

SUBSTANTIAL VARIATION PROTOCOL

Introduction

This protocol has been developed to facilitate a common approach between NHS Organisations and the Health Scrutiny Committee of Cumbria County Council as to what constitutes a 'substantial variation or development' of health services.

It is intended to promote early discussions on potential substantial variations as they are initially considered, prior to any formal consultation, so as to facilitate a more collaborative and joined up approach to substantial variations. The protocol is about working together, within the legal framework, to improve the experience of patients. Whilst concentrating on substantial variations or developments of health services, a recurrent theme is the need for the NHS Organisations and the Health Scrutiny Committee of Cumbria County Council to remain focussed on the needs of patients and opportunities to improve their care.

It is not intended that this protocol shall prejudice, conflict with or affect the exercise of the statutory functions, powers, rights, duties, responsibilities or obligations arising or imposed under any legislative provision enactment, bye-law or regulation whatsoever, nor shall it fetter the exercise of any discretion the Council or any NHS Organisation may have.

Legislative & Constitutional Context

Section 244 of the National Health Service Act 2006 authorises the Secretary of State to make regulations in relation to health scrutiny.

Regulation 23 of the Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013 (The Regulations) place an obligation on NHS Organisations to consult with the Council where they are considering any proposal for substantial developments or substantial variations to health services other than where a decision must be made as a result of the risk to safety or welfare of patients or staff.

The Council may issue a report to the Secretary of State where:

- a. the Council is not satisfied that consultation on any proposal has been adequate in relation to content or time allowed;
- b. the Council is not satisfied that the reasons given by the NHS Organisation not to consult are adequate; or
- c. the Council considers that the proposal would not be in the interests of the health service in its area.

Other than in relation to the University Hospitals of Morecambe Bay NHS Foundation Trust the Council has delegated its role in relation to the above regulations to Cumbria Health Scrutiny Committee (CHSC). This Protocol shall not apply in relation to the University Hospitals of Morecambe Bay NHS Foundation Trust whose substantial variations shall be addressed in accordance with the Council's Constitution.

Stage 1 - Substantial Variation Determination Procedure

There is no definition within the Regulations of what constitutes a substantial variation or development and as a result proposals for service change should be discussed with the CHSC at an early stage to attempt to reach a common position between the NHS Organisation and CHSC where possible.

Without limiting the previous paragraph the parties will, where appropriate, use the following procedure:

1. When an NHS Organisation develops or is made aware of a proposed variation which may be substantial it shall advise the CHSC as soon as possible.
2. The NHS Organisation shall, as soon as reasonably practicable, provide the CHSC with such information as is reasonably necessary to allow it to form a view on whether a change is substantial.
3. Both parties shall then attempt to form a common position on whether the variation is substantial. In deciding whether a change is a substantial variation the NHS Organisation and the CHSC will consider:
 - whether there is a major change to services experienced by patients and future patients;
 - the impact of the change upon patients, carers, the community, other services and the public who use a service, or may use it in the future;
 - whether the majority of patients using the service would experience a significant material change in how they receive that service, particularly in terms of access or location.
4. Where, following the parties assessment, the NHS Organisation notifies the CHSC that it considers that the variation not to be substantial, but the Council considers the variation is substantial the parties shall follow the resolution procedure below with a view to resolving the disagreement.

Relevant factors

The NHS Organisations and CHSC have agreed that the following factors may be relevant in determining the nature of a variation:

Characteristics likely to diminish defining proposals as substantial	Characteristics likely to increase defining proposals as substantial
Where questions are about quality	
<ul style="list-style-type: none"> • Area of proven practice with robust clinical governance and risk assessment arrangements 	<ul style="list-style-type: none"> • Proposal not tried and tested • Conflict or disagreement Ethical issues • Where issues of quality, or choice vs. access need to be balanced
Groups affected and nature of impact	
<ul style="list-style-type: none"> • Patients do not consider proposals significant • Proposals will have positive impact on patients and carers • Proposals to increase capacity/access/address any adverse travel implications • Proposal is for a short or temporary duration • Small number of patients / or low proportion of a particular group affected 	<ul style="list-style-type: none"> • Patients consider proposals significant • Proposals will have varying impact on different constituencies • Proposals increase inequalities in access to services • Proposal is for a permanent change to the service • Large number of patients affected, or all/most of a particular group of patients affected. <p>Wider implications:</p> <ul style="list-style-type: none"> • Adverse impact on patients groups • Lack of cohesion with other NHS or community strategies • Widening of inequalities • Cumulative effect • Effect on wider community
Climate of opinion	
<ul style="list-style-type: none"> • Clinical support for proposal • Support from community and patients through robust community and stakeholder engagement at all stages • Proposals specifically address concerns e.g. transport provision and home support for day surgery • Proposal based on need for change and agreement on way forward 	<ul style="list-style-type: none"> • Lack of clinical consensus • High level of opposition, especially from patients and public, concerns not addressed, inadequate community engagement • Rationale for proposal not clear

Stage 2 -Substantial Variation Implementation Procedure

Where the parties agree that a proposed variation is substantial the NHS Organisation shall produce a draft variation plan which it shall submit to the CHSC for consideration. The CHSC will provide comments to the NHS Organisation which will then consider the comments and go out to consultation formally with the relevant stakeholders in accordance with the relevant legislation.

The timetable for consideration of the drafts shall, unless otherwise agreed, be:

Action	Timing
Submission of draft variation plan to the Council	As soon as possible following determination that the change is substantial, but in any event within [2] weeks.
Consideration and initial comments by the Council	Comments & recommendations to be provided within [4] weeks of submission of plans.
NHS Organisation to review comments and recommendations and provide feedback on changes	Feedback to the Council on comments and recommendations within [2] weeks of receipt of comments.

Where the NHS Organisation chooses not to implement a recommendation or comment on the adequacy of the proposed consultation by the CHSC the parties shall follow the resolution procedure set out below.

Stage 3 – Consultation on the Substantial Variation

The NHS Organisation will carry out its public consultation providing details to the CHSC to allow for appropriate engagement by the Committee.

Once the consultation has been completed the NHS Organisation will report the results of the consultation back to the CHSC with its response and proposed next steps.

If at this stage the CHSC feel that the proposal would not be in the interests of the health service in its area the parties shall follow the resolution procedure set out below.

Resolution Procedure

This section sets out the process which the NHS Organisation and CHSC will go through in order to resolve disagreements over whether a change is substantial and over changes recommended and comments made by the CHSC on draft variation plans.

Should the NHS Organisation and the CHSC fail to reach agreement on any of the matters discussed above either party may:

1. Send to the other a [form/letter] setting out the area of disagreement and that party's position in relation to it. The [form/letter] shall propose not less than three dates for a meeting to discuss the dispute with the other party.
2. The Chair of the CHSC and the relevant senior officer of the NHS Organisation shall meet within 28 days of the receipt of the [form/letter] to discuss the disagreement in further detail.

3. Should an agreed position not be reached within 7 days of the meeting referred to at paragraph 2, above, the parties may make proposals for further negotiations or, if no proposals are received or accepted, this protocol will be considered exhausted and the NHS Organisation may take a decision on how to proceed. The CHSC will then make a decision on whether or not to refer the matter to the Secretary of State.

The parties shall agree minutes of dispute meetings which may be disclosed to the Secretary of State, other competent bodies or in accordance with any other obligation to disclose by either party.

