



NHS Standard Contract 2017/18 and 2018/19 (Full Length)

Consultation on proposed National Variation

March 2018

NHS Standard Contract 2017/18 and 2018/19 (Full Length) Consultation on proposed National Variation

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1 Introduction

This document sets out, for consultation, proposals for an in-year National Variation to the NHS Standard Contract 2017/18 and 2018/19 (Full Length).

A separate document, available at https://www.england.nhs.uk/nhs-standard-contract/2017-19-update-march/, sets out proposals for a National Variation to the NHS Standard Contract 2017/18 and 2018/19 (Shorter Form).

We welcome comments on the proposed National Variations, which should be sent to england.contractsengagement@nhs.net by Tuesday 3 April 2018.

2 Summary of proposals

The current NHS Standard Contract was published by NHS England (in both full-length and shorter-form versions) on 3 January 2018

This new consultation proposes changes in three areas:

- to make the Contract consistent with the General Data Protection Regulation;
- to ensure that acute providers make appropriate use of the new Genomic Laboratory Hub services being procured by NHS England; and
- to extend the range of contract performance sanctions which are suspended for providers within scope of the Provider Sustainability Fund.

3 Details of specific changes proposed

Each of the changes we are proposing is explained below.

3.1 General Data Protection Regulation

The General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679) is a regulation by which the European Parliament, the Council of the European Union and the European Commission intend to strengthen and unify data protection for all individuals within the European Union (EU). The GDPR comes into force, and becomes UK law, on 25 May 2018. As the UK is scheduled to leave the EU on 29 March 2019, there will be a period when the GDPR applies in the UK. (It is intended that similar rules to those set out in the GDPR will continue to apply after Brexit.)

NHS England has taken specialist legal advice on the impact of the new regime (having regard in particular to the *Procurement Policy Note 03/17: Changes to data protection legislation* https://www.gov.uk/government/publications/procurement-policy-note-0317), and it is clear that we need to make some significant changes to the NHS Standard Contract in order to be consistent with new GDPR requirements and to introduce some consequential additional changes. In summary, the changes we are proposing will introduce the following new requirements or obligations.

- The parties must comply with a more inclusively defined set of data protection legislation and guidance (General Condition 21).
- The provider must appoint a Data Protection Officer and keep commissioners informed as to his / her identity (General Condition 21).
- Where the provider is to process personal data associated with the services provided under the Contract as a data processor, it must comply with the detailed requirements set out in the Provider Data Processing Agreement (new Schedule 6F to the Particulars).
- The provider must put in place and maintain in force appropriate indemnity cover to protect it against the significantly increased fines which the Information Commissioner's Office may now levy for breaches of data protection legislation (General Condition 11).
- We have made amendments to make clear that the provider must indemnify
 the commissioners against any clean-up costs incurred by the commissioners
 as a result of any breach of data protection legislation by the provider
 (General Condition 11).
- Where a provider commits a personal data breach, reportable to the Information Commissioner's Office, it must report this to commissioners (General Condition 21), and this in turn enables the commissioners to terminate the Contract without notice if they choose (General Condition 17).

In order to accommodate the changes described above, as well as the changes to the operative provisions and Schedules of the Contract, a considerable number of amendments and additions are inevitably necessary to the defined terms listed at the back of the General Conditions.

In a small number of areas, we are proposing additional Contract provisions which will support the mandated provisions, such as the changes in General Conditions 11 and 17 above, for instance. These provisions are considered appropriate for inclusion in new contracts. However, we recognise that some existing contracts may have been tendered on a different, less demanding basis. We therefore propose that these supporting provisions should be included in the updated version of the NHS Standard Contract for adoption in new contracts which are let from May 2018 onwards, but should not be included in the National Variation which we will publish (to vary ongoing contracts). (The provisions affected are highlighted in yellow in the consultation version of the Contract.)

3.2 Genomic Laboratory Hubs

NHS England is running a nationwide procurement to establish new providers of genomic laboratory services (with contracts to be awarded in April and services to go live in October 2018). One of the aims of the procurement is to ensure that each NHS-funded provider of acute, mental health or community services will, over time, have access to a single genomic laboratory services provider (known as a Genomic Laboratory Hub, GLH) which will (itself or via approved subcontractors) provide a

nationally-set range of evidence-based genomic tests to defined quality standards and outcomes. The expectation is that there will be seven GLHs nationwide.

The genomic tests covered by the procurement will be listed in the National Genomic Test Directory and fall into two broad categories - rare and inherited diseases and cancer. Once the new GLHs are operational, any provider will be expected to submit samples and associated clinical data for any of the genetic tests listed in the National Genomic Test Directory only to its nominated GLH; NHS England will publish details of nominated GLHs and the names of providers that can refer to them, once the outcome of the procurement is known.

Only GLHs (or their approved sub-contractors) will be permitted to perform the genomic tests listed in the National Test Directory.

These changes will replace existing arrangements put in place locally by providers with a new nationally-managed system, providing equal access across the country to high-quality services on an effective and efficient basis. To ensure that the new arrangements deliver value for money, it is essential that providers refer all samples to the correct GLH, and we therefore propose to include a new requirement on providers operating under the NHS Standard Contract to the effect that, where they submit samples for genomic tests from the National Genomic Test Directory, they must do so via a GLH identified through the NHS England procurement.

