

Renal dialysis services

Morbid obesity surgery services

Title: A consultation on arrangements for the transfer of commissioning responsibility from NHS England to Clinical Commissioning Groups: Renal dialysis services & morbid obesity surgery services
Author: Medicines Access Team, Department of Health
Document Purpose:
Consultation
Publication date:
27 November 2014
Target audience:
Clinical Commissioning Groups, Clinical Reference Groups, patient representative groups, providers of renal dialysis and morbid obesity services, NHS England Area Teams, charities, industry, patients, carers and families, general public.
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Prepared by Medicines, Pharmacy & Industry Group, Department of Health

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## **Executive summary**

In October 2014 the Prescribed Specialised Services Advisory Group recommended to Ministers that the commissioning responsibility for renal dialysis services and morbid obesity surgery services should transfer to Clinical Commissioning Groups.

The Prescribed Specialised Services Advisory Group (PSSAG) provides ongoing advice to Ministers on which services are specialised and should therefore be commissioned by NHS England, rather than by Clinical Commissioning Groups (CCGs). Ministers' decisions about what services should be prescribed in secondary legislation as specialised services for NHS England commissioning take account of this advice.

The Group met on 30<sup>th</sup> September 2014, and (amongst other matters) considered proposals put to it by NHS England for the commissioning responsibility for two services, renal dialysis services and morbid obesity surgery services, to transfer to CCGs.

PSSAG considered the two services against the four statutory factors in the National Health Service Act 2006 and concluded that they no longer meet the requirements for commissioning by NHS England. They made some suggestions to support CCGs in taking on these functions, particularly to help maintain quality of services upon transfer of commissioning responsibilities.

We are considering transferring commissioning responsibility for these services from 1 April 2015, but are keen to ensure that:

- The transfer does not negatively impact patients and their access to services
- NHS England support CCGs to take on the commissioning responsibility for the services
- CCGs are ready to commission the services
- The changes can be reasonably and safely made in time for 1 April 2015

This consultation seeks your views on what type of support CCGs will need from NHS England to be able to commission these two services effectively and whether, if all this support can be put in place, the timing of the transfer is right.

The consultation closes on 9<sup>th</sup> January 2015. The results will then be analysed and will be used to inform our decision on when and how to transfer the commissioning responsibility for renal dialysis services and morbid obesity surgery services to CCGs. A summary of consultation responses will be published before any amendments to the secondary legislation are made.

## Introduction

### Statutory process

Most services are commissioned by groups of commissioners called Clinical Commissioning Groups (CCGs). Some services, however, such as primary care, prison health and services for people with rare and very rare conditions are commissioned by a single commissioner, NHS England. In 2012, the Health and Social Care Act 2012 amended the National Health Service Act 2006, creating CCGs and the NHS Commissioning Board (NHS England's statutory title). New regulations made under the amended 2006 Act gave NHS England commissioning responsibility for prescribed services for people with rare and very rare conditions, the new arrangements having effect from 1<sup>st</sup> April 2013.

On a more informal level we refer to these services as "specialised services". These are services which apply to much larger populations for planning purposes than most services and so tend to be provided by larger hospitals and specialist centres. This is because the larger hospitals and specialist centres are more likely to be able to recruit and retain clinical and support staff with the necessary specialist knowledge, expertise and leadership to be able to care for patients with these types of conditions.

The Secretary of State decides which services NHS England will directly commission as specialised services and makes regulations accordingly.

In deciding whether it would be appropriate for a service to be commissioned by NHS England rather than CCGs, the Secretary of State must have regard to four statutory factors (appearing in section 3B(3) of the 2006 Act, as amended by the Health and Social Care Act 2012). These are:

- the number of individuals who require the provision of the service or facility;
- the cost of providing the service or facility;
- the number of persons able to provide the service or facility; and
- the financial implications for Clinical Commissioning Groups if they were required to arrange for the provision of the service or facility

The Secretary of State must also (a) obtain appropriate advice for that purpose, and (b) consult NHS England before making regulations using these powers. The Prescribed Specialised Services Advisory Group (PSSAG) was established by the Department of Health in 2013 to provide the Secretary of State with this advice.

## Prescribed Specialised Services Advisory Group

The Prescribed Specialised Services Advisory Group (PSSAG) is a Department of Health expert committee that was established in 2013 to provide ongoing advice to Ministers on whether services are specialised and should be directly commissioned by NHS England, rather than by CCGs.

