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Introduction

We are all familiar with the various versions of the commissioning cycle that have been in circulation since 2008, but understanding how these apply to service design and delivery is often unclear. Commissioners are increasingly under pressure to deliver improved services with fewer resources. Hard decisions will be made in the current economic climate as funding is not limitless.

Clinician input at each stage of the commissioning cycle is vital as they alone have knowledge of local services and understand patient needs. In practice, commissioning without clinicians will ultimately lead to poor service or service failure. At the local and strategic level, Dermatologists can influence commissioning as clinical experts and as advocates, ensuring quality and equity for all Dermatology patients.

Areas that particularly benefit from clinical input include:

- Health needs assessment (including geographical mapping of demography and health burden)
- Risk stratification – assessing the potential levels of risk of service needs of particular patients
- Validation of data – (hospital activity) for the local secondary care department i.e. outpatient procedures undertaken in the severity of the skin disease.

In some local areas, commissioners are openly trying to engage with Dermatology clinicians and trust managers by holding consultation meetings as part of the commissioning process and discharging their responsibilities. While elsewhere, Commissioners are very difficult to communicate with and have agendas which don’t follow commissioning principles and protocols for redesigning services.

The Commissioning Cycle

The practice of Commissioning can look like a series of complex processes and tasks but at its simplest can be described in three phases:

1. Planning
2. Procurement
3. Monitoring

All three phases and associated activities must involve public, patients and Dermatology clinicians.
It is vital that Dermatology departments understand how they can input, inform and challenge commissioners on their commissioning responsibilities. The principle tasks of commissioning can also be used by Dermatology departments to help improve service design and planning.

Commissioning should start with assessing local and independent needs and identifying priorities; it is both an ongoing process and everyone’s business; it will touch patients, GPs and secondary care doctors, whether they get actively engaged or not.

1. **Planning**

Understanding the skin disease needs of your local population is essential for service delivery.

For some Dermatology departments the concept of co-design or consultation by their commissioners has been a novelty. Needless to say there is a statutory duty to consult particularly when designing services and care pathways to meet individual as well as local population skin disease needs. It is important that departments are aware of what their commissioners are planning and get involved in local discussions. If you are approached by private providers to do clinics in the community and this isn’t out f or tender then you should inform your trust and contact your commissioners to see what is going on. This can be an indicator of local GPs setting up private companies to do Dermatology community clinics, particularly where trusts have waiting lists. This should be challenged by the Trust and addressed by the Commissioner as part of its contract management obligations.

**Health Needs Assessment:**

A Health Needs Assessment (HNA) is the first step of the commissioning process and is the most effective method to determine the health needs of the local community. This involves looking at demographic profiles and geographical influences of your local population along with your hospital outpatient, day case and inpatient services. Local GPs should also be asked to provide their activity for skin disease to look at potential for unmet need. Although Dermatology Departments do not use diagnostic codes (ICD 10) in their outpatient services, much more information can be gleaned from the coded procedures (OPCS); new and follow up appointments for adult, paediatric single or multi-professional attendances.
Other sources of information include histopathology data for skin cancers, phototherapy and patch testing appointment numbers. Without this information assessing services and identifying potential gaps in services is hard to define. This also helps to define necessary outcomes for service design and delivery for both secondary care and community based services.

The health needs of the population should be identified to build a comprehensive understanding of local need including the requirement for access to different levels of service and patient care pathway and potential unmet need. This should encompass existing health, community and social service users to ensure services are targeted appropriately and sufficient capacity is commissioned.

Dermatology departments can challenge commissioners about any changes to services and request evidence of a needs assessment, particularly if you are told your service is being decommissioned. This should be coupled with appropriate patient and public engagement as part of this process. Dermatologists should inform their local HealthWatch and Health Overview Scrutiny Committee of failure by Commissioners to undertake this activity. Equally the department could undertake a needs assessment itself to present to the CCG board with an outline for the service.

