

Planning, assuring and delivering service change for patients



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Contact Details for further information	Business Unit NHS England, Operations and Delivery 3rd floor, section A, Skipton House 80 London Road SE1 6LH 0113 825 0993

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Planning, assuring and delivering service change for patients

A good practice guide for commissioners on the NHS England assurance process for major service changes and reconfigurations

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Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

Prepared by:

Kate Coole, Business Unit Manager, NHS England, Operations and Delivery

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The National Health Service Commissioning Board was established on 1 October 2012 as an executive non-departmental public body. Since 1 April 2013, the National Health Service Commissioning Board has used the name NHS England for operational purposes.

Other formats of this document are available on request

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1. Foreword

NHS England's role in reconfiguration is to support commissioners and their local partners to develop clear, evidence based proposals for service reconfiguration, and to undertake assurance as mandated by the Government.

This guidance is designed to be used by those considering, and involved in, service reconfiguration to navigate a clear path from inception to implementation. It will support commissioners to consider how to take forward their proposals, including effective public involvement, enabling them to reach robust decisions on change in the best interests of their patients.

In addition, it sets out how new proposals for change are tested through independent review and assurance by NHS England, taking into account the framework of Procurement, Patient Choice and Competition Regulations. The guidance sets out some of the key considerations for commissioners in designing service change and reconfiguration. Clinical Commissioning Groups (CCGs) are under a statutory duty to have regard to this guidance.

Increased sharing of budgets combining health and social care; collaborative commissioning; the potential of devolution of powers; and the implementation of new care models and systems, are all factors that will drive clinical commissioners and their partners to think creatively about how service provision could be improved for their local populations and reduce health inequalities. In some cases, the response may be significant reconfiguration within local health economies at a service or wider level.

By following this guidance, commissioners, NHS England regional and national teams, Vanguard and others may reduce the risk of their service changes being referred to the Secretary of State, Independent Reconfiguration Panel or judicial review. By following the process set-out below and appropriately and effectively involving local diverse communities, Oversight and Scrutiny Committees (OSC), key stakeholders and expert review (for example from Clinical Senates), later challenge can be avoided.

Service change, significant service change and the reconfiguration of services are used as descriptors within this guidance. The level of significance will be decided early on through discussion and involvement with providers, local authorities (through their OSC), local Healthwatch and commissioners. There is no pre-determined definition which will apply across the board as the impact on local health economies and communities will be different depending on location and populations.

Please contact your local NHS England office for more information and assistance:
www.england.nhs.uk/about/regional-area-teams

2. Executive summary

This guidance sets out the required assurance process commissioners follow when conducting service reconfiguration. Its purpose is to provide support and assurance to ensure reconfiguration can progress, with due consideration for the four tests of service change which the government mandate requires NHS England to test against. It also covers the agreed levels of assurance and decision making required for significant service change which the NHS England board ratified in May 2015; key themes of service reconfiguration; and the assurance process.

There is no change to any of the detail supplied in this guidance's predecessor 'Planning and delivering service change for patients'. This revision is designed to clarify the assurance process required and introduce the new assurance and decision making levels. It also signposts readers to additional policies, guidance and reference material which may need to be taken into consideration when planning significant service change or reconfiguration.

Some service changes may not be the result of a location specific reconfiguration, but may consider a single service or inter-dependent range of services across a wide geography. Service change such as those will fulfil the principles set out in this guide, though there will be slightly different processes affecting the sequence and timing of consultations, to comply with legal regulations which apply to these types of changes¹.

Service changes may also be whole system based and work across social and health care. Consideration must be given to additional processes and assurances required within partner organisations. This guidance is designed for and applicable to service change and reconfiguration occurring within the NHS environment. In the first instance, involvement of your local NHS England team will help to ensure the correct process is followed.

Who should read this guidance?

- Clinical commissioning groups (CCG(s)).
- NHS England local and regional teams and commissioners.
- Commissioning support services.
- Providers, local authorities (LA), local Healthwatch and other groups representing the public.
- Anyone involved or likely to be involved in service change or reconfiguration (including the new care models, Vanguards etc.).
- Chairs of health and wellbeing boards and health overview and scrutiny committees.

¹ See Annex 4 Nationally-led service specifications and models, and procurement.

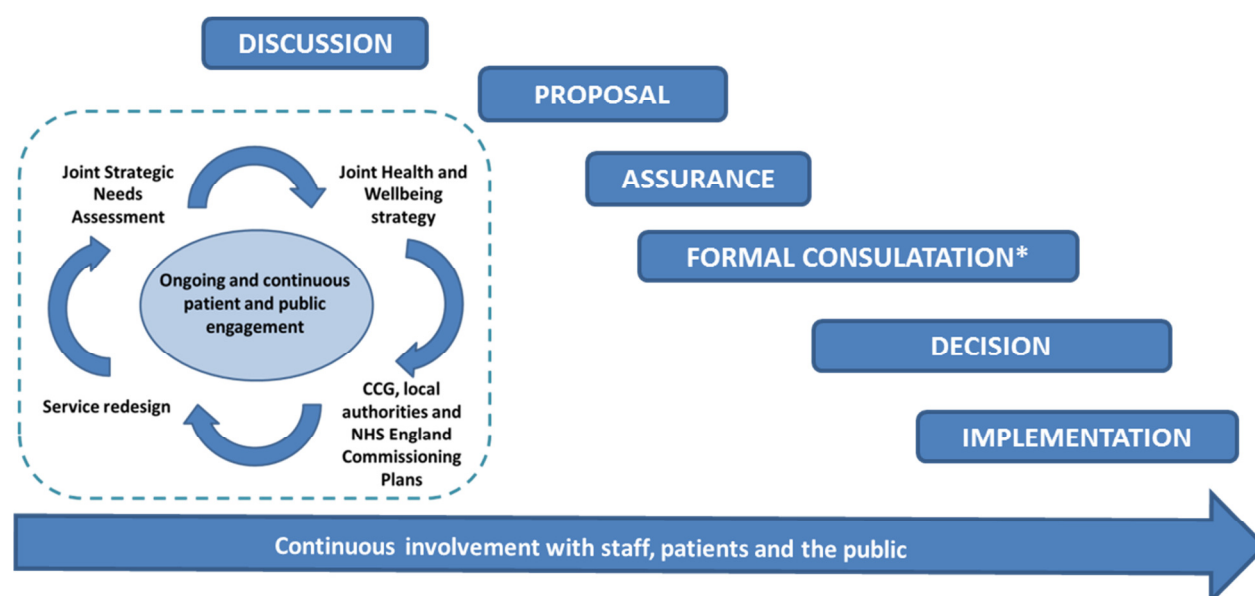
Overview of Roles and Responsibilities

Organisation		Role
NHS England	General	Service change policy framework, national evidence base and national partnerships (e.g. Monitor, NHS Trust Development Authority (TDA), royal colleges). Oversees delivery of NHS services. Leads service change for directly commissioned services. Has responsibility for assuring all service reconfiguration proposals meet the government's 'four tests'
	NHS England – Investment Committee (IC)	Oversees the assurance of service reconfiguration and has delegated powers to make decisions on those requiring NHS England board sign off. The IC also has responsibility for the oversight of certain capital expenditure and transactions
	NHS England – Chief Financial Officer (CFO)	A member of the IC, the CFO has delegated powers to make decisions and assure schemes meeting the thresholds as set out in the IC terms of reference
	NHS England – Oversight Group for Service Change and Reconfiguration (OGSCR)	Oversees the national work programme for service reconfiguration. Provides advice and recommendations to the IC in relation to service reconfiguration schemes and transactions
	NHS England – Regional Director (RD)	Assures all service reconfiguration proposals within their region except those where CFO/IC sign off is required. Has delegated powers to make decisions on certain service reconfiguration schemes (in cases where NHS England is lead or a joint commissioner)
	Clinical Senates	Sources of independent clinical advice which are hosted by NHS England
	NHS England Programme Assurance team (formerly Health Gateway)	Source of independent programme assurance
Independent Reconfiguration Panel (IRP)		Offers expert advice on proposals referred to Panel by the Secretary of State. Provides advice to NHS and other interested bodies on developing proposals for service reconfiguration

