Protecting and promoting patients' interests – licensing providers of NHS services

Your response to the consultation

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Background

This document should be read in conjunction with the document entitled ''Protecting and promoting patients' interests – licensing providers of NHS services– a consultation on the proposals'. The Department of Health has launched a public consultation on the proposed regulations on Licensing of health providers and invites you to respond.
The Licensing consultation is about:

- who will need to hold a licence from a Monitor;
- the circumstances in which providers who are licensed can have a say in any changes to the standard conditions in their licence;
- the fines Monitor will be able to impose if a provider breaches its licence conditions, delivers services without a licence or fails to supply Monitor with required information.

Please return your responses, no later than **Monday 22 October 2012** to:

By email: Licensing.Exemptions@DH.gsi.gov.uk with the subject 'Licensing Exemptions Consultation'.

By post to:

Licensing Consultation
Department of Health
Room 235 Richmond House
79 Whitehall
London SW1A 2NS

Many thanks for your response to this consultation. Please note that responses may be made public unless you state otherwise.

Personal Details

Organisation(s) represented: Diabetes UK

About Diabetes UK

Diabetes UK is the leading UK charity that cares for, connects with and campaigns on behalf of all people affected by and at risk of diabetes. We help people manage their diabetes effectively by providing information, advice and support. We campaign with people with diabetes and with healthcare professionals to improve the quality of care across the UK's health services. We fund pioneering research into care, cure and prevention for all types of diabetes. We campaign to stem the rising tide of diabetes.

About Diabetes and the state of care

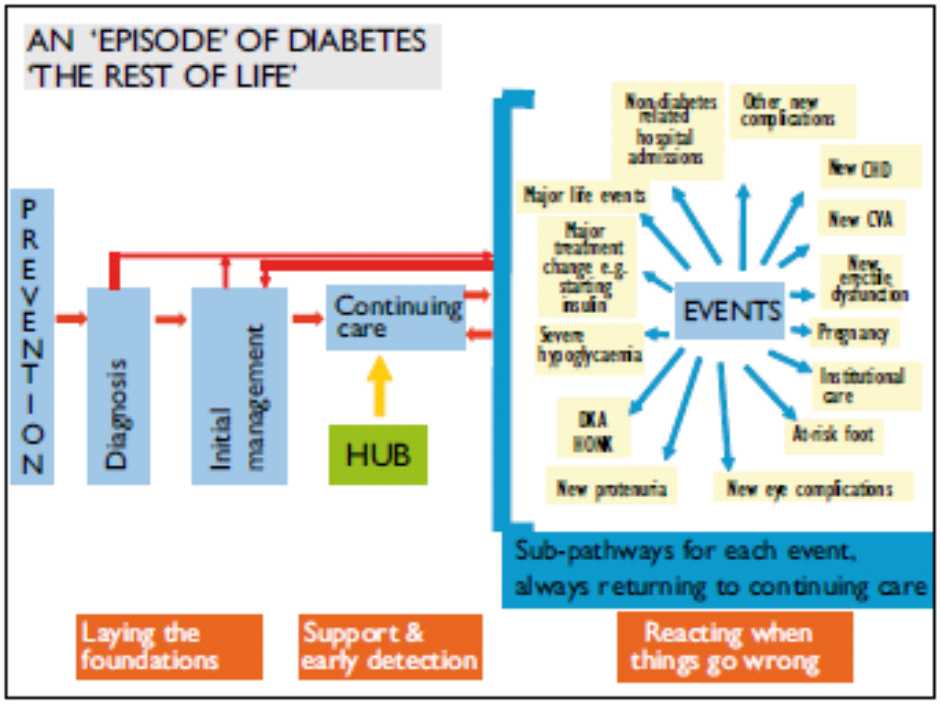
- Diabetes is the fastest growing health threat in the UK. There are currently 3.7 million people in the UK living with Type 1 and Type 2 diabetes. 2.9 million people are diagnosed[i], with an estimated 850,000 cases undiagnosed and up to 7 million people are at risk of Type 2 diabetes. If current trends continue these numbers will rise to 5 million, or 8% of the population, by 2025.[ii] There are an estimated 29,000 children and young people with diabetes in the UK.
- Diabetes is a complex condition which impacts on almost every part of the body and the NHS. In 2010/11 dealing with diabetes cost the NHS £10 billion, 10% per cent of NHS budget, 80% spent on dealing with devastating complications of blindness, heart disease, kidney disease and amputations.[iii] People with diabetes account for 15% of inpatient beds and stay in hospital up to 3 days longer than those who do not have diabetes.[iv] Up to 24,000 people with diabetes are dying each year from causes that could be avoided through better management of their condition.[v]
- Approx half of people with Type 2 and two thirds of people with Type 1 diabetes *fail* to receive all nine clinically recommended annual tests and investigations (NICE). In 2010 the percentage of people with
  diabetes receiving all nine tests and investigations ranged *from 2.6% to 69%* depending where they live. 96% of children and young people don't receive all the tests and investigations they should.[vi]
- Huge variations in standards of care demonstrate the need for organised, co-ordinated and structured models of integrated care delivery. Diabetes is complex and some aspects are better managed by specialist teams (eg pregnancy, pumps, inpatient care, children). Much of diabetes care can and is managed in primary care with good links with specialist teams (integrated care). Sometimes people need quick and timely access to specialist diabetes services as part of joined up and co-ordinated services within the local health economy to reduce the demonstrably wide variations in care.

