DH Department of Health

18th June 2012 SHA & PCT Chief Executives

Room 229ⁿ
Richmondⁿ Houseⁿ
79ⁿ Whitehallⁿ
Londonⁿ SW1Aⁿ 2NSⁿ

Approved for publication under Gateway number: 17781

Dear Colleague

Guidance Note for use of the Clinical Negligence Scheme for Trusts (CNST) cover for the management of the clinical negligence risks of qualified independent sector providers (IS Providers) of treatment delivered to NHS Patients under the NHS Standard Contract for 2012-2013

Subject

- 1. This letter provides instructions on how the clinical negligence risks associated with NHS-commissioned elective activity undertaken by IS Providers can be covered by the CNST with respect to the NHS standard contracts for services ("NHS Standard Contracts") let to IS Providers that meet the relevant qualification criteria under "Any Qualified Provider" for 2012-2013. These cover arrangements are also to apply on "Progression" ISTC procurements that are planned or are underway, where clinical negligence risks are to be covered by the CNST.
- 2. This is an interim solution, and has been put in place because IS Providers are not yet able to become members of the CNST in their own right. This solution was informed by discussions with IS Providers, the NHS Litigation Authority and other stakeholders.

Which Providers and What Procedures are covered by the CNST Indemnity?

- 3. The interim solution for CNST cover is only intended to apply to elective and certain other acute services. In particular CNST is not available for:
 - maternity services;
 - trauma and critical care services where admission is unplanned (but excluding emergency and/or ancillary services delivered during, following or as a result of an episode of treatment under an NHS Standard Contract including returns to theatre and/or emergency readmissions).
- 4. Subject to paragraph 3 above, the scope of CNST cover may be extended in an NHS Standard Contract where additional services are added with the agreement of the Commissioner and the IS Provider. This is subject always to the Commissioner's obligations under the relevant procurement rules.
- 5. Where the indemnity arrangement is used to cover a particular NHS Standard Contract, it will also cover Non-Contract Activity to the IS Provider in accordance with this Guidance. The indemnity agreement set out in Annex A to this Guidance (the CNST Indemnity Agreement) is drafted so as to enable this and no bespoke drafting will be required in individual agreements.

- The CNST Indemnity Agreement is not intended to cover contracts for waiting list transfer initiatives where, for example, NHS Trusts onward-refer activity to IS Providers; or only parts of care pathways, other than in the context of Subcontractors as defined in the CNST Indemnity Agreement.
- 7. This CNST Indemnity Agreement is intended to cover contracts between organisations and Commissioners. It does not cover contracts between individual clinicians and Commissioners. The CNST Indemnity Agreement is not available to NHS organisations that are already members of the CNST.

Consideration required

- 8. This letter sets out the consideration you need to take in any AQP qualification process and subsequent award of an NHS Standard Contract with local IS Providers, to ensure there is clinical negligence cover for their NHS patients in respect of activities under those contracts.
- 9. If IS Providers elect to use the CNST Indemnity Agreement to satisfy their obligations under clause 50 of the NHS Standard Contract:
 - (a) the form of CNST Indemnity Agreement to be used by Commissioners and IS Providers is as set out in Annex A to this Guidance; and
 - (b) the level of contribution to be charged by Commissioners to IS Providers is as set out in this Guidance.
- 10. Commissioners must work with their IS Providers immediately to execute the revised form of CNST Indemnity Agreement. Further to paragraph 3 above, Commissioners must not list a contract in schedule 3 to the CNST Indemnity Agreement if it includes any of the services which are expressly not covered by CNST. Any service listed in paragraph 3 above will not be afforded CNST coverage even if included as a "Service" as defined in the agreed NHS Standard Contract.
- 11. Once the CNST Indemnity Agreement is in place, the monthly calculation of contribution should begin from the date of the first invoice under the NHS Standard Contract. If there is a Co-ordinating Commissioner, each Commissioner should provide the information required under paragraphs 15 and 19 below. If there is a single Commissioner, each monthly invoice must include the CNST contribution as a separate identifiable sum and reports should be provided to the Co-ordinating Commissioner as required under the indemnity.