**Questions to Ask Commissioners:**

- Has a needs assessment been carried out?
- How has the local community been engaged in the process?
- Have local clinicians been engaged?
- What does the assessment reveal in terms of the local area and future patient need?
- What indicators are relevant to your local patients?
- What action is proposed to address any identified unmet need?
- How will unmet need be monitored and accommodated by provider services?
- What are the health conditions and groups that will impact on the need for Dermatology services, both now and in the longer term?

**Reviewing Current Provision:**

Current services require regular review to ensure they are adequate, appropriate and of a sufficiently high standard to meet the needs identified in the Health Needs Assessment. Patient and public choice and feedback is an essential part of the process. Services need to be examined to identify gaps in overall provision, quality, cost effectiveness and geographical distribution.

A review of current services and any gaps is required to identify areas for improvement and ensure alignment with commissioning strategy (e.g. QIPP). If the service provision is satisfactory and economic, the reasons for change may be challenged.
It is vital that planned services have sufficient capacity to cope with fluctuations in demand, avoid duplication and ensure delivery of quality. Forecasting is essential and should be informed by the Health Needs Assessment.

**Care pathways design:**

Integrated pathways are required for many conditions from primary care through to tertiary care if needed. Full pathway design for all skin conditions must be agreed with local Dermatology clinical input in any commissioning process, along with cost benefits.

**Integration:**

The local specialist clinicians, GPs, patients and carers must all be involved in the production of the service specification.

Although it is time-consuming and expensive to complete the Needs Assessment and Service Review (which inform the Service Specification), the cost of failure from poor commissioning is far greater.

**Questions to Ask:**

- How do local services compare with national best practice and NHS benchmarking criteria?
- What measures are in place to understand this (QIPP)?
- Have patients been consulted and involved?
- Have staff been consulted and involved?
- What mechanisms are in place to understand the impact on the workforce?
- What is the workforce plan and is there a risk assessment?
- What is the impact on staff for any redesign? For example, relocating a service may require staff to travel longer distances; a change in service focus may require retraining or upgrading of skills.
- Are there any unintended consequences in other parts of the service of this change i.e. will the closure of a Dermatology service have detrimental effect on other services nearby.

**2. Procurement**

Services can be clarified or changed, or a new service created to meet the requirements identified in the Health Needs Assessment. Changes will result in a new service specification being created for the new service contracts. This requires engagement with clinicians and patients over the proposed service design, prior to the specification being drawn up.

There are many forms of procurement (or securing contracts) and commissioners will try to identify possible providers and decide what contract system to use to secure their service. Common forms of contracts include:
• **Single Preferred Provider**: this is often the previous service provider unless there have been problems with meeting requirements.

• **Any Qualified Provider**: (AQP – at least an improvement on the previous Any Willing Provider): the commissioners may agree any number of AQP contracts. The award of the contract does not ensure any work will be offered and there is no financial guarantee of any income. All AQP should be offered the same contract and if other providers limit their service provision (usually opting to exclude expensive or complex treatments) then this can be challenged as a Service Variation with the Contract.

• Other options include single tender action (incontestable), Restricted or Open Competitive tender.

• **Prime Contractor / Lead Provider Model Contracts**: Under this model, the commissioners enter into a contract with a provider (the prime contractor or lead provider). That contract allocates risk and reward as between the commissioner and the prime contractor. The prime contractor then sub-contracts specific roles and responsibilities (and allocates risk associated with their performance) to other providers. The prime contractor remains responsible to the commissioners for the delivery of the entire service, and for the co-ordination of its ‘supply chain’ (i.e. its sub-contractor providers) in order to ensure that it can and does deliver that entire service. The prime contractor is likely to be a provider of clinical services itself, but it could sub-contract all but the co-ordination role.

• **Integrated pathway hub (IPH) contracts**: In this case, the commissioners enter into separate contracts with a number of providers, all of whom contribute towards the delivery of an integrated service. Risks and rewards are allocated as between the commissioner and the provider under each contract. One of the providers (the IPH provider) assumes responsibility for the co-ordination and management of the integrated service and risks and rewards are allocated as between the commissioner and the IPH provider in relation to that integration and management function. The IPH provider may be a provider of clinical services itself, but may just take on the non-clinical co-ordination and management role. No one provider is responsible for the delivery of the entire integrated pathway.