Overview and Scrutiny Committee (OSC)	A committee formed of members of the local authority with public representation. With delegated powers of oversight and scrutiny of the local health economy, they may also have powers to refer proposals to the Secretary of State on behalf of the LA
Trust Development Authority (TDA)	Regulatory oversight, assurance of quality, governance and risk in NHS trusts. Oversight of performance of NHS trusts, providing support to help improve quality and sustainability of services, and supporting the transition of NHS trusts to foundation trust status. Approval of NHS trust capital investment business cases (including those that implement service reconfiguration)
Monitor	Oversight of commissioning through the Procurement, Patient Choice and Competition Regulations and assurance of governance and finance of NHS foundation trusts

3. Service reconfiguration overview

The reconfiguration process has several phases from setting the strategic context to implementation.



*Formal Consultation may not be required in every case, and this decision should be made in collaboration with the local OSC.

The planning and development of reconfiguration proposals are rarely linear. The most successful proposals ensure continuous discussion and involvement of the local population and key stakeholders throughout the process.

3.1 The four tests of service reconfiguration

There must be clear and early confidence that a proposal satisfies the four tests and is affordable in capital and revenue terms.

The government's four tests of service reconfiguration are:

- Strong public and patient engagement.
- Consistency with current and prospective need for patient choice.
- Clear, clinical evidence base.
- Support for proposals from commissioners.

The four tests are set out in the Government Mandate to NHS England. NHS England has a statutory duty to deliver the objectives in the Mandate. CCGs have a statutory duty to exercise their commissioning functions consistently with the objectives in the Mandate and to act in accordance with the requirements of relevant regulations, such as Procurement, Patient Choice and Competition Regulations² and associated guidance from Monitor.

Commissioners should consider how they meet these duties in the planning and development of reconfiguration proposals, including duties for NHS England and clinical commissioning groups in relation to the following sections in the Health and Social Care Act 2012:

- Duty to promote the NHS Constitution (13C and 14P)
- Quality (sections 13E and 14R)
- Inequality (sections 13G and 14T)
- Promotion of patient choice (sections 13I and 14V)
- Promotion of integration (sections 13N and 14Z1)
- Public involvement (sections 13Q and 14Z2)
- Innovation (sections 13K and 14X)
- Research (sections 13L and 14Y)
- Obtaining advice (sections 13J and 14W)
- Effectiveness and efficiency (sections 13D and 14Q)
- Promotion of the involvement of each patient (sections 13H and 14U)
- Duty to promote education and training (13M and 14Z)
- Duty to have regard to impact in certain areas (13O)
- Duty as respects variations in provision of health services (13P)
- Expenditure on integration of health and social care (Better Care Fund) (223B and 223GA)

And the Health & Social Care (Quality & Safety) Act 2015:

- Consistent identifiers (251A)
- Duty to share information (251B)

Commissioners should also ensure they are familiar with Section 244 of the NHS Act 2006 regarding the duty to consult the relevant local authority in its health scrutiny capacity.

² www.gov.uk/government/publications/procurement-patient-choice-and-competition-regulations-guidance

NHS England has developed a 'Statement of arrangements and guidance for involving the public in commissioning', which sets out NHS England's arrangements for involving the public in commissioning in accordance with the section 13Q duty³. The policy provides guidance and resources for NHS England commissioners in making arrangements for public involvement and utilising existing sources of public involvement. The 'Statement of arrangements...' does not apply to CCGs, who should make their own arrangements to meet the equivalent section 14Z2 duty.

Commissioners should consider keeping a record of how the duty to have regard to Joint Strategic Needs Assessments (JSNA) and Joint Health and Wellbeing Strategies (JHWS) (section 116B of the Local Government and Public Involvement in Health Act 2007) have been taken into account as part of the decision-making process.

Commissioners should also take into account the duties placed on them under the Equality Act 2010⁴ regarding reducing health inequalities, duties under the Health and Social Care Act 2012. Service design and communications should be appropriate and accessible to meet the needs of diverse communities

Assessment can also help demonstrate compliance with the Public Sector Equality Duty (PSED), and support the meeting of the health inequalities duties as cited in the Health and Social Care Act 2012, as a result of the proposed service reconfiguration.

By using the Equality Delivery System (EDS2), NHS organisations can help deliver on the PSED. The purpose of the EDS2 is to help local NHS organisations, in discussion with local partners including local populations, review and improve their performance for people with characteristics protected by the Equality Act 2010.

EDS2 was published in November 2013 and can be accessed via the links below:
www.england.nhs.uk/ourwork/gov/edc/eds/

www.england.nhs.uk/wp-content/uploads/2013/11/eds-nov131.pdf

As part of the decision-making process, commissioners should undertake Equality and Health Inequalities Analyses, as appropriate. Guidance for commissioners on equality and health inequalities legal duties can be found here: www.england.nhs.uk/ourwork/gov/equality-hub/legal-duties/

3.2 Determining levels of assurance and decision making

Whilst most assurance will be taken at a regional level, there are some assurance and decision making roles which will be undertaken by the Investment Committee

³ See Annex 5. Section 13 duties apply to NHS England and section 14 to CCG's.

⁴ www.england.nhs.uk/commissioning/ccg-auth/

(IC) or the Chief Financial Officer (CFO) of NHS England, depending on assessment against the following set criteria.

Assurance: NHS England has a role to assure CCG activities, including service change and reconfiguration. The level of assurance for service change and reconfiguration is determined by the criteria below.

Deciding which option: NHS England has a role in making decisions to directly commissioned services either as part of a joint commissioning arrangement or as lead commissioner. If there is no direct decision making element this will sit with the CCGs. If NHS England has a role in directly commissioned services then the level of decision making is also determined by the criteria below.

These criteria are set out in NHS England's Scheme of Delegation and the IC's Terms of Reference and was agreed with the board in May 2015⁵:

- “The Investment Committee should review the assurance conclusions and take decisions for all schemes where one of the following conditions applies:
 - Impact on any NHS trust or NHS foundation trust that is in special measures⁶ or where the reconfiguration is in respect of services where there has been enforcement action⁷;
 - Requires transition or transaction support of more than £20m from NHS England funds (not including CCG funds); or
 - The total turnover of the affected services (for all sites impacted by the transition, at current prices) is above £500m in any one year.
- The Chief Financial Officer should review the assurance conclusions and take decisions for all schemes where one of the following conditions applies:
 - Impact on any of the distressed health economies as currently or subsequently defined;
 - Requires transition or transaction support from NHS England funds (not including CCG funds); or
 - The total turnover of the affected services (for all sites impacted by the transition, at current prices) is above £350m in any one year.
- All other schemes to be determined by the relevant Regional Director.”