The Interim Solution

- 12. Clause 50.2 of the NHS Standard Contract (*Liability and Indemnity*) requires all IS Providers to put in place appropriate indemnity arrangements or commercial insurance in relation to clinical negligence. These instructions describe the arrangements to be put in place where an indemnity backed by CNST cover is to be used. This does not prevent the IS Providers from obtaining their own insurance cover that satisfies the Commissioner's requirements under clause 50.2 of the NHS Standard Contract. Commissioners should seek their own advice to determine what is appropriate if IS Providers take out commercial insurances for clinical negligence.
- 13. The choice between the two approaches is at the election of the IS Provider. Where an IS Provider elects to put in place a CNST indemnity rather than commercial insurance, then the Commissioner must follow this Guidance. The CNST indemnity must be made available by Commissioners in the circumstances identified above if the IS Provider elects to use it.

Updated CNST Indemnity

- 14. If an IS Provider elects to take up the option of the CNST indemnity, then the form of agreement that must be entered into is attached at Annex A, and IS Providers and Commissioners must comply with the requirements set out below with respect to the contribution charged to IS Providers for using the CNST indemnity.
- 15. The revisions to the local CNST Indemnity Agreement include that:
 - a) It may be entered into by a Co-ordinating Commissioner (the Commissioner that is signatory to the NHS Standard Contract on behalf of itself and its Associate Commissioners). Commissioners can join the CNST Indemnity Agreement for more than one NHS Standard Contract with each IS Provider. This means that where Commissioners have entered into a "Cluster" arrangement, they may appoint the PCT Cluster lead as their CNST Co-ordinating Commissioner for the purposes of the CNST Indemnity Agreement. If Commissioners wish to have the CNST Indemnity Agreement apply to more than one NHS Standard Contract with the same IS Provider, then the Agency Agreement must also be entered into. The Agency Agreement differs from the Consortium Agreement required under the NHS Standard Contract because the parties to the Agency Agreement may differ and the "Cluster" arrangement may well be wider in relation to the CNST Indemnity arrangements.
 - b) The IS Provider must pay a monthly contribution for the indemnity, and this must be calculated according to methodology set out below.

Charges for the CNST Indemnity and associated CNST cover

- 16. CNST Contributions have already been notified to Commissioners for the current year, 2012-13, and these include a separately identified amount that has been based on each Commissioner's 2011-2012's activity commissioned from IS Providers.
- 17. Therefore, Commissioners need to charge a contribution to their IS Providers. These contributions are to be calculated by each Commissioner taking the undisputed value of the amount invoiced by the IS Provider under the relevant NHS Standard Contract by each IS Provider in accordance with clause 7 of the NHS Standard Contract and multiplying this amount by 0.85% (being the percentage for 2012-2013). The Commissioner will then raise an invoice for this amount and the contribution will be charged monthly in arrears. When disputed amounts are subsequently reconciled and become payable, then an appropriate addition, separately identified, should be made to the subsequent month's contribution. This mechanism is already contemplated under clause 7 of the NHS Standard Contract.
- 18. This CNST contribution invoice will either be:
 - a) issued to the IS Provider for payment; or
 - b) passed to the CNST Co-ordinating Commissioner (if there is one). The CNST Co-ordinating Commissioner will consolidate all contributions to be levied on an IS Provider and invoice the IS Provider with a single invoice.
- 19. The 0.85% is a level determined by the Department by dividing the total of the contributions notified by the NHSLA for all Commissioners' IS activity, by the total value of that activity. By setting the charge centrally, the Department is ensuring that charges to IS Providers will be set according to a consistent methodology by all Commissioners. The CNST contributions for the purposes of the CNST Indemnity Agreement when calculated using this methodology may be more or less than the amount charged by NHSLA to individual Commissioners for their individual IS activity.

20. That means that what Commissioners need to calculate the CNST Contribution is the undisputed amount invoiced by Provider under the NHS Standard Contract multiplied by 0.85%.

Payment under the CNST Indemnity

- 21. The payment mechanism under the CNST Indemnity Agreement is dependent on the payment/reconciliation process under clause 7 of the NHS Standard Contract. That is, the amount that the CNST Associate Commissioner is entitled to invoice the IS Provider is based on the reconciled amount that the IS Provider and the Commissioner agree is due and payable under the NHS Standard Contract.
- 22. This means that the first invoice under the CNST Indemnity Agreement can only be raised 3 months after the Service Commencement Date under the NHS Standard Contract, that is, when the first invoice is issued under that contract.
- 23. The CNST Co-ordinating Commissioner is required to invoice the IS Provider for the CNST Contribution within 10 Business Days of receipt of notification of the Invoiced Contract Activity Amount from the CNST Associate Commissioners for each NHS Standard Contract for the relevant Contract Month and a report on any Non-Contract Activity undertaken by the IS Provider for the relevant Contract Month.
- 24. The IS Provider is required to pay the CNST Contribution to the CNST Co-ordinating Commissioner in clear funds within 10 Business Days of the invoice from the Commissioner.
- 25. The CNST Co-ordinating Commissioner must remit to the CNST Associate Commissioners their share of the CNST Contribution within ten (10) Business Days of receipt of funds from the Provider.