Both the prime provider and the IPH models can be used with the NHS Standard Contract, and have specifically strengthened the provisions in the Contract around sub-contracting for 2014-15, so that they better support these models.

Consideration over the use of choice and competition will play an important role in contracting fairly. Beyond upholding patients’ statutory rights to choice as set out in the NHS Constitution, it is for commissioners to decide how best to use competition to meet the local needs of patients with a view to improving the quality and efficiency of services. In taking these decisions, commissioners will have to comply with legal requirements to ensure that their procurement decisions are transparent, non-discriminatory and proportionate and that they purchase services from the providers best placed to meet patients’ needs.
Quality stipulations need to be considered as stated in the commissioning for Quality and Innovation (CQUIN) payment framework, which sets out a commitment to make a proportion of the provider’s income conditional on quality and innovation. The indications within the new NHS Outcomes Framework are also key considerations.

Questions to Ask:

- What negotiations or discussion has been undertaken by Commissioners to existing service Contracts?
- What are the planned procurement process timelines for tendering the service?
- Is the process fair and equitable?
- What will be the impact on staff, and if there is an impact, have staff been made aware of the implications of moving to a new provider?
- Has there been a review of the quality of the existing service?
- Do the potential providers have appropriate strategies for the recruitment and retention of staff to ensure a safe and efficient service for patients?
- How will the quality of services be assessed e.g. PROMs?
- Has the proposal for a new service been approved by the Local Health and Overview Scrutiny Committee.

Service Specification:

The service specification should consider the population covered and specify where the service is not subject to patient choice and where the service is limited to a defined population. Please note: 2 week wait for skin cancer care referrals and patient management are not subject to patient choice under the IOG and cancer waiting time directives. This should have been clearly indicated in the service specification as outside of the contract due to the direct referral pathway requirements to the local Hospital MDT (level 3 and 4 care - Skin measures).

Negotiating robust contract terms and drawing up comprehensive service specification are two key areas in making sure that a contract will be fit for purpose and will place the right obligations on the provider. The Department of Health’s current procurement guide for commissioners makes it clear that commissioners must use the standard NHS contracts provided by the Department for all NHS funded services they commission. They contain very specific provisions about contract management, including an escalation system for dealing with any issues. This includes serving notices, having performance review meetings and putting in place remedial plans.

A clear specification of the services to be provided is vital to ensuring all parties are aware of the others’ expectations. A provider must meet all the requirements of the service specification. Commissioners must procure services against a service user specification which meets the service needs of their population in line with procurement. Any deviation in the treatment provided to patients by a contracted provider, is considered a ‘Service Variation’ to the NHS standard contract (section 38) and commissioners must be informed. This is particularly poignant if a trust did not win a bid and the appointed provider can’t meet its contractual obligations. We have to then question the appropriateness of the commissioners screening of its providers. Any changes to the service specification by
commissioners after local discussion and agreement should be challenged. Your local health and overview scrutiny board should be informed of these changes.

**Challenging Breaches to the Process**

Failure to comply with the Department of Health’s procurement guide can be separately challenged through the NHS procurement Dispute Resolution Process. Equally contestability is an important area of NHS policy, main policy document is the principles and rules for co-operation and competition (PRCC) published by the DH.

**Questions to Ask:**

- Is the service specification based on recognised best practice guidance for Dermatology?
- Are the patients’ best interests reflected in the specification?
- How will quality be measured and what are the outcomes?
- What will be the impact on staff?
- What evidence is there that other provider’s will be able to offer value for money?

**Managing Demand**

Services require checks and balances to ensure they are not overused (resulting in extra costs being incurred) and that any increase in demand, due to unmet need, is reported to Commissioners. Managing demand involves developing approaches to support and incentivise the optimum utilisation of services by patients. Patients will be empowered to allow them make more informed decisions about their treatment and encouraged to take more responsibility for their care, which impact on both demand and utilisation.