4 Service reconfiguration – key themes

This section sets out some of the key considerations that are taken into account during the assurance process for service reconfiguration. There are many different ways to achieve positive change for patients and this guide does not attempt to cover in detail all the things that CCGs and their partners will need to take into account. Commissioners should always ensure that they are acting consistently with

⁵ <https://www.england.nhs.uk/wp-content/uploads/2015/07/Item-2-Minutes1.pdf>

⁶ www.nhs.uk/nhsengland/specialmeasures/pages/about-special-measures.aspx

⁷ www.gov.uk/government/publications/nhs-foundation-trust-directory/nhs-foundation-trust-directory

their regulatory obligations, including the Procurement, Patient Choice and Competition Regulations.

4.1 Preparation and planning

There should be a planned and managed approach from the start which establishes clear roles, a shared approach between organisations, and builds alignment on the case for change.

All service change needs commissioner ownership, support and leadership (even if change is initiated by provider or other organisation). This is so any major service change aligns with commissioning intentions and plans. Where services are commissioned by two or more commissioners, it is essential that proposals align with each organisation's commissioning intentions, including estates strategies.

Commissioners (or providers leading service change) should:

- be active in leading service design and change;
- ensure commissioning intentions reflect the local commissioning plans and vice versa; and
- work closely with local authorities who have an important role in the development of proposals, as well as discharging their scrutiny functions.

The Independent Reconfiguration Panel (IRP) has a series of papers 'Learning from Reviews' which set out reasons why proposals are referred. There are a number of factors such as inadequate community and stakeholder involvement in the early planning stages, and weak clinical integration across sites.

www.gov.uk/government/collections/irp-learning-from-reviews

The IRP can also provide informal advice on developing proposals. Their website is: www.gov.uk/government/organisations/independent-reconfiguration-panel/about

4.2 Evidence

Commissioners should:

- have early and ongoing discussions with their local NHS England team;
- ensure the four tests of service change are embedded into their planning process;
- set a high bar of evidence for change in the discussions with providers and local authorities;
- work with Health and Wellbeing (H&WB) Boards to ensure service reconfiguration proposals reflect JSNA and JHWS⁸; and
- request regular updates to financial planning and forecasting as proposals are developed.

⁸ see section: 5.1 Setting the Strategic Context

Service reconfiguration must be evidence-based and this evidence should be publicly available during the consultation and decision making stages.

A clear clinical evidence base

This ensures service reconfiguration proposals are underpinned by clear clinical evidence and align with clinical guidance and best practice.

Commissioners should oversee the development of the clinical case for change, as part of the outline case. Medical directors and heads of clinical services of any providers involved can help build the clinical evidence base.

It is important that front-line clinicians affected by the proposed changes are involved. Clinicians are powerful advocates and play an important role in communicating the benefits of change to a wider community.

Assessment against this test should be overseen by an appropriate clinical lead. Where possible, the clinical lead should include views from senior clinicians not directly connected with the services under review.

For complex service reconfiguration, commissioners should consider clinical senate advice.

4.3 Leadership and clinical involvement

- Chairs, accountable officers, chief executives and medical directors should exercise collective and personal leadership and accountability when considering the development of proposals.
- Front line clinicians and other staff should be involved in developing proposals, and in their engagement and implementation.
- Directors of public health, directors of adult social services and directors of children's social services have an important role in bringing their professional perspectives where reconfigurations span health, social care and public health.

Clinicians should determine and drive the case for change, based on the best available evidence.

4.4 Involvement of patients and the public

It is critical that patients and the public are involved throughout the development, planning and decision making of proposals for service reconfiguration. Early involvement with the diverse communities, local Healthwatch organisations, and the local voluntary sector is essential, as well as engaging Monitor and TDA where appropriate. Early involvement will give early warning of issues likely to raise concerns in local communities and gives commissioners' time to work on the best solutions to meet those needs.

Engagement, consultation, participation and patient voice are all phrases that can be used to describe different types of involvement activity. Effective involvement means being open and transparent about proposals enabling local stakeholders to have the opportunity to influence change. Sometimes the most logical and well planned changes are not achievable due to inability to effectively involve the local population.

5 The assurance process

The assurance process is rarely linear and involvement of the public, patients and stakeholders should continue throughout the life of the scheme. Consideration of financial implications and other external factors may require initial proposals to be amended as new ideas are brought forward. Returning to earlier stages to ensure the proposal is still sound strengthens the final proposal and ensures time is spent progressing on only viable and supported options.

5.1 Assurance process

An effective external assurance process should give confidence to patients, staff and the public that proposals are well thought through, have taken on board their views and will deliver real benefits. NHS England's external assurance process should give confidence, be supportive and add value by helping to mitigate risk.

Effective assurance is required to secure consistency across the NHS commissioning system in respect of:

- the four tests and standards that should underpin service change proposals;
- the strength of pre consultation business cases, clinical evidence and public involvement;
- proposals having regard to relevant national guidance and complying with legislation;
- the programme management that underpins the planning and delivery of schemes; and
- deliverability on the ground and affordability in capital and revenue terms.

Internal assurance

Self-assurance should be put in place as part of the programme governance. CCGs can seek advice from NHS England regional teams when putting in place arrangements. If public or patient representatives can be involved in internal assurance, this would support transparency and accountability moving forward.

NHS England's role in assuring service change

NHS England has a remit to assure CCGs against their statutory duties and other responsibilities under the CCG Assurance Framework. It has a role to both support and assure the development of proposals by commissioners. CCGs are required to consider this guidance in their exercise of commissioning functions.

Assurance will be applied proportionately to the scale of the change being proposed, with the level of assurance tailored to the service change. The process should be commissioner-led, whole system based and have consideration of arms-length bodies involvement.

NHS England will work with the NHS Trust Development Authority (TDA) where reconfigurations relate to NHS trusts and Monitor in relation to the commissioning regulations.

TDA and Monitor support will ensure consistency in quality and planning of schemes, and that good practice and lessons learnt are shared.

National oversight of the assurance framework

The oversight of the national work programme for service reconfiguration takes place by the sub-committee of the IC: the OGSCR.

Investment Committee (IC) – As well as providing assurance on service reconfiguration, the Committee has the power to confirm which business cases meet criteria for agreement at officer level (subject to compliance with the Scheme of Delegation). Membership is decided by the NHS England Board and will include (but is not limited to) the Chief Financial Officer, Chief Operating Officer and National Director: Policy.

Oversight Group for Service Change and Reconfiguration (OGSCR) – Supports the Investment Committee to oversee the implementation and continued working of the assurance process. Membership includes (but is not limited to) Regional Directors, Clinical Director - Medical, Director of Strategic Finance, and Head of Operations, Commissioning Operations.

NHS England will operate a two stage assurance process:

- a strategic sense check; and
- an assurance checkpoint.

Decisions about the extent of assurance required by NHS England will be informed by the scale of the service change proposals under consideration.

Stage 1 - Strategic sense check

This will determine the level for the next stages of assurance and decision making. Clinical senates may at this stage be asked to review a service change proposal against the appropriate key tests (clinical evidence base).

1. Takes place once the commissioner concludes they have a sufficiently robust case for change and set of emerging options, or earlier if the potential implications are far reaching.
2. Involves a formal discussion between commissioners leading the change and the relevant local office within the NHS England regional team.
3. Purpose:
 - Explore the case for change and the level of consensus for change.

- Ensure a full range of options are being considered; that potential risks are identified and mitigated; and that options are feasible.
- Ensure high level capital cost and revenue affordability implications are being properly considered.
- Show impact on neighbouring commissioners and populations has been considered.
- Ensure assessment against the 'four tests' is ongoing and other best practice checks are being applied proportionally.
- Agree a proportionate framework for stage two assurance based on the four tests and best practice checks
- Determine the level of assurance and decision making and whether the process is likely to require sign off from IC, the CFO or whether it rests with the relevant RD.