We propose that the new requirement should become effective from 1 October 2018. The proposed wording is set out at Service Condition 36.52 of the Contract, and the necessary new defined terms are listed at the rear of the General Conditions.

(Payment arrangements for GLH services are not a matter for this consultation, but it may be helpful to explain that NHS England will pay the GLH direct for rare disease testing. For cancer tests listed in the National Genomic Test Directory the provider ordering the test will pay the GLH at the rate agreed via the NHS England procurement; this is necessary because the costs of cancer-related genomic tests are included within current National Tariff prices.)

3.3 Financial sanctions in respect of national standards

NHS England and NHS Improvement have recently set out revised planning guidance for the NHS (<u>Refreshing NHS Plans for 2018/19</u>). Paragraph 2.8 of the guidance makes this commitment in relation to the NHS Standard Contract:

Providers who accept their control totals and so have access to the Provider Sustainability Fund for 2018/19 will continue to be exempt from the application of an agreed range of contractual performance sanctions, as set out in the existing NHS Standard Contract. NHS England will shortly consult on changes to the Contract to extend this exemption to all national contractual performance sanctions except those relating to mixed sex accommodation, cancelled operations, Healthcare Associated Infections and the duty of candour, on the basis that continuing NHS Improvement oversight, including the NHS Improvement Single Oversight Framework, will ensure that NHS

providers continue to perform to acceptable levels against all national standards.

The key benefit of the suspension of additional performance sanctions for providers within scope of the Provider Sustainability Fund (PSF) is that it will provide a further incentive for NHS providers to sign up to financial control totals – and adherence to control totals will be crucial in ensuring that the NHS provider sector achieves financial balance in 2018/19.

The suspension of sanctions does not reduce the need for providers to make every effort to comply with the full range of national standards set out in the Contract. The PSF and the Contract continue to require providers to sign up to improvement trajectories or assurance statements in relation to their performance against standards for which sanctions are suspended; providers within scope of the PSF must agree these trajectories or assurance statements with NHS Improvement and NHS England, and our expectation remains that they will then be reflected in local commissioning contracts as Service Development and Improvement Plans. NHS Improvement will monitor provider compliance through their oversight systems, as will commissioners through local contracting arrangements.

In terms of the practical arrangements, the national standards affected by this change are set out in Schedules 4A and 4B of the Particulars. To give effect to the proposed change, we have expanded the list of standards for which sanctions are suspended (this is done simply by showing the affected standards in bold italics). We have also updated references within the Contract, so that they now refer to the PSF rather than the Sustainability and Transformation Fund (Service Condition 36.37, General Condition 9.26, definitions) and to 2018/19 only, rather than to 2017/18 and 2018/19.

4 Presentation of consultation materials

Ultimately, following consultation, NHS England will publish

- a National Variation document for each of the full-length and shorter-form versions of the Contract, which commissioners can use to incorporate the new provisions into their existing contracts; and
- an updated edition of each version of the Contract, which commissioners can
 use where they place any new contract with a provider.

When we most recently consulted on a National Variation, in autumn 2017, the individual changes we were proposing were self-contained and free-standing. We therefore published a draft National Variation only at the consultation stage, as a way of setting out our proposed changes in a succinct way. The full revised Contract was then only published after the consultation was complete.

With this new National Variation, the nature of the changes required relating to GDPR is such that we will be amending many different sections of the Contract in an inter-related way. We have therefore reversed our approach, so that we are

presenting the full revised Contract documents themselves for consultation at this stage, on the basis that it will then be easier for consultees to understand how the proposed new requirements and wording fit together. We will publish the National Variation documents only at the final stage, once NHS England has reviewed the consultation feedback and made changes as appropriate.

5 Applicability and implementation of the National Variation

Subject to the outcome of this consultation, our intention is that a final version of the National Variation will be published during April 2018, with the expectation that commissioners will then implement the National Variation in their local contracts by no later than 25 May 2018 (the date when the GDPR requirements take effect). At the same time, we will also publish on our website an updated version of the full 2017-19 Contract, for use in any situations where commissioners are letting new contracts with providers. The NHS Standard Contract econtract system will also be updated as soon as possible following this publication.

6 Separate consultation on arrangements for research

A separate consultation has just concluded on important changes in the processes which Trusts must follow for commercially-funded research trials (for further detail, see https://www.engage.england.nhs.uk/consultation/simplifying-research-arrangements/). The consultation included proposed changes to the terms of the NHS Standard Contract.

The consultation closed on 1 February 2018. NHS England is now reviewing the responses received and will set out next steps shortly.

To avoid confusion, we have not included the draft Contract wording proposed for research in this new (March 2018) consultation. However, we anticipate that, following assessment by NHS England of the consultation feedback on the research proposals, final Contract wording on research will be included in the final National Variations and updated Contracts which we expect to publish in April 2018.

7 Consultation responses

We welcome comments on this proposed in-year National Variation to the NHS Standard Contract 2017/18 and 2018/19 (Full Length). Comments on the proposals should be sent to england.contractsengagement@nhs.net by Tuesday 3 April 2018.