**Questions to Ask:**

- Is the monitoring process for the service contract transparent?
- Are patient’s needs at the centre of the monitoring process?
- How is the quality of the service being assessed?
- How are Patient Reported Outcome Measures assured?
- What happens if a new provider does not meet the required service specifications standards?
- What provisions will be made (e.g. continuation of services to patients) if the provider is no longer able to offer a safe, effective and high quality service?

3. **Monitoring**

Monitoring of services is critical to ensure providers are delivering in accordance with their contract, within budget and to an acceptable level of agreed quality. Monitoring will include regular information of the volume of services utilised, quality of services (patient engagement), resources committed through new referrals and any anticipated budget over
run. Quality markers may include data on day case and outpatient numbers, as well as procedures undertaken, and patient reported outcome measures (PROMS). Review of services and providers including financial reports of value for money and audits are required to confirm commissioning is conforming to required disease pathways and suitable for patients.

GPwSI services will be contracted using the NHS Community service contract. Clarification should be sought on the accreditation of each GPwSI if there is not local Consultant involved in their ongoing accreditation. The BAD and RCGP are currently looking at the accreditation of GPwSIs.

Any provider (including GPwSIs) who is awarded a NHS contract must provide the service as stipulated in the service specification. Any changes to services without approval from the Commissioner should be challenged by the trust. Those community providers who ‘cherry pick’ the simple patient cases referring more complex patients onto secondary care, should be taken to task. Such variations from the service specification should be reported to the commissioner to be addressed as part of their contract management responsibilities.

4. Patient and Public Engagement

Engagement with patients and public requires an ongoing, two-way dialogue. Feedback must be incorporated within every stage of the commissioning cycle; it is not a standalone process. Further information on the patient engagement process can be found on the BAD website: http://www.bad.org.uk/healthcare-professionals/clinical-services/patient-and-public-involvement Commissioner must demonstrate genuine public and patient involvement in local service design. Patient panels, which many departments encourage, may be very helpful in stating independently their views on Dermatology services.

Commissioners must demonstrate genuine public and patient involvement in local service design. Patient panels, which many departments encourage, may be very helpful in stating independently their views on Dermatology services.

5. Top Tips for Influencing Commissioning Discussions

Influence by Being Proactive

It is important that Consultants are proactive in local service design of their community services, even if the initial engagement from commissioners is not forthcoming. An offer of your assistance to help them with meeting their ‘clinician engagement and consultation responsibilities’ should act as a gentle reminder. This is absolutely essential to ensure the appropriate clinical knowledge is used in the design of patient pathways.

To be effective in influencing commissioning, local Dermatology departments need to start early:
• Investigate opportunities to join consortium Dermatology subgroups, particularly those exploring service redesign. This could involve directly contacting the lead commissioner, or your local Medical Committee (LMC).
• Try to get involved in discussions about local needs, the design of services and commissioning process itself
• Find out from commissioners where they are in the commissioning cycle so that you can plan ahead.

**Influence by Identifying Trends**

High-quality commissioning is linked to a process of understanding the needs of a population, clarifying which services are in place, undertaking a ‘gap’ analysis, deciding with all of the key stakeholders (including users) on the model of care that will best meet the population’s needs, and then prioritising the necessary changes and commissioning services on that basis.

Explaining the epidemiology of skin disease trends seen by your department is essential as commissioners only using the departments’ coded activity to inform this process. Commissioners are supposed to carry out a needs assessment. By telling commissioners about demographic trends and your patient profiles you can open up a discussion with commissioners about needs and future services.

**Influence by Sharing Experience**

Invite commissioners to visit your trust, attend your events or offer to organise events or training together with them. By encouraging commissioners to see how you work, they will have a better understanding of the realities faced by staff delivering services and the experiences of service users. This is also a good way to open up discussion with commissioners.

**Influence by Producing Evidence**

It is very important to collect evidence of the outcomes of your services. By showing how your services support people to make significant changes or improvements to their lives, you can present a strong case to commissioners. You can use case studies, service user feedback, letters or quotes from people who work with you, etc to show successful outcomes.