The level of involvement of the IC, CFO or RD will be indicated in relation to financial thresholds therefore it is important that initial financial information is available as soon as possible, particularly where there may be a call on capital, transitional or transactional funds.

The strategic sense check provides the opportunity to discuss:

- organisational roles (particularly relevant for multi-organisation schemes);
- the level of key stakeholder involvement and support to date, and ongoing involvement plans;
- financial and legal considerations;
- interdependencies with other commissioning plans or services, including neighbouring health economies; and
- to determine any subsequent level of independent assurance or external advice (for example from clinical senate or Health Gateway Team).

For the majority of schemes, it is expected they will undergo a subsequent assurance checkpoint.

Stage 2 – Assurance checkpoint

For significant service change, it is best practice to seek the clinical senate's advice on proposals again at this stage.

1. Takes place in advance of any wider public involvement or formal consultation process or a decision to proceed with a particular option.
2. Involves assurance of the evidence provided by commissioners against the four tests and NHS England's best practice checks⁹ by a panel decided upon in the strategic sense check. It may also incorporate other external independent advice.
3. The purpose is to undertake formal assurance of, and minimise risk in commissioner proposals. The assurance panel will need to consider whether it was assured, partially assured or not assured against each of the agreed criteria. This would form the basis of the panel's report, along with any risks, issues or other recommendations they identified.

Assurance of directly commissioned services

⁹ See Annex 3 Best Practice Checks

Service reconfiguration which results in changes to directly commissioned services will require a separate assurance approach to avoid internal conflicts of interest. In this case assurance will need to be undertaken and overseen by an NHS England panel involving staff who are not otherwise involved in the development of the proposals.

Independent advice to inform the assurance process

Programmes should seek independent advice:

- to assess the programme management arrangements and strength of the business case; and
- to assess the strength of the clinical case for change as to whether the proposed changes are supported by a clear clinical evidence base and will improve the quality of the service provided.

Monitor offers independent advice to commissioners about achieving reconfiguration. The decision to request external clinical advice should follow discussions between the relevant commissioners and regional teams at the strategic sense check.

Where the clinical case for change is more complex, commissioners may require an independent clinical review. This would usually be through the clinical senate, although in some cases (for example, very specialist services) it may be appropriate to obtain a review from another independent source such as a royal society or clinical networks.

NHS England Programme Assurance team (formerly Health Gateway) – provides organisations with assurance and support for business change programmes and projects. It is designed to support successful delivery of the programme and project.

Clinical senates support health economies to improve health outcomes of their local communities by providing impartial, independent and evidence-based clinical advice to commissioners and providers on major service changes and transformation. There are 12 clinical senates across the country. You can find out more about clinical senates here: www.england.nhs.uk/ourwork/part-rel/cs/

Clinical networks support local health economies to improve the health outcomes of their local communities by connecting commissioners, providers, professionals, patients and the public across a pathway of care/service areas to share best practice and innovation, measure and benchmark quality and outcomes, and drive improvement.

Following a strategic sense check or assurance checkpoint, NHS England will either support or not support a commissioner taking forward their proposals in their current format. Where NHS England does not support a commissioner proceeding to consultation, there will be a discussion about the subsequent assurance process. This will be proportionate to the level of risk and the concerns identified.

5.2 Setting the strategic context

Effective proposals for service reconfiguration are those which build on the wider considerations of the health and wellbeing needs of the population and reflect existing commissioning plans.

Commissioners are under a statutory duty to consider relevant Joint Strategic Needs Assessments (JSNAs) and Joint Health and Wellbeing Strategies (JHWSs).

JSNAs and JHWSs

JSNAs – local assessments of current and future health and social care needs and assets produced by health and wellbeing boards. They are unique to each local area.

JHWS – strategies for meeting the needs identified in JSNAs. They explain the priorities Health and Wellbeing (H&WB) Boards have set in order to tackle the needs in the JSNA.

For more information please see the guidance from the Department of Health: ‘Statutory Guidance on Joint Strategic Needs Assessments and Joint Health and Wellbeing Strategies’:

www.gov.uk/government/uploads/system/uploads/attachment_data/file/223842/Statutory-Guidance-on-Joint-Strategic-Needs-Assessments-and-Joint-Health-and-Wellbeing-Strategies-March-2013.pdf

In light of the legal duty consider JSNA and JHWS, there is an expectation that proposals will have a clear alignment to the JSNA and JHWS. There are a number of advantages to this:

- H&WB boards can bring a multi-service and professional perspective, meaning proposals can be considered holistically across the local health and care system.
- H&WB boards must involve local diverse communities when preparing JSNAs and JHWSs.
- Where communities have already been involved in the shape of health services in their area it provides a strong platform for more in-depth conversations on potential changes.
- Where there is local consensus about health and care needs and priorities it creates space for conversations on what this could mean for the configuration of front line services.

5.3 Proposal development

Commissioners should build their proposal by identifying the range of service change options that could improve outcomes within available resources.

Work would be required to develop:

- A more detailed case for change and evidence base.
- Specific service configuration options.
- The plan for involving wider stakeholders, staff, patients and the public.

Commissioners have a statutory duty¹⁰ to involve service users in the development of proposals. It is good practice for commissioners to involve stakeholders in the early stages of building a case for change.

A clinically-led group should oversee the design and development of proposals, and commissioners should ensure that clinical ownership and leadership of plans is part of any governance arrangements.

A proposal should cover:

- analysis of the full range of potential service changes that can achieve the desired improvement in quality and outcomes;
- the development of a range of options based on the above analysis;
- an assessment against legal duties and obligations including the Public Sector Equality Duty¹¹ (PSED) and the duty to have regard to the need to reduce inequalities;
- dialogue that seeks to align proposals with the plans and priorities of partners;
- consideration of whether proposals represent a substantial service change (to be agreed locally);
- assessment against the four tests;
- any potential financial implications (capital spend, transactional or transitional funds, savings, core costs etc.) which may impact on the range of options taken forward;
- any outline plans which can demonstrate how each of the options would be implemented and show that there are plans to ensure that safe services are maintained in the interim;
- a privacy impact assessment identifying requirements for lawful information sharing¹²;
- analysis of demographic and other factors likely to influence future demand for the service;
- service models and learning from elsewhere including national / international experience; and
- deliverability in estates terms (if appropriate).

Commissioners should assure themselves that they have sought a comprehensive range of perspectives for the case for change. Proposals should be discussed with TDA and Monitor where appropriate. This will be particularly important where trusts will need to access Public Dividend Capital to deliver options which may be consulted upon.

The level of planning, clinical and management input should be proportionate to the scale and complexity of the change being proposed.

¹⁰ Sections 13Q and 14Z2 of the NHS Act 2006 as amended by the Health and Social Care Act 2012

¹¹ Section 149 of the Equality Act 2010, section 14T and section 13G of the NHS Act 2006

¹² See Annex 5 Information Commissioner's Guidance on privacy

Clinical commissioner leadership and collaborative decision making

- **Single CCG: planning and decision making through the governing body or by creating a specific committee.**
- **NHS England directly commissioned services: NHS England make arrangements for senior clinicians to be part of the governance arrangements.**
- **Multiple commissioning organisations based on two models: Committee in common or joint committees.**

For more information please see Annex 1 - Clinical commissioner leadership and collaborative decision making.

If the commissioner is content the options are viable, it should then progress with undertaking an assessment of these proposals against the four tests.