VAT

26. Although the NHSLA does not currently charge CNST members VAT on their contributions to the scheme, the DH anticipates that the indemnity arrangement will be subject to VAT and this should be charged when IS Providers are invoiced for the CNST Contribution. No relief, refund, or price adjustment is to be given for any VAT that is charged to IS Providers.

Off-setting CNST Contributions against amounts owing to the IS Provider under an NHS Standard Contract.

- 27. Clause 6 of the CNST Indemnity Agreement requires the CNST Co-ordinating Commissioner to clearly and transparently invoice the amount calculated to be due for CNST cover to IS Providers, and the IS Provider to remit payment within 10 business days.
- 28. However, where the IS Provider has persistently failed to pay the CNST Contribution due or persistently pays the CNST Contribution later than required under the CNST Indemnity Agreement, then the CNST Co-ordinating Commissioner will notify each CNST Associate Commissioner and each CNST Associate Commissioner will then be able to set off any money owed as part of the CNST Contribution from the amounts it is due to pay the IS Provider for Services under a NHS Standard Contract. In these instances, Commissioners will still need to make VAT invoices available to reflect the VAT that will have to be included in the amount that is offset.

Completing an Agency Agreement

- 29. Where there is more than one Commissioner who is a party to a CNST Indemnity Agreement an Agency Agreement in the form set out at Annex B must also be entered into.
- 30. An Agency Agreement should be completed by those Commissioners who want to appoint a CNST Co-ordinating Commissioner to liaise and co-ordinate issuing of invoices and collection of payment from an IS Provider.
- 31. As the Consortium Agreement to the NHS Standard Contract only applies to the matters set out in the NHS Standard Contract, all Commissioners who are parties to an NHS Standard Contract must also complete the Agency Agreement if they wish to appoint a CNST Co-ordinating Commissioner for the purposes of providing the CNST indemnity cover.
- 32. Therefore, the CNST Co-ordinating Commissioner under the Agency Agreement may be a different organisation to the Co-ordinating Commissioner under the NHS Standard Contract. A CNST Co-ordinating Commissioner under the CNST Indemnity Agreement may take on the co-ordination role for a number of NHS Standard Contracts.

Administration of payment where there is a CNST Co-ordinating Commissioner

- 33. Where the CNST Indemnity is contracted for and administered on a CNST Co-ordinating Commissioner basis under an Agency Agreement, the CNST Co-ordinating Commissioner should invoice the IS Provider for CNST usage for its own activity and that of the CNST Associate Commissioners. The CNST Associate Commissioners must deliver to the Co-ordinating Commissioner the information necessary to make an accurate and timely charge for CNST to the IS Provider within five (5) Business Days of receipt of a monthly activity statement and invoice from an IS Provider under the relevant Contract.
- 34. Where CNST Co-ordinating Commissioner arrangements are planned, an Agency Agreement in the form set out at Annex B should be completed by the planned CNST Co-ordinating Commissioner and CNST Associate Commissioners. This document is in addition to the Consortium Agreement required under the standard contract.

Removal of the right to charge termination / "run-off" sums

- 35. Contributions to the CNST are set at a level to cover amounts that are expected to be paid out by the CNST in the year for which the contributions are charged. There is a time-lag in payment of claims that means that at the end of any year there are unpaid liabilities that have to be paid by participants in the scheme in subsequent years. This "overhang" could be removed by charging termination or run-off payments when annual contracts expire. However, in practice, NHS providers are not subject to such charges unless they choose to leave CNST altogether and it is not therefore intended that IS Providers should be subject to them.
- 36. Termination sums are not therefore to be charged to IS Providers upon expiry of the NHS Standard Contracts and no right is included in the CNST Indemnity Agreement or any other contract to make such a charge.

Who the CNST Indemnity applies to

37. The CNST cover provided by CNST Indemnity Agreement will cover the IS Provider, its Staff (as defined in the NHS Standard Contract and which includes Consultants) and those Material Subcontractors who are engaged to provide clinical services on behalf of

- the IS Provider provided that those Staff and Material Subcontractors comply with the CNST Membership Rules and other indemnity requirements as set out in the CNST Indemnity Agreement, in particular Schedule 2 of the CNST Indemnity Agreement.
- 38. Material Subcontractors include all subcontractors who perform part of a clinical pathway ("Pathway" is defined in the NHS Standard Contract). This also includes the use of "ad hoc" or locum consultants as Commissioners should be agreeing with IS Providers in advance how IS Providers will use locums and what agencies IS Providers would use to arrange replacement staff in an emergency.

