such as a register, to search for a regulated practitioner by treatment and procedure. Ultimately, there will be nowhere for people to go to find a regulated practitioner.

I am wondering how the situation could be addressed through the phases. I will give an example. It is 2017, when the regulation is in place, and I am on a street in Scotland. On that street is a doctor who has previously done a lot of NHS work but that work now constitutes only 10 per cent of his practice and the remaining 90 per cent is private work. That doctor would not need to be regulated. On the same street is a doctor who works in NHS hospitals 50 per cent of his time. He has invested in a private clinic where he treats his private patients. That doctor would be regulated.

There is also a nurse who rents a room in a beauty salon on that street. She would be regulated. If she rents three rooms in the city, that will be at three times the cost, if she wants to maintain that business. Then there is a prescribing pharmacist who rents a room in the same salon and who would not be regulated. There is a dental practice that is 50 per cent NHS and 50 per cent private. That dental practice would not need to register. However, the dentist has a good friend who is a doctor and who rents a room in his practice. Guess what—that doctor would have to be regulated. There is a beauty therapist on that street who would not need to be regulated and will not be inspected. We do not know what the licensing landscape will look like, because that will be done by someone else. Then there is the icing on the cake. I have a friend on the same street who has a flat above the doctor and who does treatments in his kitchen with his kids and cats running around. He would not need to be regulated.

The idea is to reduce the risk for members of the public. I am on that street but, given that I have no resource to identify who is regulated, what would I be driven by? Out of those eight examples, three practitioners would be regulated and five would not be. In that scenario, I would still have the same chance of going to someone who has not been affected by the regulation.

My final point is that I feel sorry for the nurse who, outside her NHS job, provides sports massage one day a week. It brings in limited revenue, but she does it to top up her salary. We know of the pressures on the NHS and junior doctors. She would have to be regulated, so she will stop doing it.

The Convener: We have your written evidence, too, Mr Collins. Does Kevin Freeman-Ferguson want to respond to that? I will then go directly to Simon Withey, because the clock is running down quickly.

Kevin Freeman-Ferguson: I will comment on there being a resource for finding out whether services are registered. The purpose of applying to be registered is to go on a register. We have a register of independent healthcare services, and the independent clinics will be added to that register once they are registered. We are required to have that register publicly available, and it is available on our website, where anyone can go to search for a service provider by the type of service that they provide and by location.

I would concede that the register is not particularly well marketed, because the amount of services on there is quite limited. It is well known that independent hospitals are regulated and that anyone who is looking can find out information about them. We will be able to do some work to promote the register.

I make it clear that there is a register, that the services will be on a register, because that is the purpose of applying to be regulated, and that that register is publicly available.

Simon Withey: The Care Quality Commission has had quite a lot of problems recruiting expert advisers for its inspections. It is important to understand that, particularly if there are anomalies such as dental practices being inspected in other ways. It is important that both systems have

equally expert people going in. One of the weaknesses that the Care Quality Commission identified when it was going round doing inspections was that it did not have people who were adequately trained to do the inspections.

13:45

The Convener: Are there any more points on the capacity to carry out responsibilities?

Robbie Pearson: We are recruiting a core of inspectors, but we are also budgeting for clinical expertise and advice to support those inspections, because that will be crucial.

The Convener: The process has to be self-financing, but written evidence has questioned that and indicated that you are underestimating the number of people who would need to be registered. I think that your costing calculation was based on your estimate that 400 or so practitioners and clinics would need to be registered. At least one person has said that that is an underestimate. If your business plan is not right, something will have to give: either you will not have enough inspectors and quality to do your job, or fees will need to go up. What would happen in that situation? How confident are you about those estimated figures?

Robbie Pearson: The caveat that I gave at the start is that to an extent we are dealing with a very opaque and quite invisible market. We can see a hospice or private hospital, but individual procedures done in people's homes are not as visible. Every day, we are counting the numbers of people who are coming forward to seek to register with us or to seek advice and have that dialogue. Kevin Freeman-Ferguson might have the latest figures on that.