For each option to be shared with the public, further consideration of the financial proposal and its sustainability should be made at this stage. It is essential that only those options that are sustainable in service, economic and financial terms are offered publicly. At this early stage, before pre-consultation business case (PCBC), and again before the decision making business case (DMBC) it is helpful to take account of the requirements that individual providers' capital investment business cases will need to satisfy if they are to be able to support the formal proposals endorsed at DMBC stage.

	Income and Activity assumptions
1	Confirmation of the extent to which the NHS England and CCG commissioners support the activity and income assumptions contained within the business case.
2	Confirmation of the extent to which these assumptions correspond with NHS England and CCG commissioning plans, including any forecast growth assumptions, current and expected lower levels of activity, and levels of repatriated activity.
3	Confirmation that the activity and income assumptions have been appropriately sensitivity tested by the trust, to provide assurance that the business case remains robust and sustainable under a range of plausible scenarios.
4	Confirmation that the baseline activity in year 1 of the planning period covered by the business case is consistent with the expected previous year's outturn position on NHS England and CCG commissioned activity, and whether this provides a robust basis on which the future years' activity and income assumptions are modelled.

5	Confirmation that the activity and income assumptions in the latest version of the trust Long Term Financial Model (LTFM) which supports the business case and (if applicable) foundation trust application align with the NHS England and CCG commissioner planning assumptions, and with the NHS Five Year Forward View planning assumptions.
6	Consideration of the extent to which the new service developments set out in the trust's business case are considered appropriate, affordable and in alignment with NHS England and CCG commissioning intentions.
7	If there is a disconnect between the activity and income assumptions in the business case and those of NHS England and CCG commissioners and/or the NHS Five Year Forward View planning assumptions and/or the trust LTFM, then it will have to be explained. The explanation will discuss why this does not matter or alternatively, what has been done to mitigate the risks to all parties, and/or the alternative level of activity and income that NHS England and the CCGs are prepared to support, with clear rationale.

At this stage, further assurance requirements may be determined and consideration will be given as to whether the decision making business case requires review before final decisions are made.

Pre-consultation business case

To inform assessment of proposals against the four tests of service change, and NHS England's best practice checks, the proposing body should develop a pre-consultation business case (PCBC). The lead commissioners will prepare the business case.

The PCBC will vary, however they should:

- be clear about the impact in terms of outcomes;
- outline how stakeholders, patients and the public have been involved, proposed further approaches and how their views have informed options;
- outline the case for change;
- identify governance and decision making arrangements;
- be explicit about the number of people affected and the benefits to them;
- identify indicative implementation timelines;
- include an analysis of travelling times and distances;
- outline how the proposed service changes will promote equality, tackle health inequalities and demonstrate how the commissioners have met PSED;
- explain how the proposed changes impact on local government services and the response of local government;
- demonstrate how the proposals meet the four tests;
- demonstrate links to relevant JSNAs and JHWSs, and CCG and NHS England commissioning plans;
- summarise information governance issues identified by the privacy impact assessment;
- identify any clinical co-dependency issues, including any potential impact on the current or future commissioning or provision of specialised or other services; and
- show that options are affordable, clinically viable and deliverable:

- Demonstrate evaluation of options against a clear set of criteria.
- Demonstrate affordability and value for money (including projections on income and expenditure and capital costs/receipts for affected bodies).
- Demonstrate proposals are affordable in terms of capital investment, deliverability on site, and transitional and recurrent revenue impact.

The PCBC can also form the starting point for a Strategic Outline Case (SOC) as required by TDA and Monitor for those trusts for whom they will be required to provide approval on health community schemes.

Early engagement with TDA and Monitor can ensure that the later decision making business case includes content to enable it to function as a programme-wide SOC to underpin those provider capital business cases that will follow.

Robust public involvement

- **The pre-consultation business case should include clear involvement plans.**
- **Involvement activity should:**
 - **Be proactive to local populations.**
 - **Be accessible and convenient.**
 - **Take into account different information and communication needs.**
 - **Consider how clinicians should be involved.**
- **Commissioners should assure they have taken appropriate involvement for each stage of the process.**
- **Further guidance on public participation is available in NHS England's guidance 'Transforming Participation in Health and Care'**
www.england.nhs.uk/wp-content/uploads/2013/09/trans-part-hc-guid1.pdf

Where proposals concern integration across NHS, social or public health services, the relevant social services and public health directors of each impacted local service should be involved in the process.

Commissioners and providers must also give due consideration to potential impacts of any proposed service changes on the ability of the NHS to effectively plan for and/or respond to an emergency. As a minimum there should be a formal modelling exercise to identify any potential impact and clear evidence of mitigating actions planned or undertaken to ensure effective Emergency Preparedness, Resilience and Response (EPRR) is maintained.

Support for proposals from clinical commissioners test

- CCGs should assure themselves that those proposals have the support of their member practices.
- For directly commissioned services, regional teams should ensure proposals have support of their medical directors and understand the views of CCGs on the proposed change to ensure alignment between commissioners.
- Commissioners need to be sensitive to any actual or perceived conflicts of interest. For more information please refer too:
www.england.nhs.uk/wp-content/uploads/2014/12/man-confil-int-guid-1214.pdf
- Disputes should be acted upon in accordance with the CCG's dispute resolution process as set out in its Constitution. Refer to:
www.england.nhs.uk/resources/resources-for-ccgs/ccg-mod-cons-framework/

Concluding the assessment against the four tests

Commissioners should consider the balance of evidence and be sensitive to any concerns raised. The decision should be recorded and made available to public scrutiny.

If, following discussion with their local NHS England team, commissioners are content that the outline proposals meet the four tests, and they can evidence that they have sought and acted upon the feedback, they should progress to a formal presentation of proposals.

Whilst it is sensible to refine options, commissioners should be aware of the drawbacks of ruling out options on which it may be helpful to undertake subsequent wider stakeholder and public feedback.

5.4 Discussion of formal proposal with local authorities

Commissioners should discuss their proposals with local stakeholders prior to any formal consultation, in particular with local OSC. The discussion ensures alignment of the case for change, avoids proposals being developed in isolation, and ensures the wider health system is considered.

The purpose of this stage is to:

- Ensure commissioners legislative requirements on consulting local authorities responsible for discharging health scrutiny functions are met.
- Follow good practice that H&WB boards have an opportunity to feed into the development of proposals.

Health scrutiny

NHS bodies have a legal duty¹³ to consult local authority OSC.

Although it is strongly advised that local authority scrutiny functions are involved throughout development, commissioners should hold a separate formal discussion

¹³ www.england.nhs.uk/wp-content/uploads/2013/03/a-functions-ccgs.pdf

on the final set of proposals on which they intend to consult. This is referred to as 'pre-consultation'.

Pre-consultation seeks to build alignment between NHS commissioners and local authorities:

- **Build on the case for change.**
- **Demonstrate -that all options, benefits and impact on service users have been considered.**
- **Demonstrate - that the planned consultation will seek the views of patients and members of the public who may potentially be impacted by the proposals**

Health and Wellbeing boards

H&WB boards can provide invaluable insights in a way that is complementary to the discussions with OSC.

The extent of involvement is dependent on local circumstances and level to which the H&WB board has previously been involved.

5.5 Public consultation

Before moving on to formal consultation, financial information should be revisited to ensure the figures remain correct and suitable sources have been identified.

Subject to feedback from local OSC, the proposing body may decide to progress to formal public consultation on the range of options that will be tested with staff, patients and the public, subject to assurance by NHS England.

NHS England has a role in the assurance of all schemes and a role in the decision making stage for those meeting the agreed thresholds¹⁴. This will ensure consistency across the NHS commissioning system and ensure that good practice and lessons learnt are shared.