Staff Letters – Schedule 2 to the CNST Indemnity

- 39. All Staff and Material Subcontractors who are engaged to provide clinical services on behalf of the IS Provider under the NHS Standard Contract must sign the Staff Letters in Schedule 2 to the CNST Indemnity Agreement.
- 40. This includes all subcontracted medical staff working for the IS Provider on an NHS Standard Contract provided that they meet the definition of "Staff". This includes Consultants or Material Subcontractors who are engaged to provide clinical services on behalf of the IS Provider and who agree to be bound by the indemnity arrangements set out in the CNST Indemnity Agreement and complete the letter attached at Schedule 2 of the CNST Indemnity Agreement.
- 41. Staff Letters are to be sent to the CNST Co-ordinating Commissioner upon request for its records and retention pursuant to clause 5.2(e) of the CNST Indemnity. Staff Letters are not to be sent to NHSLA or to the DH. However, NHSLA may ask for sight of Staff Letters from the Commissioner in the event a claim is made.
- 42. Staff performing activity under one or more NHS Standard Contracts may sign one Staff Letter in respect of all CNST indemnity Agreements entered into by the Commissioner(s) and the IS Provider if it is clear:
 - (a) which NHS Standard Contract(s);
 - (b) which Commissioner(s); and
 - (c) which CNST Indemnity Agreement(s),
 - the Staff Letter relates.
- 43. Staff Letters should be in place when the first activity is performed by the relevant member of Staff or Subcontractor. For the avoidance of doubt, where a member of Staff or Subcontractor has previously signed a letter in 2011-12 they are not required to sign a further letter for 2012-13.

Fragmented/Split/Segmented Care Pathways

- 44. Commissioners must know where NHS Patients are being treated.
- 45. If a Provider (NHS or non-NHS) is not able to perform a service, either because it does not have the capacity or ability, it must refer the Patient back to the Commissioner. Providers must not transfer NHS Patients to another Provider without the knowledge or authority of the Commissioner. If they do so, the Provider performing the treatment will not have CNST cover under the CNST indemnity.
- 46. Providers (**First Provider**) are entitled to transfer NHS Patients to another Provider (**Second Provider**) in circumstances where:
 - a) the Second Provider is an authorised subcontractor under a NHS Standard Contract; or

- b) the Commissioner has approved the care pathway for the treatment of the NHS Patient under a NHS Standard Contract (for example, where a Provider is only performing part of a care pathway and the First Provider is referring NHS Patients to the Second Provider as part of the care pathway) and the Commissioner has approved the transfer of the Patients completing the Transfer of Patients Letters in the forms attached at Annexes 1 and 2: or
- in the case of unplanned activity or onward referral for cancer or other significant pathology the Provider has notified the Commissioner by completing the Transfer of Patients Schedule.

Non-Contract Activity

- 47. Under the CNST Indemnity Agreement, an IS Provider is required to notify the CNST Coordinating Commissioner of the NCA activity that has occurred in the preceding Contract Month (even though the IS Provider will issue an invoice to the Commissioner who is the Referrer of the Patient). The CNST Co-ordinating Commissioner then charges the IS Provider the CNST Contribution in respect of that Non-Contracted Activity. The IS Provider then has CNST cover in respect of those NCA Patients.
- 48. Where Commissioners have entered into separate CNST Indemnity Agreements for one NHS Standard Contract the process below must be followed to ensure clarity as to which Commissioner should be notified of the NCA under the relevant contract.
- 49. The Commissioner who is to be notified of the NCA is the "Co-ordinating Commissioner" or "Lead Commissioner" under the NHS Standard Contract with the IS Provider. The referring Commissioner should be notified and invoiced pursuant to the NCA Guidance as usual.

Updating Contracts covered by the CNST Indemnity

50. If a CNST Indemnity is being co-ordinated by a CNST Co-ordinating Commissioner, the list of NHS Standard Contracts which fall within the remit of that CNST Co-ordinating Commissioner can be updated from time to time. It is not a requirement of the CNST Indemnity Agreement that all Contracts must be entered into on the same date. Updated lists of NHS Standard Contracts should be sent by the Co-ordinating Commissioner to the NHSLA.