Membership of the group includes representatives from the Royal Colleges and from CCGs, lay members to represent the interests of patients and the general public and members with financial and technical expertise who can offer assistance with matters relating to the technical

aspects of how specialised services are best commissioned. The full PSSAG membership is at Annex A.

Evidence, supporting information and activity on those services currently prescribed in legislation for direct commissioning by NHS England and any new services identified as potentially specialised are made available to PSSAG from a range of sources, which may include Clinical Reference Groups (CRGs), patient groups, clinicians, commissioners and members of the public. The proposals the group considers are in large part generated by NHS England through its CRGs.

PSSAG's work programme will also include review of services previously identified by its predecessor advisory group, the Clinical Advisory Group (CAG) for "early review". (CAG advised on the initial list of specialised services that was in place at the time of the transition to the new commissioning arrangements.) These services were mostly recommended by CAG for review in two to three years once the new commissioning arrangements were established. The majority of these were services that it recommended for commissioning by NHS England in the first instance with a view to elements being considered for commissioning by CCGs in the future. In addition, CAG recommended three services for commissioning by NHS England in the future.

PSSAG draws upon clinical, commissioning and other relevant expertise and the contribution of lay members in making its recommendations to the Secretary of State for Health.

#### Substantive functions

PSSAG considers four specific questions:

- Whether the services currently included on the list of prescribed specialised services set out in legislation should continue to be commissioned by NHS England.
- Whether there are services currently commissioned by NHS England, which would be more appropriately commissioned by CCGs.
- Whether there are services currently commissioned by CCGs, which would be more appropriately commissioned by NHS England.
- Whether there are innovative new treatments and interventions that are not part of existing services and which should be commissioned by NHS England.

When considering if a service is specialised or not the group must review existing services and assess new ones on the basis of the four factors within the National Health Service Act 2006 which are:

- the number of individuals who require the provision of the service or facility;
- the cost of providing the service or facility;
- the number of persons able to provide the service or facility; and
- the financial implications for Clinical Commissioning Groups if they were required to arrange for the provision of the service or facility.

In developing its advice, PSSAG may also consider such matters as:

- How activity can be identified to enable separate contracting, monitoring and payment
- Likely running costs associated with separate and direct commissioning
- Defining elements of service to be commissioned
- The number of provider contracts NHS England is likely to need to develop to directly commission the service

The specialised services directly commissioned by NHS England are listed in Schedule 4 of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 (SI 2012/2996, as amended). Ministers make decisions on which services should be prescribed in these Regulations after taking advice from PSSAG. Legislation then requires that Ministers consult with NHS England before deciding whether to make regulations.

It is NHS England's responsibility to determine how these services are commissioned. Service descriptions for each of the specialised services are set out in NHS England's 'Manual for prescribed specialised services' (first published November 2012 and updated in January 2014). The Manual should be considered alongside service specifications, NHS England commissioning policies and the technical requirements NHS England imposes on providers.

## Purpose of this consultation

PSSAG met on 30<sup>th</sup> September 2014 and considered proposals by NHS England that renal dialysis services and morbid obesity surgery services should be no longer commissioned nationally by NHS England. PSSAG considered the two services against the four statutory factors and has concluded that they no longer meet the requirements for national commissioning by NHS England as opposed to commissioning by CCGs.

PSSAG has recommended to Ministers that commissioning responsibility for these two services should transfer to CCGs. In addition to the statutory consultation with NHS England required by the Health & Social Care Act 2012, Ministers have requested a wider consultation on the logistics and timing of the transfer of these commissioning responsibilities.

It will be important that CCGs are ready and able to take over the commissioning responsibility for these two services from 1 April 2015. This consultation is seeking views on whether the timing of the transfer is right and can be achieved safely with minimal impact on CCGs and patient care, and also about what support CCGs will need from NHS England to make this a success.

We see the preparation of commissioning guidance for CCGs by NHS England for these two services as integral to the process of transition. NHS England Area Teams will need to provide support to CCGs in the initial stages after introduction of the changes and effective monitoring arrangements will need to be put in place to ensure that the changes are not leading to any negative impact on patient care and access to services.