It is good practice that when undertaking formal consultation on a specific set of configuration options, proposing bodies have:

- An effective public communication and media handling plan.
- A detailed plan for reaching all groups who will be interested in the change, including those that are hard to reach
- Staff involvement plans.
- Clear, compelling and straightforward information on the range of options being tested.

¹⁴ Section 3.3 'Determining levels of Assurance and Decision making'

Schemes have struggled to build public support where they have not adequately addressed public concerns that:

- **The proposals are perceived to be purely financially driven.**
- **Patients and their carers will need to make journeys that may reduce access.**
- **Emergency services will be too far away, putting people at risk.**

By the time a scheme moves to formal consultation, effective involvement will have identified any potential issues or barriers from within the local population and health economy which could compromise plans. Final proposals should take into consideration these concerns and seek to address them where appropriate.

Further guidance on involving the public in commissioning processes and decisions is available from NHS England's publication 'Transforming Participation in Health and Care'¹⁵ and also 'Statement of arrangements and guidance for involving the public in commissioning'.

5.6 Decision

The commissioners' decision is to be based on the best balance of clinical evidence and evidence gained through public support and consultation. A clear audit trail to evidence how the decision was reached, and the considerations taken, is to be captured. If capital requests to TDA or Monitor are likely to be made, these discussions should have occurred well before the pre-consultation business case and should be refreshed well before the production of the decision making business case (DBMC).

Before individual organisations incur major cost on health community schemes, they should ensure that they have agreed with NHS England, TDA and/or Monitor (as the case may be) how the requirement for demonstrating at Strategic Outline Case (SOC) level of confidence will be satisfied; with what formality; and that they have a reasonable indication that a source of funding will be available for the scheme. Until approval for the SOC is in place organisations - particularly NHS trusts - should not incur material costs progressing to the next formal stages of the scheme (OBCs and FBCs).

Decision making business case

The pre-consultation business case should be refreshed to reflect the final proposal, including any impact assessments, financial analysis etc. This is then called the decision making business case (DMBC).

The DMBC should ensure that the final proposal is sustainable in service, economic and financial terms and can be delivered within the planned for capital spend. It can be built from the PCBC and the stakeholders' work to anticipate and satisfy in the DMBC the wider requirements of a programme wide SOC. There is considerable advantage in engaging with TDA and Monitor well in advance of preparing the DMBC so that all other approval requirements can be taken full account of.

¹⁵ www.england.nhs.uk/wp-content/uploads/2013/09/trans-part-hc-guid1.pdf

For more complex schemes it may be assured by NHS England before decision making, and should include how views captured by consultation were taken into account. The decision on whether or not the DMBC needs to be formally assured will be discussed at the assurance checkpoint. This is to ensure that any major deviation from the original proposals have been looked at and to assure that the new proposals have been consulted upon, are clinically sound and financially viable.

A pause is important to ensure that the DMBC validates consultation outcome and ensures that progress to implementation is fully informed by solid detail analysis to allow continuity rather than delay. This ensures TDA, Monitor and DH are sighted on any capital that has been planned for.

Upon decision making, the proposing organisation (whether CCG/s [Committee in Common/Joint Committee], NHS England or a combination) announces the decision and communicates to:

- **Patients and the public.**
- **Staff.**
- **Media – which should follow an existing dedicated media handling plan.**
- **Health and wellbeing board(s).**
- **Local authorities discharging health scrutiny functions or a joint overview and scrutiny committee.**
- **Local Healthwatch, local voluntary sector and other relevant groups representing patients.**
- **MPs.**

Scrutiny

Situations may arise where consensus over service reconfiguration cannot be agreed between the commissioner and relevant local authority. Wherever possible, decisions about how the NHS is run should be made locally by those directly involved. Local authorities may refer proposals to the Secretary of State, if:

- The consultation has been inadequate in relation to the content or the amount of time allowed.
- The NHS body has given inadequate reasons where it has not consulted for reasons of urgency relating to the safety or welfare of patients or staff.
- A proposal would not be in the interests of the health service in its area.

Before making a referral, organisations involved must satisfy themselves that all other options for local resolution have been fully explored. Upon receipt of a local authority referral, the Secretary of State may ask the IRP to carry out an initial assessment however this does not mean that all referrals will be reviewed in full. Further details can be found in their document 'The Review Process' found on the IRP website¹⁶.

¹⁶ www.gov.uk/government/organisations/independent-reconfiguration-panel

The Department of Health's guidance 'Local Authority Health Scrutiny: Guidance to support Local Authorities and their partners to deliver effective health scrutiny' provides further information and specific guidance on the above points¹⁷.

5.7 Implementation

Following the decision on which option (or variant) to take forward, an implementation plan should be set out on how the changes will be taken forward, when and by whom. The plan should identify a clear benefits realisation timetable with key milestones against which progress can be monitored. NHS England's local teams will offer commissioners support, guidance and ongoing assurance through the implementation phase.

Commissioners may wish to undertake further independent reviews to help assure ongoing programme implementation.

It is good practice that commissioners and providers continue to involve stakeholders, patients and the public until such time as the changes are in place and considered business as usual. During this time oversight reverts to the commissioner leading the plans with support from local NHS England offices, Monitor and other partners.

¹⁷

www.gov.uk/government/uploads/system/uploads/attachment_data/file/324965/Local_authority_health_scrutiny.pdf

Annexes

Annex 1 - Clinical commissioner leadership and collaborative decision making

Proposals which involve a single CCG

- Arrange planning and decision making either through the governing body, an existing committee with a relevant remit and delegated authority or by creating a specific committee and delegating the exercise of the relevant functions to it.
- It is good practice that a clinically-led group should oversee the design and development of proposals, and commissioners should ensure that clinical ownership and leadership of plans is part of any programme and governance arrangements.
- Where schemes relate exclusively to services directly commissioned by NHS England, arrangements will be made for senior clinicians to be part of the governance structure for schemes.

Proposals which involve multiple commissioning organisations

Collaborative commissioning is where two or more CCGs, and/or NHS England, work together in order to commission services for which they are responsible.

- CCGs should be clear in advance what responsibilities they have, individually and together, for ensuring full support for a collective decision.
- CCGs should set up an oversight board. Each of the participating CCGs should be represented. Advance agreement should be reached regarding how lack of consensus or conflicts of interest should be handled.
- Where CCGs engage in collaborative arrangements, the individual CCGs will retain liability for the exercise of the respective statutory functions for their areas – this cannot be delegated or shared.
- Section 14Z3 of the NHS Act 2006 (as amended by the Health and Social Care Act 2012) allows any two or more CCGs to make arrangements for one CCG to exercise any of the commissioning functions of another on its behalf, or for all the CCGs to exercise any of their commissioning functions jointly.

A CCG may make provision:

- for the appointment of committees or sub-committees of the clinical commissioning group; and
- for any such committees to consist of or include persons other than members or employees of the CCG.

Collaborative commissioning arrangements can be based on two models: committee in common or joint committees.

Joint committees

- The NHS Act 2006 has recently been amended to allow CCGs to form joint committees with each other and/or NHS England.
- CCG(s) in the committee are able to delegate their decision making function to the joint committee.
- A joint committee may also be formed between NHS England and CCGs and the joint committee will exercise its management of functions in accordance with the agreement entered into between NHS England and the CCG.
- The Legislative Reforms encourage integration and more streamlined collaborative decision making than committees in common (see below).
- CCGs constitutions and governance arrangements must permit the formation of a joint committee. Most CCGs have already amended their constitutions to allow this but if in doubt this should be checked.
- Where amendments to the constitution are required, CCGs will need to obtain the appropriate internal approvals to the proposed changes and seek the approval of their members prior to submitting their amended constitutions to NHS England.
- In joint commissioning arrangements, individual CCGs and NHS England remain accountable for meeting their own statutory duties.