**Influence by Participation**

Although this takes a lot of time, it is important to participate in consultation meetings, networks and forums relevant to your work. These meetings can be an opportunity to meet commissioners and influence thinking.
Influence by Involving Users

Commissioners should be engaging public and patients/carers locally from primary and secondary care as part of their engagement and consultation responsibilities. This can be an opportunity to invite service users to talk about their experience, needs and opinions about the services you provide. Setting up a patient panel for your department gives your patients a chance to voice their opinion on the importance of the secondary care treatments they receive.

Influence by Building Relationships

Build relationships with potential allies (local networks/forums, LINks, Health and Overview Scrutiny Boards, local councillors, etc) to make the case for appropriate community Dermatology service design, and how it links to specialist services provided by the trust.

Contact your Local Health Overview Scrutiny Committee (part of the Local Council) and Local Involvement Network (LINks – soon to be Health Watch) and tell them about your Dermatology service. Invite them in for an educational evening to meet staff and patients. Any changes to health care services in primary care and the trust must go through the HOSC. These groups work together and have power to influence service changes.

6. Procurement, Patient Choice and Competition Regulations

The Regulations are made under section 75 of the Health and Social Care Act 2012 (the 2012 Act). They set certain requirements on commissioners of NHS health care services to be enforced by Monitor. These Regulations will apply alongside the Public Contracts Regulations 2006 and do not affect their application. The Regulations build on the existing administrative rules, The Principles and Rules for Cooperation and Competition, first established by the Government in 2007 to protect patients’ interests.

The Procurement, Patient Choice and Competition Regulations create a framework for procuring NHS health care services that is designed to ensure that commissioners secure high-quality, efficient services that meet the needs of patients. The regulations also include requirements that are designed to protect patients’ rights, set out in the NHS Constitution, to choose their health care provider and prohibit anti-competitive behaviour by commissioners unless this is in the interests of patients.

The regulations are structured as follows:

- Regulation 2 sets out the objective that commissioners must pursue whenever they procure NHS health care services. This objective is to secure the needs of patients who use the services and to improve the quality and efficiency of the services, including though the services being provided in an integrated way (including with other health care services, health-related services or social care services).
Regulation 3 sets out a number of general requirements that commissioners must comply with whenever they procure NHS health care services. Complying with these general requirements will help commissioners to achieve their overall objective in Regulation 2.

Regulation 3 includes requirements:

- to act transparently and proportionately, and to treat providers equally and in a non-discriminatory way;
- to procure services from one or more providers that are most capable of delivering commissioners’ overall objective and that provide best value for money;
- to consider ways of improving services (including through services being provided in a more integrated way, enabling providers to compete and allowing patients to choose their provider); and
- to maintain a record of how each contract awarded complies with commissioners’ duties to exercise their functions effectively, efficiently and economically, and with a view to improving services and delivering more integrated care.

Regulations 4 to 12 set out more specific requirements that commissioners must comply with. Complying with these requirements will help commissioners to comply with their overall objective in Regulation 2 and the general requirements in Regulation 3. Regulations 4 to 12 include:

- requirements about where and how to publish a contract opportunity where a commissioner decides to advertise a contract;
- a requirement to make arrangements for providers to express their interest in providing services; a
- prohibition on awarding a contract for services where a conflict of interest affects or appears to affect the integrity of the contract award;
- a prohibition on engaging in anti-competitive behaviour unless this is in the interests of people who use health care services;
- a requirement to establish and apply transparent, proportionate and non-discriminatory qualification criteria;
- a requirement to ensure that those providing commissioning support and assistance act consistently with certain requirements in the regulations;
- a requirement to publish information about contracts that commissioners award; and
- various requirements to protect the rights of patients, set out in the NHS Constitution, to choose who provides their health care

These rules provide a framework for commissioners when deciding what services their patients need and how to go about securing them. The framework is relevant whenever commissioners are awarding new contracts or making material variations to existing contracts.
7. Challenging the Procurement Process for Dermatology Services

Challenging Commissioning Decisions and Dispute Resolution

The significant changes to the health sector in recent years have brought to the fore the issue of competition law in the NHS. Private sector providers and NHS bodies equally are caught by the need to comply with EU and UK competition law and the rules on state aid in any situation where they are exercising economic activities in a competitive market place, in the same way as any other commercial enterprise. However, NHS organisations are also subject to specific statutory obligations under the Health and Social Care Act 2012 and the NHS (Procurement, Patient Choice and Competition) (No.2) Regulations 2013 (“NHS Procurement Regulations”) for England. These Regulations impose requirements on the NHS England and clinical commissioning groups (“CCGs”) to ensure good practice when procuring health care services for the purposes of the NHS. They are overseen by a separate competition regulator in the form of Monitor.