We would welcome your views on:

 What support CCGs will need NHS England to provide to enable them to take on this new role

- How long this support might be needed for
- What can be put into place to ensure that renal dialysis services and morbid obesity surgery services are commissioned and delivered to a high standard
- What ongoing monitoring arrangements should be put in place and who should be responsible for ensuring that the transfer is effective and is working well
- If all these safeguards and support can be put in place, whether the timing of the transfer is right

Before any action can be undertaken to transfer the commissioning responsibility to CCGs, we will need to be sure that Clinical Commissioning Groups can be made ready and able to take over the commissioning responsibility for these two services by 1 April 2015. We are asking for your views on the questions above to help Ministers to take a balanced and informed decision about when and how the transfer should take place.

The consultation closes on 9<sup>th</sup> January 2015.

Consultation responses will be analysed by Department of Health officials and a summary of consultation responses will be published on the Department of Health pages of the Gov.uk website. The information received as part of the consultation will be used by Ministers to inform their final decisions on the transfer of these two services and by the DH legal team to inform the drafting of regulations.

## **Proposals**

## Renal dialysis services

#### **Current arrangements**

Each year, in England, about 5,800 people start treatment for kidney failure and there are currently about 46,000 people receiving treatment for kidney failure. Not treating or withdrawal of treatment leads to death in the majority of patients within three weeks. Of those affected:

- about half are treated with a kidney transplant either from a living or deceased donor.
- about four in 10 are treated with haemodialysis. Haemodialysis involves circulation
  of blood through a machine that removes toxins and fluid returning the cleaned
  blood back into the body. This requires a surgical operation to join an artery and
  vein, or insertion of a tube into a large vein, usually in the neck, to create 'vascular
  access'. Most people receive three treatment sessions a week, each lasting about
  four hours, which can be done at home after training or in a dialysis unit under the
  supervision of health care professionals.
- about one in 10 are treated with peritoneal dialysis. Peritoneal dialysis, which is carried out at home, involves using the peritoneum (a thin membrane that lines the inside of the abdomen) as a filter. This requires the initial insertion of a small flexible tube, known as a catheter, into the peritoneal cavity (the space that contains the bowels and other abdominal organs). A special dialysis fluid is run into the peritoneal cavity and waste products are filtered into this fluid before being drained out. This exchange of 'used' with 'fresh' dialysis fluid lasts roughly 35 minutes and is either repeated about four times each day or performed overnight. Most often the patients are trained to carry out these treatments themselves but some patients have this treatment with the supervision of healthcare professionals.

NHS England commissions renal dialysis services from Adult Specialist Renal Centres, all of which operate satellite haemodialysis units to reduce the distance patients have to travel to receive treatment.

Renal dialysis services comprise:

- All chronic dialysis services
- Intermittent haemodialysis (and plasma exchange) for patients with acute kidney injury of such severity that without treatment they would die
- Outpatient assessment and preparation for renal replacement at Adult Specialist Renal Centres; this includes Low Clearance Clinics and procedures relating to establishing renal access prior to dialysis, for example, creating arteriovenous fistulae or inserting peritoneal dialysis catheters

As well as renal dialysis for adults, NHS England also commissions:

 All transplant-related care provided by Adult Specialist Renal Centres and Adult Renal Transplant Centres, including the work-up of potential living donors

- Renal dialysis and transplant services for children
- Encapsulating peritoneal sclerosis (EPS) treatment services for adults. EPS is a rare complication arising from the long-term use of peritoneal dialysis. The service undertakes about 40 primary surgical interventions per annum at two expert centres

#### CCGs commission:

- Inpatient and outpatient renal services (including services for acute kidney injury for
  patients not requiring dialysis or plasma exchange). The majority of general
  nephrology patients have chronic kidney disease, which is not so severe as to
  warrant treatment with either dialysis or transplantation
- Transport for haemodialysis patients
- Continuous haemodialysis/filtrations treatments when used as a component of intensive and high dependency care

As the single national commissioner of dialysis services in England, NHS England has developed national service specifications for dialysis services through its Clinical Reference Group (CRG) structure. CRGs bring together clinical experts with stakeholders (including patients and professional bodies) in order to ensure that there is high quality advice to inform the commissioning of specialised services.

NHS England has also developed a national policy in respect of patients receiving dialysis 'away from base', i.e. at a location different to their usual care provider (which may be abroad).

In line with the commissioning of all specialised services, NHS England has assessed all providers of specialised services against key requirements in service specifications. Where a key requirement is not met, NHS England agrees a 'derogation' with the provider; this means that they can continue to run the service whilst improvements are made or further planning is carried out.