The Legislative Reform (Clinical Commissioning Groups) Order 2014 (LRO) came into force on 1 October 2014. The LRO amends the National Health Service Act 2006 to enable:

- **two or more CCGs to establish a joint committee so that they can exercise their functions as a joint committee of the groups; and**
- **CCGs and NHS England to establish joint committees so that they can exercise certain CCG functions jointly.**

Committee in common

- As set out above, since the Legislative Reform (Clinical Commissioning Groups) Order 2014 (LRO) came into force, it is no longer necessary for CCGs to operate arrangements such as “committees in common” when they wish to make joint and binding decisions. However, committees in common are still an option and may be convenient when collaborating with non-NHS bodies such as local authorities.
- Each CCG can delegate any functions required for developing service reconfiguration proposals to a committee consisting of its members or employees and those from other CCGs involved in the service reconfiguration. That would enable all involved CCGs to have committees consisting of the same people and those committees could then meet in common for the purposes of decision making.
- It is good practice that membership of the ‘committee in common’ is drawn from CCG chairs or accountable officers (where these are GPs) or a nominated senior clinical GP lead from each CCG, and the medical director of the relevant team(s) where schemes have a component of direct commissioning.
- It is also good practice that the CCGs consider whether they should establish a separate programme (or advisory) board consisting of commissioners,

providers, local authorities and other relevant stakeholders to make sure all relevant information is fed into the reconfiguration process.

- A programme board would not be able to exercise any function on behalf of any CCG (Section 14Z3) but could support the development of shared proposals and provide recommendations to the 'committee in common' or CCG governing bodies.

Annex 2 – Commissioning regulations

Commissioners should always comply with the Procurement, Patient Choice and Competition Regulations

The Procurement, Patient Choice and Competition Regulations provide a framework for commissioners to drive positive change that benefits patients. Monitor's substantive guidance on the regulations sets out a series of questions commissioners should ask themselves to ensure they are meeting the needs of patients within the framework of the regulations. These questions are:

- What are the needs of the health care service users we are responsible for?
- Are those needs currently being met? Have they changed since services were last reviewed?
- What level of involvement with the local community, patients and patient groups, clinicians and others should we undertake?
- How good are current services? How can we improve them?
- How can we make sure that the services are provided in a more joined-up way with other services so that they are seamless from the perspective of the patient? How can we get the professionals that are responsible for different elements of a patient's care to work together more effectively for patients?
- Could services be improved by giving patients a choice of provider to go to and/or by enabling providers to compete to provide services?
- How can we identify the most capable provider or providers of the services? Is the current provider the only provider capable of providing the services?
- Are our actions transparent? Do people know what decisions we are taking and the reasons we are taking them? Do we have appropriate records of our decisions?
- How can we make sure that providers have a fair opportunity to express their interest in providing services? What do we need to do to make sure that we do not discriminate against any providers?
- Are there any conflicts between the interests in commissioning the services and providing them? If so, how can we manage them to make sure that they do not affect or appear to affect the integrity of the award of any contract at a later point in time?
- Are our actions proportionate? Are they commensurate with the value, complexity and clinical risk associated with the provision of the services in question and consistent with our commissioning priorities?

Annex 3 – Best practice checks

These are some of the best practice checks that should be undertaken. This list is not exhaustive and should be agreed with local NHS offices.

Criteria	Key Tests	Example Evidence
4 key tests	<ul style="list-style-type: none"> Strong public and patient engagement, Consistency with current and prospective need for patient choice A clear clinical evidence base Support for proposals from clinical commissioners 	<ul style="list-style-type: none"> See communications and clinical quality and activity sections below Documented evidence of support
Best Practice Checks		
QIPP / Finance	<ul style="list-style-type: none"> How does the proposal support commissioner financial sustainability and what is the impact on providers? Does the proposed change improve quality and reduce cost? How (e.g. reduced duplication, increased efficiency)? What are the savings in financial terms? What changes to capacity are proposed? How, when and where is a saving made? Is it a cash releasing saving? Are the transitional costs (including non-recurrent revenue and capital) identified and properly accounted for? How will they be funded? Capital investment implications have been considered in terms of the viability, deliverability and sustainability of the proposal and the economic (value for money) impact Finance links consistently to workforce and activity models 	<ul style="list-style-type: none"> Business case (if available) or strategic outline case including worked through financial models Evidence of aligned financial, workforce and activity models Capital investment implications identified to NHS England Project Appraisal Unit for review
Clinical quality and strategic fit	<ul style="list-style-type: none"> Clear articulation of patient, quality and financial benefits Clinical case fits with national best practice Fit with local H&WB strategy and aligned with the objectives and commissioning intentions contained in local commissioners strategic plans Options appraisal (inc. consideration of a network approach, cooperation and collaboration with other sites and/or organisations) Macro-impact is properly considered Alignment with QIPP workstreams Full impact analysis across CCG / NHS England commissioned services and shared sign up of all parties to analysis Does the proposal align to the new models of care in the Five Year Forward View? 	<ul style="list-style-type: none"> Clinical case for change including risk analysis Reference to national evidence base which could include NCD reports, NICE, Royal College or NHS Evidence. Narrative demonstrating alignment with strategic objectives Options appraisal for network / collaborative / cooperative approach Analysis of macro-impact Identify links to local strategic plan and QIPP workstreams Analysis of impact on CCG / NHS England commissioned services, including potential co-dependencies and unintended consequences, endorsed by relevant parties.
Activity	<ul style="list-style-type: none"> All relevant patient flows and capacity are properly modelled, assumptions are clear and reasonable What are the changes in bed numbers? Activity and capacity modelling clearly linked to service change objectives Activity links consistently to workforce and finance models Modelling of significant activity, workforce and finance impacts on other locations / organisations 	<ul style="list-style-type: none"> Outputs of accurate modelling with assumptions clearly stated and sensitivity analysis Clear explanation of reduction in bed numbers Narrative explaining link between modelling and service change objectives Aligned financial, workforce and activity models Analysis of key risks and any mitigating actions
Workforce	<ul style="list-style-type: none"> Do you have a workforce plan - integrated with finance and activity plans? Are you making most effective use of your workforce for service delivery and is it compliant with all appropriate guidance? Consider the implications for future workforce Have staff been properly engaged in developing the proposed change? 	<ul style="list-style-type: none"> Supply high level workforce risks and mitigating actions Statement of assurance including reference to all appropriate standards Changes to provider Learning Development Agreements Evidence of appropriate staff engagement
Travel	<ul style="list-style-type: none"> Has the travel impact of proposed change been modelled for all key populations including analysis of available transport options, public transport schedules and availability / affordability of car parking? 	<ul style="list-style-type: none"> Travel impact assessment
Resilience	<ul style="list-style-type: none"> How will the proposed change impact on the ability of the local health economy to plan for, and respond to, a major incident? Has a business impact analysis been conducted for all impacted organisations and appropriate changes made to Business Continuity Plans? Local Health Resilience Partnership impact assessment on resilience? 	<ul style="list-style-type: none"> Statement of assurance Evidence the proposed service change and the impact on resilience has been assessed at the Local Health Resilience Partnership (LHRP) Business impact analysis
Ambulance services	<ul style="list-style-type: none"> Have the implications for ambulance services (emergency and PTS) been identified and impact assessed and appropriate discussions been held with ambulance service providers? 	<ul style="list-style-type: none"> Statement of ambulance service engagement and impact assessment
Comms and Engagement	<ul style="list-style-type: none"> Are there plans to appropriately and effectively engage and involve all stakeholders (to include: staff, patients, carers, the public, Healthwatch, GPs, media, local authority overview and scrutiny functions, Health and Wellbeing Boards, local authorities, MPs, other partners and organizations) and fulfil commitments under s.14Z2 and s.13Q of the Health and Social Care Act? 	<ul style="list-style-type: none"> Consultation plan and draft consultation document Public / stakeholder involvement strategy Communications plan including full stakeholder map with timelines, key messages, named clinical spokespersons, sample materials and plans to reach seldom heard groups
Equality Impact	<ul style="list-style-type: none"> There has been an appropriate assessment of the impact of the proposed service change on relevant diverse groups? Has engagement taken place with any groups that may be affected? What action will be taken to eliminate any adverse impacts identified? 	<ul style="list-style-type: none"> Completed EqIA and Action Plan Evidence that decision-making arrangements will pay due regard to equalities issues
TDA/Monitor	<ul style="list-style-type: none"> Is proposal aligned with the TDA's / Monitor's approach 	<ul style="list-style-type: none"> Business case (if available) or strategic outline case
IT	<ul style="list-style-type: none"> Does proposal make best use of technology? Assessment of the impact on local informatics strategy & IT deployments Are there likely to be any data migration costs? Are there any implications for specialist or network technology/equipment contracts associated with the service? 	<ul style="list-style-type: none"> Evidence of a review of how technology may support the service change been undertaken Detail of any changes to local informatics strategy and deployment plan, inc. information flows and governance. Key risks are highlighted and mitigating actions identified
Others	<ul style="list-style-type: none"> Consistent with rules for cooperation and competition (Monitor/OFT/CC) Consideration given to the most effective use of estates Robust programme and risk management arrangements Identify and reduce the privacy risks 	<ul style="list-style-type: none"> Assurance from commissioners Estates impact assessment Gateway Team report and response to recommendations Conduct a privacy impact assessment (PIA)