A Procurement Alternative to Litigation

The NHS Procurement Regulations provide an alternative procurement dispute resolution mechanism to procurement challenges available to operators via the courts. Investigation and enforcement is to be provided by Monitor, the independent health regulator and can arise via complaints made to it or as an own initiative action. This is a new departure under UK procurement rules which are based on review proceedings before the High Court/Courts of Session in Scotland. This may be attractive to disappointed bidders who have grievances but do not wish to invest in litigation. Thus the NHS Procurement Regulations apply alongside the Public Contracts Regulations 2006 (“PCR”) and do not affect their application. Given the strict limitation periods applicable to challenges brought under the PCR, a potential challenger will need to reach an early decision as to which route to follow. Monitor may not investigate where the person making the complaint has brought an action under the PCR in relation to that matter. However, it appears possible in a case with several different challengers that some may opt for a court resolution while others the alternative dispute resolution route. There are currently no limitation restrictions on the bringing of a complaint or action under the NHS Procurement Regulations (save those arising under general law applicable to a breach of statutory duty).

The powers given to Monitor are found in Regulation 15 and these include the power to direct a commissioning body to vary or withdraw an invitation to tender or to vary an arrangement for the provision of health care services in order to prevent or remedy a failure to comply with a requirement imposed by Regulations 2-8 and 10. A new clause has been added in Regulation 15 to clarify that Monitor does not have the power to direct a commissioning body to hold a competitive tender for a contract for the provision of health care services.
Advertising

Under PCR, healthcare services are classified as "Part B services" for which there are no formal procedural requirements as to whether, when and how to tender services. Without reference to the application of any financial thresholds, the NHS Procurement Regulations requires the NHS England to maintain and publish details of a website dedicated to advertising opportunities for health care service provision and the publication of records of contracts awarded (name, address, description, amount paid or payable, dates for service provision and process for selecting provider). This was previously NHS Supply to Health which has been replaced with Contracts Finder since April 2014.

The CCG must have an audit trial of procurement decisions to demonstrate compliance with the regulations, evidence that conflict of interest issues have been considered and evidence of due process if any decision is challenged.

Contract notices for healthcare services must be advertised and include a description of the services required and the criteria against which any bids for the contract will be evaluated. There is no requirement to use a particular tendering procedure (such as open, restricted, negotiated, competitive dialogue used in PCR), nor any obligation to use a standard form notice. All relevant bodies must maintain records of contracts awarded on the website.

In terms of the services covered by the NHS Procurement Regulations, healthcare services are defined in section 64(3) and (4) of the Health and Social Care Act 2012. Where the value of goods to be supplied is greater than £200,000 these should be advertised on Contract Finders regardless of the procurement method used, including single tender actions.

Equal Treatment

A potentially important difference between the regulation 3(2) obligation in the NHS Procurement Regulations and Regulation 4(3) of PCR is that, under the former, commissioners must not treat a provider more favourably "in particular on the basis of its ownership".

Award of Contracts without a Competition

Regulation 5 of the original NHS Procurement Regulations, which relates to the award of a new contract without a competition, has been amended to reflect the fact that the determination as to whether an award should be made to a single provider rests solely with the relevant body commissioning the services. There is no longer any reference to how or why this might come about (no restrictions on grounds of technical reasons or for reasons of extreme urgency). The Department of Health explained that this amendment was to remove wording that "inadvertently" created the impression that there were only very narrow circumstances in which commissioners could award a contract without a competition.
Declarations of Ineffectiveness

Monitor’s powers of decision under the NHS Procurement Regulations include the power to make a declaration of ineffectiveness. The power is wider than the equivalent power under the PCR as the breach need only be "sufficiently serious", by contrast to the rules in PCR Regulation 47K, which for example requires there to be a breach of the standstill provisions. The provisions relating to Monitor’s powers to investigate (Regulation 13) and declarations of ineffectiveness (Regulation 14) are unchanged in the NHS Procurement Regulations.