#### Why the commissioning of this service should transfer to CCGs

NHS England believes that there could be significant advantages in renal dialysis services being commissioned by CCGs:

- Many patients on renal dialysis have co-morbidities such as diabetes where care is delivered on a primary care basis and/or where associated secondary care is commissioned by CCGs. Commissioning separately between NHS England and CCGs is a barrier to integrating services around people who need dialysis as well as non-specialised services.
- The split of commissioning between CCGs and NHS England has created an
  artificial divide in the patient pathway that separates the commissioning
  responsibility for preventing and reducing the incidence of end stage renal failure
  and that for treating end stage renal failure. This is a barrier to investing more in
  preventing and reducing the incidence of end stage renal failure.
- CCGs already commission patient transport services one of the biggest sources of complaint about access to dialysis services. Bringing responsibility for

commissioning of these services together could enable significant improvement in the alignment of patient transport services with dialysis sessions.

#### Proposal put to PSSAG by NHS England

NHS England has proposed it should no longer commission dialysis services and that the commissioning responsibility should transfer to CCGs. Specifically this would mean that CCGs would commission:

- All dialysis services (including plasma exchange) for patients with acute kidney injury
- Outpatient assessment and preparation for renal replacement, including procedures related to the establishment of renal access prior to dialysis

NHS England would continue to commission:

- Adult renal transplant services
- Renal dialysis and renal transplant services for children
- Encapsulating peritoneal sclerosis treatment services for adults

#### **Consideration against the four statutory factors**

NHS England has proposed that renal dialysis services no longer meet the four factors as follows:

- About 46,000 individuals are receiving treatment for kidney failure per annum
- Whilst the total cost of delivering renal dialysis services is high, the cost in individual cases is not considered to be high.
- There are many providers able to deliver renal dialysis services, with some activity taking place outside specialist centres and in patients' homes (NHS England contracts with about 50 providers of renal dialysis services)
- Funding would transfer via the allocations process. All renal dialysis and associated activity is covered by national tariffs

#### **View of PSSAG**

PSSAG agreed that, on the basis of the four statutory factors, this service did not meet the requirements for commissioning by NHS England. The number of individuals requiring the provision of renal dialysis was high – according to NHS England, about 46,000 individuals are receiving treatment for kidney failure per annum. PSSAG agreed that whilst the total cost of delivering renal dialysis services is high, the cost in individual cases was not considered to be high. There were many providers able to provide renal dialysis, with some activity taking place outside of specialist centres. PSSAG also felt that there would be no specific financial risk to CCGs of having to commission this service because all activity is charged at national tariffs and NHS England would transfer the corresponding budget for the number of patients for whom it had commissioning responsibility.

PSSAG welcomed the suggestion put to them by NHS England of retaining a national service specification and policies for a locally commissioned service, but felt that there could be issues for some CCGs around meeting the terms of the current national service specification. PSSAG felt that if the commissioning of this service were to transfer to CCGs there ought to be a mechanism for assuring that standards and adherence with policies were being maintained.

PSSAG signalled they were content to recommend that this service be commissioned at CCG level, but would wish for their advice to also include a recommendation that NHS England explore options for putting Key Performance Indicators in place on both commissioners and on providers. They also felt there needed to be a "due-diligence" process whereby NHS England ensured that it provided CCGs with relevant information about the extent to which, for example, providers were meeting service specifications.

### Morbid obesity surgery services

#### **Current arrangements**

Secondary prevention treatments for obesity include behaviour modification interventions such as: diet; exercise and life style; referral to specialist weight-loss clinics; drug therapy; low and very low calorie diets; and behaviour modification therapies. Surgery to aid weight reduction may be considered when all other non-invasive measures have been tried but have failed and the patient has been adequately counselled and prepared for surgery.

Morbid obesity surgery is one component of the multimodality lifetime treatment pathway of morbid obesity which consists of:

- multidisciplinary medical assessment and management of co-morbidities
- lifestyle and dietary improvements
- nutritional replacement, and
- lifelong follow up care

Morbid obesity surgery is commonly referred to as the 'tier 4' element in the pathway of obesity services.

Morbid obesity surgery is delivered in a number of NHS providers, although some only operate on relatively small numbers of patients. There are also a number of private sector providers. About 8,000 operations are performed per annum.