Kevin Freeman-Ferguson: Currently, we are in conversation with 150 services where both parties agree that the service will need to move forward and register next year. We also have 348 services on our research list that we think would need to be registered. We have communicated with them in writing, but we have not heard back from them yet.

The Convener: So you have communicated with those on the list of 348.

Kevin Freeman-Ferguson: We are now sending out different communications to the different groups. We are still sending out more general information to the 348, but we now know what the 150 who have been in touch with us are doing, so they get much more targeted communications.

Pat Kilpatrick: I have a couple of points. First, Mr Collins made what might be a fundamental misinterpretation. NHS dental practices are very heavily regulated. It is a very detailed, robust, time-consuming and expensive process, but they are well regulated. There is absolutely no question about that and everybody in this room should understand that. All that we are saying is that the wholly private sector, which treats no NHS patients, will be brought into line with the existing regulatory system.

Secondly, in the comprehensive practice inspections system, which is the robust regulation that is operated at health board level, all the inspection work is done by trained, qualified and experienced dentists. I would like Robbie Pearson to clarify whether we will see parity, consistency and that same level of professional inspection across the piece, as we would like to see.

Thirdly, we do not represent dental care professionals, but we work very closely with them as part of a dental team. From a professional point of view, we would like to know who is going to inspect them and how that will be set up, because that is an important element that is not understood in Scotland.

The Convener: The point was made earlier that dentistry sits outside all the other regimes that have been set up and we are just wondering why that is the case. It is not that dentistry is not being regulated and is not providing good-quality and safe care; it is about why dentists have a different regime.

Mike MacKenzie has been waiting patiently to come in. I am sorry to say that we have a difficulty with the time left, because the meeting cannot go beyond the time when business begins in the chamber. However, we have all the written evidence and we will take that into account for our meeting with the minister on 23 February.

Mike MacKenzie: I am very glad that I do not live in the street that Mr Collins described. The very thought of it makes me feel unwell. It sounds like the set for one of those dreadful health soaps.

I seek reassurance from Healthcare Improvement Scotland because of my growing concern, given what I have heard in the meeting, about the possibility of inspection driving underground practitioners who are not up to standard. I am quite sure that inspection will not pose many problems for reputable people.

Picking up on Richard Lyle's points about the cost of fees and so on, I wonder whether there has been too much concern about the process being self-financing, with full cost recovery from fees, and not enough concern about effectiveness. We heard from Ms Kilpatrick that although teeth whitening by beauticians is not legal, it goes on daily in back-street outlets. If such a business becomes regulated and I walk in looking for a Simon Cowell smile but walk out with no teeth,

who is going to pay for the reconstructive surgery or whatever to remedy that situation?

The Convener: Who is going to take that one? Will regulation reduce risks or cause different behaviours to take place?

Robbie Pearson: At the moment, the risk sits with individuals who access such unregulated procedures. We are seeking people who undertake those procedures to come forward. The widespread feedback that we have had from the consultation is that people who are reputable professionals are very happy to engage with regulation because they want their work to be registered and want the quality of the service that they deliver acknowledged on the register—that has been a strong point.

I will leave Kevin Freeman-Ferguson to answer the question on compensation for procedures that go wrong. I am not sure what the legal basis is, but it involves a private individual's relationship with a commercial entity. That relationship will be much better if individual services are regulated. If people put themselves on the register and demonstrate through inspection and regulation that they deliver a high-quality service, they will have nothing to fear.

Kevin Freeman-Ferguson: We are the body that receives complaints about independent healthcare services, and clinics will fall under that. We will investigate complaints about service delivery and assess whether it has met the standards in our remit. We will look at whether the service complies with the national care standards in the legislation. If there was a clinical decision-making issue regarding whether a dentist's decision to take teeth out was right, we would refer that matter to the General Dental Council.