Approval by Contract as opposed to site (as with ECN/FCN):

51. Under the CNST Indemnity Agreement, cover is granted over the activity performed in the NHS Standard Contracts referred to in Schedule 3 of the CNST Indemnity Agreement, rather than by site.

Possible Longer term arrangements:

- 52. There is currently a central review of the CNST arrangements and the rules for membership of that scheme, so the arrangements set out in the CNST Indemnity Agreement and this Guidance have been put in place as an interim arrangement only. One possibility is that membership of CNST is extended to be available to IS Providers. If so, all CNST Indemnity Agreements will terminate.
- 53. The charging arrangements set out above are fixed for 2012-13 only. There could be changes in the basis for the charge if interim arrangements are still in place for 2013-14. If so, these will be notified to Commissioners in Autumn 2012.

Termination of indemnities issued under these interim arrangements

- 54. These indemnities will terminate the earlier of:
 - (a) the date on which the IS Provider is no longer providing services under any NHS Standard Contract within the CNST Co-ordinating Commissioner's region, if the CNST indemnity has been provided by a CNST Co-ordinating Commissioner on behalf of itself and others, or
 - (b) the date on which the IS Provider has ceased providing services for an individual Commissioner, if the indemnity has been issued by a single Commissioner;
 - (c) the date 3 months after the date on which the IS Provider becomes a member of the CNST Scheme.
- 55. If the Termination Date is not on or prior to 31 March 2013 (when Primary Care Trusts are to be abolished), then notwithstanding any other provision of this Agreement, this Agreement shall terminate on 31 March 2013.

Notifying NHSLA

- 56. A copy of the completed CNST Indemnity Agreement should be sent to the NHSLA for their records. It should be sent by the Co-ordinating Commissioner to the NHSLA by e mail ISINDEMNITY@NHSLA.COM
- 57. Where the Commissioners have entered into the Agency Agreement a copy of the Agency Agreement should also be provided to NHSLA.
- 58. NHSLA no longer needs copies of whole time equivalent forms or Activity Plans as part of these indemnity arrangements. As part of the CNST Indemnity Agreement IS Providers are required to provide information on activity performed under the NHS Standard Contract to the NHSLA in order that appropriate levels of contribution for 2013-14 can be set.

Next Steps

- 59. Where IS Providers elect to take up the option of a CNST indemnity, it is the intention to have all updated CNST Indemnity Agreements in place at the same time that Commissioners and IS Providers enter into new NHS Standard Contracts for 2012-2013. Commissioners should work with their IS Providers immediately to put in place the above arrangements as quickly as possible.
- 60. Commissioners are reminded that the arrangements are mandatory where the IS Provider of NHS-commissioned elective services elects to choose cover through a CNST Indemnity Agreement and the CNST.

Yours sincerely

Bob Ricketts CBE Director of Provider Policy

Encs

Annex A: Updated Standard Form CNST Indemnity Agreement (attached as separate

document)

Annex B: Coordinating Commissioner Agency Agreement (attached as separate

document)

Annex C: Commissioner Referral Confirmation Precedent

Annex D: Commissioner Referral Confirmation Letter to Provider Precedent

Annex C Commissioner Referral Confirmation Precedent [To be printed on Commissioner letterhead]

Date:
[Insert Provider 1 Address]
Dear [], Transfer of Patients
The Patients set out in schedule 1 to this letter were referred to you under the <i>[insert</i>]

name of Provider 1 Contract]. They received their first definitive treatment in an outpatient clinic and a decision to treat was made.

The Commissioner has decided that it would be more appropriate for these Patients to receive their treatment at *[insert name of Provider 2]* (**Provider 2**). The Patients have agreed to be transferred to Provider 2 for treatment.

In the circumstances, please could you arrange for these Patients to be transferred on behalf of the Commissioner to Provider 2. Please could you also arrange for all relevant patient information and records to be sent to **[insert contact name]** at Provider 2.

Yours sincerely

[Commissioner Representative]

Schedule 1

List of Patients

Annex D Commissioner Referral Confirmation Letter to Provider Precedent [To be printed on Commissioner letterhead]

Date:
[Insert Provider 2 Address]
Dear [],
Transfer of Patients [insert name of Provider 2 Contract]
Further to our discussions, we have arranged for [insert name of Provider 1] to transfer to [insert name of Provider 1] on our behalf the patients set out in schedule 1 to this letter.
These patients are to be treated subject to and in accordance with the <i>[insert name of Provider 2 Contract]</i> (as amended).
Yours sincerely
[Commissioner Representative]
Schedule 1

List of Patients