NHS England commissions specialist morbid obesity services from Specialist Morbid Obesity Centres. This includes all surgery and associated care delivered by the Specialist Centre, including medical care and specialist weight management care for patients unsuitable for or not requiring surgery.

CCGs are responsible for commissioning medical weight management services, commonly known as 'tier 3 services'. Not all CCGs commission tier 3 services, which has led to some issues with patients accessing services.

Local authorities commission local weight management services, commonly known as 'tier 2 services'. In some localities, local authorities also commission the medical weight management (tier 3) services.

As the single national commissioner of morbid obesity surgery services in England, NHS England has developed a national service specification for morbid obesity surgery services through its Clinical Reference Group (CRG) structure. CRGs bring together clinical experts with stakeholders (including patients and professional bodies) in order to ensure that there is high quality advice to the commissioning of specialised services.

NHS England has also developed a national policy in respect of patients receiving morbid obesity surgery services, which has been used as the basis for implementing equity of access

across the country. NHS England has invested £7.5m on a recurrent basis to 'level up' morbid obesity surgery services.

In line with the commissioning of all specialised services, NHS England has assessed all providers of specialised services against key requirements in service specifications. Where a key requirement is not met, NHS England agrees a 'derogation' with the provider; this means that they can continue to run the service whilst improvements are made or further planning is carried out.

### Why the commissioning of this service should transfer to CCGs

NHS England believes that there would be significant advantages in morbid obesity surgery services being commissioned by CCGs:

- The split of commissioning responsibility between CCGs and NHS England has created an artificial divide in the patient pathway which is a barrier to integrating services around people needing the full suite of obesity services.
- The split of commissioning responsibility between CCGs and NHS England has separated responsibility for morbid obesity surgery from measures aimed at obesity prevention. This may have inadvertently dis-incentivised the need to deliver or commission activity to prevent and reduce obesity.
- Having a single commissioner should be a major step forward in creating better incentives to invest in lower tier services. There are a number of areas where patients have not been able to benefit from tier 4 obesity services because of the lack of tier 3 (specialist weight management) obesity services (NICE guidelines state that patients must exhaust tier 3 services before accessing tier 4 services). NHS England has invested recurrent funding to ensure that there is equitable access to tier 4 morbid obesity surgery services across the country. CCGs may choose to use the funding innovatively across tier 3 and 4 services thus facilitating investment in tier 3 services where this had not been previously feasible.

#### Proposal put to PSSAG by NHS England

NHS England has proposed it should no longer commission morbid obesity surgery services and that the commissioning responsibility should transfer to CCGs. Specifically this would mean that CCGs would commission:

- Medical weight management services known as Tier 3 services (already the commissioning responsibility of CCGs)
- In adults, morbid obesity surgery services and associated care, including medical care and specialist weight management for patients unsuitable for or not requiring surgery

NHS England would continue to commission:

Morbid obesity surgery services for children

#### **Consideration against the four statutory factors**

NHS England has proposed that morbid obesity surgery services no longer meet the four factors as follows:

- About 8,000 operations undertaken per year
- There are 138 surgeons able to deliver obesity surgery services
- Specialist morbid obesity surgery and associated activity is covered by national tariffs
- CCGs would receive appropriate budgets, and funding would transfer via the allocations process

#### **View of PSSAG**

PSSAG agreed that, on the basis of the four statutory factors, this service did not meet the requirements for commissioning by NHS England. Figures provided by NHS England showed that the number of operations undertaken per year was around 8,000. PSSAG agreed that whilst the total cost of delivering the service is high, the cost in individual cases is not considered to be high. NHS England reported that there are 138 surgeons suitably qualified and experienced to deliver obesity surgery services. NHS England confirmed that specialist morbid obesity surgery and associated activity was covered by national tariffs and that CCGs would receive appropriate budgets. PSSAG therefore felt that there would be no specific financial risk to CCGs of having to commission this service.

PSSAG considered that this could be a complex issue for CCGs to take on and to mitigate this they felt that providers and commissioners at all levels need to be working in partnership. Many CCGs already work in partnership with other CCGs to commission tier 3 services and this was the model PSSAG had in mind here. PSSAG felt that consideration should be given to whether CCGs should continue to use the national service specification and associated access policy to commission this service, noting that the future direction of travel may be to invest in Tier 3 obesity services and thus prevent patients needing care at Tier 4 level. PSSAG also recommended that NHS England explore options for putting Key Performance Indicators in place on both commissioners and on providers and that any indicators would need to reflect this direction. PSSAG suggested that NHS England would need to provide CCGs with information about waiting lists for surgery.