What is integrated care to people with diabetes?

- A variety of services need to be joined up for people with diabetes. The complexity of services needing to be available staffed by competent staff during the lifetime of someone with diabetes is significant. From prevention of Type 2 diabetes through the NHS health checks programme, to

ongoing care planning and structured education, the completion of the 9 NICE-recommended care processes, to the effective management of complications.

- People with diabetes need to be clear about which services they need to go to and how often they need to go. They need consistent information about their diabetes from appropriately qualified healthcare professionals, access to test results before consultations and to be involved as experts about their condition in their care and treatment decisions, wherever they are on the care pathway. When people with diabetes develop complications, they need quick access to specialist services, such as MDT foot teams. To support these things, information needs to be shared well between services so that people receive all of the care and support that they should.
- To create effective integrated services focused on early identification, prevention of complications and management of complex problems requires input from a range of provider teams. Primary care, community services, specialist teams and tertiary services, alongside people with diabetes, need to work together to advise on local pathways, commissioning and co-ordination between providers through effective local diabetes networks. Diabetes care cannot be delivered by one provider alone. Local primary, community, voluntary and private providers their own can't do it on their own and they shouldn't think they can. The new NHS levers need to reflect this and licensing and regulation arrangements should include all the components of care required to enable delivery of systematic and person centred care within integrated pathways to assure integrated care.
- The systems in place to deliver integrated care should be specifically included within the provider licensing system to protect patient interests. These include sharing of information between patients and providers, continuity of care, referral and communication pathways and processes, monitoring of clinical and experiential outcomes (by all providers), feedback and reporting, clinical governance requirements and gaining appropriate local clinical engagement.



NHS trusts

Question 1: Do you think NHS trusts should be exempt from the requirement to hold a licence, but expected to meet equivalent requirements to those in the general, pricing

(where appropriate), choice and competition and integrated care sectors of Monitor's licence?

☒**Yes** ☐**No**

Question 2: Is there anything you want to add?

We agree that it is unnecessary for Monitor to regulate providers if another body, such as the NHS Trust Development Authority (NHS TDA), has performance management functions to enforce requirements and enable integration. It is however essential that the roles, responsibilities of such bodies are explicitly publicised so commissioners, providers and patients are aware of them to avoid confusion. Furthermore, the standards and regulatory requirements enforced by each body must be consistent so that patients can be assured that the rules and safeguards are applicable across all providers. Without this patients are at risk of falling through the gaps in the services (and the handoffs between different providers). The governance of different providers also needs to be assured across all organisations.

Private and voluntary providers of hospital and community services

Question 3: Do you agree that it is not appropriate to license small and micro providers of NHS funded services, at this stage, pending further review of costs and benefits?

Do you agree? ☐**Yes** ☒**No, proceed to question 7.**

Question 4: If so, do you agree that providers of NHS services with fewer than 50 employees (FTEs) and income from the provision of NHS hospital and community healthcare services of less than £10 million should be exempt from the requirement to hold a licence?

Do you agree? ☐**Yes, proceed to question 7** ☐**No**

Question 5: Alternatively, do you think a *de minimis* threshold based on a provider fulfilling one of the two conditions would be more appropriate (eg. <50 staff (WTEs) or <£10m turnover)?

☐**Yes** ☐**No, proceed to question 6**

If so, which? ☐**<50 Staff (WTEs)** ☐**<£10m turnover**

Question 6: If not, on what basis should small and micro providers be exempt?

Question 7: Is there anything you want to add?