Compensation would be a civil matter between the patient and the dentist.

The Convener: Mike MacKenzie wants another quick question before I go to Nanette Milne.

Mike MacKenzie: I suppose that I should rephrase my question, because I am not absolutely sure that its thrust was understood. We have discussed how the regulation will be implemented and so on and so forth, but how sure are we that the regulatory framework will be effective in driving forward better standards and giving protection to the public?

Robbie Pearson: My view is that it is an important step forward in the sense that individuals will not be practising in the dark but be visible to everybody and will require to be registered. The quality of the service will be inspected and we will publish reports about it, which individuals will be able to access. Ultimately, it will be an offence to operate without a licence and registration. I suppose that that is the stick. The carrot must be that everybody is raising standards and improving the quality of the procedures that they are undertaking.

The Convener: Currently, what route can we take if there is a complaint about unregulated services? There is no route, is there?

Robbie Pearson: There is not. Complaints can be made on a professional basis to the professional regulatory body.

The Convener: Yes, but what happens apart from that regulation of practice and behaviour? For instance, how will the ombudsman fit into the situation in the future?

Kevin Freeman-Ferguson: The Scottish Public Services Ombudsman has no remit for this area because it does not involve public services. Currently, we are usually the end stage for complaints about independent hospitals. Normally, a service user would complain to the hospital to begin with, then go through a number of processes with that service. If they were still not satisfied at the end of that, they could come to us, although they could come to us at any time. In the same way, an NHS patient would complain to the board, but when they got to the end of the process with the board, they could go to the ombudsman.

The Convener: Simon Withey has his hand up, but I am going to bring in Nanette Milne first as she has a question.

Nanette Milne: I was going to ask about independent midwives, convener, but you got in first, so you can move on.

Simon Withey: Did Mr Pearson say that it would be an offence to practise without being on the register? That would be a very complicated situation, would it not? It would be very complicated if it was an offence for a qualified doctor with professional qualifications to do something, but someone else who was completely untrained could do it because they were on the register.

Robbie Pearson: Kevin Freeman-Ferguson might be able to clarify the language that is used. In the circumstances that you described, a person would not be permitted in law to carry out a procedure if they were unregistered.

Kevin Freeman-Ferguson: It will be an offence within the legislative framework to operate an unregistered independent healthcare service. Once the legislation has commenced, it will be an offence to operate an independent hospital if it is not registered; ergo, once the regulations on clinics commence, it will be an offence to operate an unlicensed clinic.

The Convener: Brett Collins has his hand up. I am going to give people the opportunity of a three-second pitch at the end. I am conscious that some have not had the same opportunity to speak as others. Brett, you have three seconds to make your point: ready, steady, go!

Brett Collins: Just pushing back on Simon Withey's comment, I think that the issue is that currently a beautician cannot be prosecuted but a nurse, doctor or dentist can be. So, under existing regulation, a nurse can be prosecuted but a beautician doing the same treatment cannot.

The Convener: You have made that point. Does Pat Kilpatrick wish to leave us with a final point?

Pat Kilpatrick: We welcome regulation but would like inspection to be done by dentists.

The Convener: Would David Moulsdale like to say anything?

David Moulsdale: Given all that has been said, it is clear that there is a need for increased regulation. There is a big difference between qualified private practices and unqualified practitioners providing procedures. There is a bigger risk with the latter group. Most qualified medical professionals have a responsibility and a duty of care to their patients and are worried about getting struck off, so there is almost self-regulation with qualified people and registered medical professionals. The bigger issue is unqualified practitioners performing procedures in the back street, where there is no real control and no penalty if they get it wrong. That issue probably needs to be explored beyond the context of this meeting.

The Convener: On behalf of the committee, I thank you all for your attendance and your written evidence. It has been very useful for us to have you here today. We will reflect on today's evidence, which will shape our questions to the minister on 23 February. Thank you very much indeed for your time today.

13:59

Meeting continued in private until 13:59.

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