## Support and monitoring

## Support for CCGs and monitoring

No transfer of commissioning responsibility from NHS England to Clinical Commissioning Groups (CCG) should take place without ensuring that CCGs have the capability and capacity to commission these services effectively and safely.

Ministers have asked for guarantees from NHS England that national commissioning guidance would be developed and provided for all CCGs on the commissioning of both renal dialysis services and morbid obesity surgery services. CCGs would be mandated to have regard to the national commissioning guidance for these services.

NHS England has committed to developing and issuing this guidance, in partnership with key stakeholders, for services that are transferred. It is anticipated a range of products would make up this commissioning guidance including: national service specifications, national standards and contracting information.

In addition NHS England is proposing to progressively develop:

- transparent data on the outcomes (which could be added to the CCG dashboard) and cost-effectiveness of services to enable CCGs to commission for value
- an enhanced role for Clinical Reference Groups to review and advise on the quality and cost-effectiveness of services across the country, and to ensure that everyone has access to a high standard of service

## Consultation questions

### Renal dialysis services

- Q1. Are the proposals NHS England has made for producing commissioning guidance to support Clinical Commissioning Groups in taking on the commissioning responsibility for renal dialysis services appropriate?
- Q2. Is there any additional support that Clinical Commissioning Groups might need from NHS England to enable them to take on this new role and ensure renal dialysis services are commissioned and delivered to a high standard?
- Q3. How long might this support be needed for?
- Q4. What ongoing monitoring arrangements should be put in place and who should be responsible for ensuring that the transfer is effective and is working well?
- Q5. Subject to the safeguards and support described in this document, do you think it is feasible to transfer commissioning responsibility for renal dialysis services to Clinical Commissioning Groups from 1 April 2015?

## Morbid obesity surgery services

- Q6. Are the proposals NHS England has made for producing commissioning guidance to support Clinical Commissioning Groups in taking on the commissioning responsibility for morbid obesity surgery services appropriate?
- Q7. Is there any additional support that CCGs might need from NHS England to enable them to take on this new role and ensure morbid obesity surgery services are commissioned and delivered to a high standard?
- Q8. How long might this support be needed for?
- Q9. What ongoing monitoring arrangements should be put in place and who should be responsible for ensuring that the transfer is effective and is working well?
- Q10. Subject to the safeguards and support described in this document, do you think it is feasible to transfer commissioning responsibility for morbid obesity surgery services to Clinical Commissioning Groups from 1 April 2015?

## Costs and benefits & equality analysis

### **Impact**

During the development of these proposals we have given thought to the likely costs and benefits and the possible impact that the proposals might have. None of the proposed changes represent a change in policy intent with regard to the development of high quality services for the relevant conditions. The proposed changes to commissioning responsibility put in place a new commissioner of renal dialysis services and morbid obesity surgery services.

NHS England has indicated that they would expect existing contracts with providers to novate to the new commissioners, meaning that in the short term, the organisations providing the services will remain the same. These changes are expected to remove artificial breaks in the patient pathway.

We intend to gather further evidence on any potential issues and impact of these changes as part of this consultation and review these before final decisions are made.

## **Equality**

The Department of Health is covered by the Equality Act 2010, and specifically, the Public Sector Equality Duty.

The duty covers the following protected characteristics: age; gender, disability, race (includes ethnic or national origins, colour or nationality), gender and gender reassignment; pregnancy and maternity; religion or belief (includes lack of belief); and sexual orientation.

There are three parts to the Duty and public bodies must, in exercising their functions, have due regard to all of them:

- 1. The need to eliminate unlawful discrimination, harassment and victimisation;
- 2. Advance equality or opportunity between people who share a protected characteristic and people who do not; and
- 3. Promote good relations between people who share a protected characteristic and those who do not.

The proposed changes to commissioning responsibility put in place a new commissioner of renal dialysis services and morbid obesity surgery services. Given the nature of these services, a change in the responsible commissioner has the potential to impact on people with the protected characteristics. We consider that there will be a positive impact for patients associated with the change in commissioning responsibilities through restoring pathway integrity for these services. We acknowledge that there are also potential risks associated with the transition to new commissioning arrangements, and have set out the safeguards that will be put in place to protect patients and enable the safe and effective transfer of commissioning responsibilities. We are actively seeking stakeholder views on these support arrangements and any additional support that might be needed.