Diabetes UK has significant concerns about this proposal. The emphasis on economic impact is currently placed on the size of the provider and the cost being paid to buy services by the commissioner. Too much emphasis is placed on 'impact on the market and market power'. It does not take any account of the impact a poorly integrated provider service might have on the service such as through service disruption or fragmentation within an existing pathway. It also does not take account of the impact this can have on patient care, experiences and outcomes, which may be high, even if the cost of the services being commissioned is low. Economic impact of care is broader than the cost of the service alone as it needs to take account of the cost of the service providing low standards of care to patients. In the case of diabetes, these will only be identified in the future as complications develop as up to 80 per cent of the budget spent on diabetes is spent on complications. Short term cost savings which impact on quality in the future are short sighted and are not in the best interests of patients[i].

We are particularly concerned about the impact that this will have on patients and existing services in respect to Any Qualified Provider (AQP) core podiatry services for example. Evidence shows that there is a tenfold variation in amputation rates across England[vii] and this is caused by how local services are organised. The annual costs to health care agencies in England of foot ulcers and amputations are estimated to be between £600 and £700 million[viii]. Changing the structure of local foot care services requires delivery of an integrated pathway for diabetes foot care[ix]. This is a central to improving the quality of care and outcomes for people with diabetes to reduce limb loss by amputation, as well as overall costs. The focus of the AQP for podiatry community services is placed on making more services available to people whose feet are at low risk and this may have significant impact on specialist teams if resources are moved. The purpose of assessing risk is to identify those at increased risk and refer to Multidiscplinary foot protection and treatment teams. Significant concerns exist about how integrated care will be assured with small podiatry teams delivering new AQP services if they are not licensed or regulated. Without a clear system for assuring competency of staff or ability of the employing organisation to put appropriate systems in place to follow up by specialist services, the feet of people with diabetes at increased risk of amputation are put at significant risk. What requirements are in place to ensure staff checking the feet of people with diabetes are adequately trained and know what to look for? What is in place to ensure that people are followed up and referred appropriately to services competent to prevent escalation of disease and amputation? It does not matter whether or not the provider of a service is small, what matters is that the provider organisation meets national standards, is co-ordinated within the existed NHS pathway and has effective links with local clinicians and the local diabetes network. Diabetes UK strongly recommends that this exemption is reviewed and an assessment made of 'not licensing' such providers.

The proposals appear inconsistent. In section 34 the document refers to all private and voluntary providers of hospital and community services being required to hold a licence (which Diabetes UK supports). However, section 38 recommends that "*there should be an exemption based on a de minimis threshold...We propose to exempt providers if they have fewer than 50 employees and NHS turnover of less than £10m.*" (which Diabetes UK does not support). This appears to contradict the previous recommendation and further clarification is needed. The proposal to exempt any provider not registered with the Care Quality Commission (CQC) means that there will be some providers who have absolutely no regulation of the quality or impact of the services provided and this is not in the best interests of patients. What mechanisms will be in place to ensure that such services are appropriately integrated into local pathways of care and have appropriate systems for delivery of the key components of quality care and clinical governance?

Family Health Services

Question 8: Do you agree that providers of primary medical services and primary dental services under contracts with the NHS Commissioning Board should initially be exempt from the requirement to hold a licence from Monitor?

Do you agree? ☐ **Yes** ☐ **No**

Question 9: Is there anything you want to add?

Adult social care

Question 10: Do you think providers of adult social care who also provide NHS services should be required to hold a licence, unless they fall below a *de minimis* threshold?

☐ **Yes** ☐ **No, proceed to question 15**

Question 11: If so, do you think that threshold should be fewer than 50 employees (FTEs) and income from the provision of NHS hospital and community healthcare services of less than £10 million?

☐ **Yes** ☐ **No, proceed to question 13**

Question 12: Alternatively, do you think a *de minimis* threshold based on an adult social care provider fulfilling one of the two conditions would be more appropriate (ie <50 staff (FTEs) or <£10m turnover)?

☐ **Yes** ☐ **No**

If so, which? ☐ **<50 Staff (FTEs)** ☐ **<£10m Turnover**

Question 13: Do you know of any adult social care providers who also provide NHS services who would not fall below this specific *de minimis* threshold?

Option 1: For fewer than 50 employees and income <£10m? ☐ **Yes** ☐ **No**

Option 2: For fewer than 50 employees only? ☐ **Yes** ☐ **No**

Option 3: For income <£10m only? ☐ **Yes** ☐ **No**

If yes to any of the above, please provide details:

Question 14: If you think there should be a different *de minimis* threshold, what is that threshold?