Annex 4 – Nationally led service specifications and models, and procurement

Some changes may not be the result of a locally driven, location-based reconfiguration, but a national service review which may consider standards and services across a wide geography.

These reviews will fulfil the principles set out in this guide, though the sequence and timing of consultations will be slightly different to comply with legal regulations which apply to this type of change.

Section 75 of the Health and Social Care Act 2012 requires commissioners to ensure the award of contracts to the most capable provider or providers, having regard to the quality and efficiency of services, and taking into consideration integration, choice and competition. For many prescribed specialised services, where there is relationship of volumes treated to clinical quality, or the capital intensity and thus economies of scale and scope, a limited number of providers of care over a wider geography may achieve better outcomes for patients. However, commissioners need to carefully consider the above factors in relation to each service commissioned, rather than making an assumption, if a limited number of providers is preferred.

Based on evidence and national clinical reference groups' advice, commissioners need to determine the appropriate range of providers and interplay of key access requirements such as travel time.

Prior to procurement it would be expected that:

- Patient groups and clinical reference groups are involved in contributing to the review of key factors and options for clinical and service models.
- National formal consultation(s) on the service model and potential implications for service changes had been proportionally undertaken and any further representations such as OSC are considered.

The consultation determines the approach to procuring the services and should demonstrate compliance with the four tests of service change. Under procurement law the final outcome may be subject to challenge within mandatory time limits, but the contract awarded must be substantively the same as the bid for which was procured. For this reason it is not possible to make changes to the service specification or criteria for assessing the most capable provider post consultation and it is important that consultation obligations are met prior to the procurement stage.

For NHS England prescribed services, the Specialised Commissioning Oversight group provides review and assurance that these requirements have been met before authorising the consultation stage, before authorising full procurement and before authorising award of contract.

Annex 5 – Key resources

- A mandate from the Government to NHS England: April 2014 to March 2015:
www.gov.uk/government/publications/nhs-mandate-2014-to-2015
- Transforming Participation in Health and Care
www.england.nhs.uk/wp-content/uploads/2013/09/trans-part-hc-guid1.pdf
- Cabinet Office guidance on Consultation Principles
www.gov.uk/government/publications/consultation-principles-guidance
- Statutory guidance on Joint Strategic Needs Assessments and Joint Health and Wellbeing Strategies www.england.nhs.uk/wp-content/uploads/2013/09/trans-part-hc-guid1.pdf
- Independent Reconfiguration Panel's (IRP) 'Learning from Reviews'
www.gov.uk/government/collections/irp-learning-from-reviews
- IRP homepage www.gov.uk/government/organisations/independent-reconfiguration-panel/about
- Managing conflicts of interests: Guidance for clinical commissioning groups
www.england.nhs.uk/wp-content/uploads/2014/12/man-conflict-int-guid-1214.pdf
- Model constitution framework for clinical commissioning groups
[www.england.nhs.uk/resources/resources-for-CCG\(s\)/ccg-mod-cons-framework/](http://www.england.nhs.uk/resources/resources-for-CCG(s)/ccg-mod-cons-framework/)
- Guidance to support Local Authorities and their partners to deliver effective health scrutiny
[www.gov.uk/government/uploads/system/uploads/attachment_data/file/324965/Local authority health scrutiny.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/324965/Local_authority_health_scrutiny.pdf)
- The functions of clinical commissioning group [www.england.nhs.uk/wp-content/uploads/2013/03/a-functions-CCG\(s\).pdf](http://www.england.nhs.uk/wp-content/uploads/2013/03/a-functions-CCG(s).pdf)
- Equality and Health Inequalities legal duties: Guidance for NHS Commissioners on Equality and Health Inequalities legal duties
www.england.nhs.uk/ourwork/gov/equality-hub/legal-duties/
- The Equality Delivery System (EDS) resources
www.england.nhs.uk/ourwork/gov/edc/eds/
- Statutory guidance for Trust Special Administrators appointed to NHS foundation trusts www.monitor-nhsft.gov.uk/home/news-events-publications/our-publications/browse-category/guidance-health-care-providers-and-co-5

- Statutory guidance for Trust Special Administrators appointed to NHS Trusts www.gov.uk/government/uploads/system/uploads/attachment_data/file/212850/statutory-guidance-trust-special-administrators.pdf
- Terms of Reference for the NHS England Investment Committee: www.england.nhs.uk/wp-content/uploads/2013/05/pol-0103.pdf
- Monitor's substantive guidance on the Procurement, Patient Choice and Competition Regulations www.gov.uk/government/publications/procurement-patient-choice-and-competition-regulations-guidance
- CCG Assurance framework www.england.nhs.uk/commissioning/ccg-auth/
- Cabinet Office guidance on Consultation Principles www.gov.uk/government/publications/consultation-principles-guidance
- NHS England Patient and Public Participation Policy <https://www.england.nhs.uk/ourwork/patients/>
Please note as at publication of this guidance, the above policy is in development. A draft is available on the NHS England website, where the final policy will also be published in due course.
- NHS England Statement of arrangements and guidance for involving the public in commissioning *This currently being drafted and the final versions will be available on the NHS England website*
- NHS England Programme Assurance Team england.pmo@nhs.net
- Information Governance Alliance guidance on information sharing <http://systems.hscic.gov.uk/infogov/iga/resources/infosharing>
- Information Commissioner's guidance on privacy by design including the *Conducting privacy impact assessments code of practice* <https://ico.org.uk/for-organisations/guide-to-data-protection/privacy-by-design/>