## Conclusion

The Department of Health welcomes feedback from NHS employees, commissioners, providers, patients, their families and patient groups and anyone else with an interest in the commissioning and provision of renal dialysis and morbid obesity surgery services. This consultation seeks to gather information to assist Ministers in making important decisions about when and how to transfer the commissioning of renal dialysis and morbid obesity surgery services to CCGs.

You may use the online consultation response tool "Citizenspace" to respond to this consultation, or you may complete the proforma attached to this consultation document.

Please return all consultation responses either through Citizenspace; by email to specialisedservicesconsultation@dh.gsi.gov.uk; or as a hard copy to:

Medicines Access Team
Department of Health
Room 2E14, Quarry House
Quarry Hill
Leeds
LS2 7UE

Thank you for your interest.

## Responding to this consultation

### Consultation process

The consultation is being run, as far as is practical, in accordance with the Cabinet Office Code of Practice on consultation (reproduced below). The closing date for the consultation is 9<sup>th</sup> January 2015.

There is a consultation response form on the GOV.UK website which can be printed and sent by post to:

**Specialised Commissioning Consultation** 

Department of Health

Room 2E14

**Quarry House** 

**Quarry Hill** 

Leeds

LS2 7UE

Completed questionnaires can also be sent electronically by email to: specialisedservicesconsultation@dh.gsi.gov.uk

Alternatively you may complete the online consultation response document at: http://consultations.dh.gov.uk/medicines-access-team/specialisedservices

### Criteria for consultation

This consultation follows the Government Code of Practice, in particular we aim to:

- formally consult at a stage where there is scope to influence the policy outcome;
- consult for a sufficient period;
- be clear about the consultations process in the consultations document, what is being proposed, the scope to influence and the expected costs and benefits, and clearly targeted at those people it is intended to reach;
- keep the burden of consultation to a minimum to ensure consultations are effective and to obtain consultees "buy-in" to the process;
- analyse responses carefully and give clear feedback to participants following the consultation; and
- ensure officials running consultations are guided in how to run an effective consultation exercise and share what they learn from the experience.

The full text of the code of practice is on the Better Regulation website at: www.bis.gov.uk/policies/better-regulation/consultation-guidance

### Comments on the consultation process itself

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

Consultations Coordinator, Department of Health, Room 2E26, Quarry House, Quarry Hill, Leeds, LS2 7UE.

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 www.dh.gov.uk/en/FreedomOfInformation/DH\_088010

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 (FIOA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

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 consultation responses

A summary of consultation responses will be made available before or alongside any further action, such as laying legislation before parliament, and will be placed on the GOV.UK website (www.gov.uk/dh).

## Annex A – PSSAG Membership

#### **PSSAG Chair**

Professor Sir Ian Gilmore

#### **CCG** representatives

- Dr J. E. Tim Burke (Clinical Commissioning Group South)
- Dr Chris Clayton (Clinical Commissioning Group North)
- VACANCY (Clinical Commissioning Group London)
- Dr Christine Moss (Clinical Commissioning Group Midlands and East)

#### Royal College representatives

- Helen Donovan (Royal College of Nursing)
- Dr Andrew Goddard (Royal College of Physicians)
- Dr Bronwyn Kerr (Royal College of Pathologists)
- Professor Paul O'Flynn FRCS (The Royal College of Surgeons of England)
- Dr Archie Prentice (Royal College of Pathologists)

#### Lay representatives

- Professor Bhaskar Choubey (lay representative)
- William Savage (lay representative)
- Dr Rebecca Strachan (lay representative)

#### NHS England representatives

- Dr Mike Bewick (NHS England Medical)
- Ceri Townley (NHS England Informatics)
- Fiona Marley (NHS England Operations)
- Tabitha Gardner (NHS England Finance)
- Michelle Mello (NHS England Nursing)

## Consultation response form

#### **Freedom of Information**

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

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes. The relevant legislation in this context is the Freedom of Information Act 2000 (FOIA) and the Data Protection Act 1998 (DPA).

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. However, the information you send us may need to be passed on to colleagues within the UK Health Departments and/or published in a summary of responses to this consultation.