Question 15: Is there anything you want to add?

Objection percentage threshold

Question 16: Do you think a 20% threshold would be suitable for the standard condition modification objection percentage?

☐ **Yes** ☐ **No**

Question 17: If not, what figure do you think would be suitable?

Question 18: Is there anything you want to add?

Share of supply objection percentage

Question 19: Do you think the share of supply threshold should be calculated by defining share of supply as the number of licence holders affected by the proposed modification, weighted by NHS turnover?

☐ **Yes** ☐ **No**

Question 20: Do you think the threshold itself should be 20% as with the objections percentage?

☐ **Yes** ☐ **No**

Question 21: Do you think variations in the costs of providing NHS services should be taken into account when calculating share of supply?

☐ **Yes** ☐ **No**

Question 22: Is there anything you want to add?

How Monitor will enforce licence conditions

Question 23: Do you think the calculation of turnover for the purposes of the variable monetary penalty maximum should be based on turnover from provision of NHS funded turnover?

☐ **Yes** ☐ **No**

Question 24: If not, how do you think turnover should be calculated?

Question 25: Is there anything you want to add?

Diabetes UK would like to raise some key points and concerns which are not specifically being consulted upon within this consultation. These are described below.

Criteria to define and enable integrated care

The approach to licensing is based on establishing safeguards to protect patients' interests in the provision of NHS services, irrespective of who provides them. The consultation document states that a comprehensive set of rules will be applied across all providers to promote economy, efficiency and effectiveness, whilst preventing anti-competitive behaviour and enabling integration. It is proposed that a modular approach be adopted consisting of seven conditions. One of the licence conditions is focused on enabling integrated care. However there is a lack of clarity about what principles, systems and criteria define 'enabling integrated care'. Without this clarity it is not possible to identify what criteria will be assessed within the licence or how it should be applied within the new licensing arrangements.

Integration of care is key to all people living with, and at risk of, diabetes. Effective systems are needed to deliver quality integrated care across multiple providers with strong communication, integrated IT systems[x], and relationships between patients, multidisciplinary team-working, providers and commissioners. Patients access to their own records[xi], as well as multiple providers, is ideal. Licensing must take account of the requirements needed to achieve integration across multiple providers and it is not clear how this will be done within the proposals as they stand. It is essential that patients interests are protected through licensing regulations of provider services and that this licensing covers all providers commissioned by the NHS. Ensuring the governance arrangements are robust and have means of gaining patient feedback and involvement is an essential element of delivering a responsive and effective integrated care service. Diabetes UK recommends that governance is a condition included within the licence for all NHS providers irrespective of their size, albeit the specific governance arrangements should be proportionate.

Diabetes UK is disappointed that the licensing proposals are focused on value for money rather than integration. The report prepared for Monitor in May 2012, "Enablers and barriers to integrated care and implications' recommends the publishing of "*guidance that clearly sets out the criteria it will use to determine when integrated care initiatives: are very unlikely to pose any competition concerns; may pose some concerns; and are likely to be a problem*"[xii]. These licensing proposals do deal sufficiently with 'ensuring integration' particularly across single or multiple complex pathways. We recommend the need to be explicit about the criteria for when integrated care initiatives and include this within the licensing proposals to ensure that all providers meeting the licensing requirements also meet the requirements for ensuring integration. Essential components of integration which should be incorporated into the licensing arrangements include:

- sharing information between providers and teams within a single or multiple care pathway/s
- sharing information about care and quality with people with long term conditions such as diabetes
- explicit requirements to work and train together with other providers involved in a care pathway, for example multidisciplinary team working, training and local diabetes networks,.
- Clear roles, responsibilities and pathways agreed with all providers
- Engagement with patients in service delivery, design and quality monitoring
- IT systems accessible by all care providers, including patient access to records
- Call and recall systems, and referral protocols in place facilitating timely access to specialist care.
- Information and signposting about all services within an individual's care pathway including points of access during crises provided to patients.
- Quality assurance, clinical audit and clinical governance systems with clear complaints procedures
- Education and training from quality assured programmes to assure skills and competencies.

Without joint working, planning, identification of roles and responsibilities and processes for ensuring co-ordinated care with clinicians and organisations it will not be possible to deliver integrated or continuous care which is so important to people living with and at risk of diabetes for example.