Damages

The NHS Procurement Regulations do not confer on Monitor the power to make a damages award and it may be inferred that, as with competition law, a "follow on" action would need to be brought in the courts to recover damages, based on a favourable decision of Monitor made under the NHS Procurement Regulations. It will also be possible to bring an action directly in the courts to enforce the NHS Procurement Regulations and seek damages, which could be useful in circumstances where an action under the Public Contracts Regulations would be time barred. Where an action for loss or damage has been brought under the PCR, an action under section 76(7) of the Health and Social Care Act is ruled out in respect of the same loss or damage.

Anticompetitive Behaviour

A significant area of novelty is the rule in Regulation 10 that commissioners must not engage in anticompetitive behaviour unless to do so is in the interests of people who use health care services for the purpose of the NHS (including services being provided in an integrated way or by cooperation between the persons who provide the services in order to improve their quality). This is said to reflect the Government’s view that competition is a means to improving services and not an end in itself. In this regard, the intention is that any restrictive terms and conditions would not be considered in isolation from the objective of improving quality or efficiency but rather the matter be considered in the round. However, it is less than clear how this obligation may be interpreted and arguably it simply adds to the duties on commissioners without any clear benefits being in evidence.

Monitor’s Investigation and Enforcement Powers

The Procurement, Patient Choice and Competition Regulations give Monitor the following investigation and enforcement powers:

- Regulation 13 gives Monitor the power to investigate potential breaches of Regulations 2 to 12 of the Procurement, Patient Choice and Competition Regulations or Regulations 39, 42 or 43 of the Responsibilities and Standing Rules Regulations. It also gives Monitor the power to require a commissioner to provide Monitor with information that it may require for the purposes of carrying out an investigation.
- Regulation 14 gives Monitor the power to declare that an arrangement (or a term or condition of an arrangement) for NHS health care services is ineffective if they are
satisfied that there has been a sufficiently serious breach of certain requirements in the Procurement, Patient Choice and Competition Regulations.

- Regulation 15 gives Monitor the power to issue a wide range of directions. These include the power to direct a commissioner to put in place measures to prevent breaches, remedy breaches or mitigate the effects of breaches; to vary or withdraw an invitation to tender for the provision of NHS health care services and to vary an arrangement for such services in certain circumstances.
- Regulation 16 also gives Monitor the power to accept an undertaking from a commissioner to take any action that could have been the subject matter of a direction under Regulation 15.

**Enforcement Procedures**

**Case Initiation**

Monitor may open an investigation under the Procurement, Patient Choice and Competition Regulations in two circumstances:

- On its own initiative for investigations into breaches of the prohibition on anti-competitive conduct (regulation 10 of the Procurement, Patient Choice and Competition Regulations).
- In response to a complaint that a commissioner has breached a requirement in regulations 2 to 12 of the Procurement, Patient Choice and Competition Regulations or regulation 39, 42, or 43 of the Responsibilities and Standing Rules Regulations where we consider that the complainant has sufficient interest.

They will consider on a case-by-case basis whether a complainant has a sufficient interest. The following complainants may have a sufficient interest (among others):

- providers;
- other commissioners;
- users of health care services (including individual patients); and
- patient groups.

Monitor cannot investigate a complaint where the complainant has brought proceedings against a commissioner under the Public Contracts Regulations 2006 (by issuing a claim form).

A person who considers that a commissioner may have breached or is going to breach the Procurement, Patient Choice and Competition Regulations or the relevant provisions of the Responsibilities and Standing Rules Regulations may contact Monitor to raise his or her concerns.

Further guidance on how to make a complaint to Monitor is available on their website.