I do not wish my response to be passed to other UK Health Departments					
I do not wish my response to be published in a summary of responses					
Please indicate all the countries to which your comments relate:					
UK-wide		and/or			
England		Northern Ireland	d		
Scotland		Wales			
Are you responding: - as a member of the public - as a health or social care professional - on behalf of an organisation					
Country of qualification					
Please indicate as appropriate:					
UK		Other EEA		Rest of World	

### Area of work:

NHS	
NHS – Clinical Commissioning Groups	
NHS England Clinical Reference Groups	
NHS England Area Teams	
Social Care	
Private Health	
Third Sector	
Regulatory Body	
Professional Body	
Education	
Trade Union	
Local Authority	
Trade Body	
Independent Contractor to NHS	
Manufacturer	
Supplier	
Other (Please give details)	

# If you are responding on behalf of an organisation, please indicate which type of organisation you represent:

NHS	
NHS – Clinical Commissioning Groups	
NHS England Clinical Reference Groups	
NHS England Area Teams	
Social Care	
Private Health/Independent Sector	
Third Sector	
Regulatory Body	
Professional Body	
Education	
Trade Union	
Local Authority	
Trade Body	
Independent Contractor to NHS	
Manufacturer	
Supplier	
Other (Please give details)	

In which of the following areas do you live:		
(please tick <u>one</u> box only)		
North East		
North West		
West Midlands		
South East		
London		
Humberside/Yorkshire		
East Midlands		
East of England		
South West		
No answer		
South Central		

1 What is your gender? 1 (tick one box of	only)
Male	
Female	
Prefer not to say	
Troid field day	
2 What is your age range? (tick one box	conly)
Under 18	
18-25	
26-35	
36-45	
46-55	
56-65	
66-75	
76-85	
Over 86	
The Disability Discrimination Act (DDA) de a physical or mental impairment that has a her ability to carry out normal day to day a I have a longstanding illness I have a disability Prefer not to say	efines a person with a disability as someone who has a substantial and long-term adverse effect on his or
	al or mental ill-health/disability or problems related to
Yes	
No	
No	
Prefer not to say	

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<sup>&</sup>lt;sup>1</sup> If responding on behalf of an organisation you do not need to fill this information out. If responding as an individual we would appreciate your participation in this monitoring exercise to help us identify any gaps in engaging individuals.

5 What is your ethnic group? (tick one box only			
A White			
British			
Irish			
Any other White background, write below			
B Mixed			
White and Black Caribbean			
White and Black African			
White and Asian			
Any other Mixed background, write below			
C Asian, or Asian British			
Indian			
Pakistani			
Bangladeshi			
Any other Asian background, write below			
D Black, or Black British			
Caribbean			
African			
Any other Black background, write below			
E Chinese, or other ethnic group			
Chinese			
Any other, write below			

6 What is your religion or belief? (tick one box only)			
Christian includes Church of Wales, Catholic, Protestant and all other Christian denominations.			
None			
Christian			
Buddhist			
Hindu			
Jewish			
Muslim			
Sikh			
Prefer not to say			
Other, write below			
7 Which of the following best describes your sexual orientation? (tick one box only)			
Only answer this question if you are aged 16 years or over.			
Heterosexual Straight			
Lesbian / Gay Woman			
Gay Man			
Bisexual			
Prefer not to say			
Other, write below			

## Renal dialysis services

Q1. Are the proposals NHS England has made for producing commissioning guidance to		
support Clinical Commissioning Groups in taking on the commissioning responsibility for renal		
dialysis services appropriate?		
Yes	No	Don't know
Add text:		
Q2. Is there any additional	support that Clinical Commissioni	ng Groups might need from
	take on this new role and ensure	
commissioned and delivered to		Terial dialysis services are
Yes	No	Don't know
. 30		
Add text:		
Q3. How long might this su	pport be needed for??	
Add text:		
O.A. NA/Ib at an analysis as an artistic	an amaginary and all and the most in	ala a a and cola a ala colal la a
	ng arrangements should be put in	
responsible for ensuring that the	e transfer is effective and is working	ig weii?
Add text:		
Add lext.		

Q9. What ongoing monitoring arrangements should be put in place and who should be responsible for ensuring that the transfer is effective and is working well?  Add text:		
Q10. Subject to the safeguards and support described in this document, do you think it is feasible to transfer commissioning responsibility for morbid obesity surgery services to Clinical Commissioning Groups from 1 April 2015?		
Yes	No	Don't know
Add text:		