The licensing process should set out all the conditions that all providers (licence holders) will have to meet in order to provide funded services that meet quality criteria and integrated services. This includes cost efficiency, choice, clinical effectiveness, safety, equity, timeliness and person-centredness. The licensing conditions, as part of continuity of care, will need to take account of integration and if it is in the best interests of patients to have services commissioned as an integrated pathway then it should not be subject to competition. In the absence of clear criteria around this there is a risk that value for money will override the requirements of local providers to deliver high quality integrated care which meets the needs of patients and the aspirations of the NHS.

Proposition 1 – Overriding requirements to protect continuity of services.

It is being proposed that all providers hold a licence if they are going to be providing services that the commissioner has identified as ones to which they want the continuity of licence conditions to apply. The definition of 'continuity' is yet to be determined. In the absence of any details about what this means of any definition of what type of services this might apply to, it is not possible to say if this will or will not put services or patient interests at risk. The complexity of diabetes care services to deliver the diabetes care pathway requires that roles and responsibilities for different aspects of care are clearly

defined within the model of care and local care pathway. There are risks associated with splitting the care pathway so that different providers provide different elements of the pathway. The screening and identification of complications and new morbidity is a key part of ongoing diabetes care and breaking up existing care pathways, to be provided by new services, presents significant risks of people with diabetes falling through the gaps created when there are more hand offs to other organsiations and risks in terms of competency to deliver quality care. The processes for referral, communication between and multidisciplinary team working must be enshrined within the definition of continuity of service. As new providers enter a market this could impact negatively on other NHS care services currently required as part of the continuity of care licence. Part of the licence criteria needs to assess the impact of taking services away from current providers where there is a reduced supply of competent staff. For example, the impact of removing trained diabetes podiatrists from foot protection teams, to make available more services for those whose feet are at less risk will undoubtedly make it more difficult for specialist services to employ competent staff to deal with complex disease. In other words, the establishment of a new provider service may undermine the capacity of current providers to maintain existing services.

Equalities Issues

Question 26: Do you have any evidence that the proposals in this document will impact adversely or unfairly on any protected groups?

Do you have any evidence? ☐ **Yes** ☐ **No**

If so, please provide details.

How to Respond

The deadline for responses to this consultation is **22 October 2012.**

e-mail licence.exemptions@dh.gsi.gov.uk

contact Licensing Providers of NHS services
Department of Health
Room 235
Richmond House
79 Whitehall
London
SWIA 2NS

online An online response form is available on the DH website[1].

Comments on the consultation process itself

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please

contact Consultations Coordinator
Department of Health
3E48, Quarry House
Leeds
LS2 7UE

e-mail consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter.

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

[1] http://www.dh.gov.uk/health/category/publications/consultations/

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and, in most circumstances, this will mean that your personal data will not be disclosed to third parties.

Summary of the consultation

A summary of the response to this consultation will be made available before or alongside any further action, such as laying legislation before Parliament, and will be placed on the consultations website at http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/index.htm

[i] Analysis of APHO and QOF Prevalence data

[ii] Figures based on AHPO diabetes prevalence model http://bit.ly/aphodiabetes. The AHPO model estimates that by 2025 there will be 4,189,229 people with diabetes in England

[iii] Hex, N., Bartlett, C., Wright, D., Taylor, M., Varley, D. Estimating the current and future costs of Type 1 and Type 2 diabetes in the United Kingdom, including direct health costs and indirect societal and productivity costs. Diabetic Medicine. In press

[iv] National Diabetes Inpatient Audit (2012)

[v] National Diabetes Audit Mortality Analysis 2007-8, (2011), NHS Information Centre

[vi] *National Diabetes Audit Executive Summary 2009-2010.* Available: http://www.ic.nhs.uk/webfiles/Services/NCASP/Diabetes/Last accessed 24th April 2012.

[vii] N. Holman & R. J. Young &W. J. Jeffcoate (2012); Variation in the recorded incidence of amputation of the lower limb in England. Diabetologia: 55:1919–1925

[viii] Kerr M. 2012. *Foot Care for People with Diabetes: the Economic Case for Change.* NHS Diabetes and Kidney Care

[ix] Diabetes UK. March 2012. Putting Feet First Campaign. Commissioning/planning a care pathway for foot care services for people with diabetes care.

[x] Young, R (2010) The organisation of diabetes care, *J R Coll Physicians Edinb,* 40(Suppl 17):33–9).

[xi] Renal Patient View: accessed 10 October 2012. https://www.renalpatientview.org/

[xii] Frontier Economics. (May 2012). Enablers and barriers to integrated care and implications for Monitor A report prepared for Monitor.