**Appendix 1**

**Clinical Waste contracting**

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| 1. **Purpose** |

* 1. The purpose of this briefing is to provide information for the proposed NHS England & NHS Improvement (NHS E/I) centrally led Direct Award for Clinical Waste 2021/22 across the Humber, Coast and Vale and to request support from CCGs to progress to Contract Award.

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| 1. **Background** |

2.1 NHS England is responsible for the collection and disposal of unwanted medicines from pharmacies; GP practices are responsible for the collection and disposal of clinical waste from GP practices, which is reimbursed under the Premises Cost Directions 2013. In most cases, historic PCT legacy contracts are in place across the region for both Pharmacy and GP practices, of which management is overseen by NHS England.

2.2 Clinical waste for GP practices was delegated to Clinical Commissioning Groups under the NHS England delegation agreement.

2.3 In April 2016, NHS England produced a handbook for local areas to facilitate the procurement of a clinical waste service for GP practices and Community Pharmacies in line with the National Framework. In May 2017, the National Framework was suspended due to a legal challenge, this included all current and planned procurement of clinical waste provision.

2.4 As a result of the suspension of the framework, no new clinical waste services were procured across Humber, Coats and Vale, therefore all existing services have been rolled over on existing terms and conditions. Whilst the legal challenge was eventually resolved in late 2019, the National Framework was only in place until April 2020, therefore it was no longer possible to use the Framework to procure future Clinical Waste provision.

2.5 The following key challenges with clinical waste that have been noted nationally:

* Poor performing clinical waste services
* Market conditions – e.g. lack of historic investment in infrastructure/processing sites; unsustainable contracts; market dominance of a few larger providers that hold contracts with processing sites
* Cabinet Office commissioned a Market Health Assessment in 2021 – findings included historic contracts favour the buyer/commissioner; significant capital set up costs are high barriers to new market entrants; critical market infrastructure is aging and failing;
* Commissioning/contracting – e.g. limited contractual leverage (limited commissioner capacity - time consuming, historic contracts unavailable/expired); inefficient use of resources (limited invoice validation; limited data; non-compliance of waste segregation by producers of waste)

1. **Proposed Re-procurement programme**

3.1 A national working group was established in March 2020, which has focused on the following two related workstreams on behalf of Regions and Systems:

* to update all legacy (former PCT) contracts with clinical waste providers that NHS E/I inherited. This is planned to be undertaken through direct contract award for 12 months duration (with optional 6 months extension) with updated T&Cs and pricing in 21/22 (current estimated commencement from 1st August 2021); and
* plan and undertake national procurements to secure longer term clinical waste services from 22/23

3.2 **Direct Award**

In trying to address both the delay in the re-procurement programme and improve the ability to better manage clinical waste services that would tackle some of the key challenges detailed above, the national clinical waste project board is recommending a national direct award to all current incumbent providers. The key objectives of the direct award include:

* Extend the current contracts for 12 months with the option to extend for a further 6 months, with a view to re-procure new services for August 2022 onwards.
* All services will be contracted on the latest NHS contract terms and conditions, ensuring standardisation across the country
* The national team will review and agree new prices**,** which may be more sustainable for the market to meet the needs of PC services, whilst seeking to maintain good value for money. By facilitating centrally, the national team can benchmark across different areas and clinical contractors to help understand the market rates.
* Operationalise a shift in waste container types to enable better waste segregatione.g. more normal use of tiger bags instead of orange bags
* The national team will explore the key issues and pressure points each clinical waste contractor may experience to identity opportunities to improve resilience of the service for Primary Care sites.
* Introduce contingency options for when services fail e.g., terms to allow the commissioner to ‘step-in’ to appoint temporary alternate provisions to cover missed collections, or introduce additional storage capabilities (to ensure waste is removed from PC sites, even if processing sites are unavailable).
* Improve data transparency and tracing so all parties can monitor performance and be more responsive to emerging issues, and better plan service delivery. Including seeking confirmation (through levers) when waste is destroyed to prevent build up from over storage by market.
* Consolidate contracts to more meaningful geographies (e.g., ICSs), improving how we manage CW contractors now and in the future.

If the CCG decides not to proceed with the national NHS England direct award, individual contact procurements will need to take place at local level and will therefore not include the same benefits and aims as listed above.

3.3 **Managing Agent**

In addition to the direct award, the national clinical waste procurement project board is also recommending the inclusion of a managing agent.

The aim of the managing agent is to

* + Reduce burden on commissioners
  + Increase responsiveness to issues
  + Reducing costs incurred by challenging invoices

The role of the managing agent will include:

* Act as main point of access for all aspects of the clinical waste ‘pathway’ including different commissioners, primary care services in scope, and all aspects of clinical waste supply chain, including managing communications
* Supporting operational and contractual management of these contracts and all parties included in the waste process on behalf of commissioner(s) (e.g. escalations)
* Support data collection, provide reports on waste volumes, performance, compliance, audit and other key issues experienced with contract
* Review and match invoices for any discrepancies before commissioner processes for payment.
* Supporting re-procurement of new contracts following termination or notice to/by a CW contractor

NHS England and NHS Improvement have already committed to funding the managing agent for the community Pharmacy patient returned medicines service.

3.4 **Full Re-procurement 2022/23 Onwards**

Once the direct award has commenced, focus will move to the redesign and full re-procurement of clinical waste services from August 2022 onwards. There are several aspects being considered on how we may redesign how clinical waste is commissioned, to meet some of the objectives captured in other related strategies and address some of the issues we experience currently. For example:

* How to configure services, e.g., option to procure different parts of supply chain separately, rather than the traditional end to end contracts, to ensure waste is processed in the most regulatory compliant and environmentally compliant way.
* How to organise services for commissioners who have different contracting authority responsibilities, whilst reducing the complexity this has on the market
* How we more proactively respond to the changing needs of PC sites?
* Are there opportunities to align waste management across other NHS and Social care organisations, including those hosted in property services organisations?
* Are there opportunities to support local authorities with home patient responsibilities?
* How do we contribute to the reduction of carbon emissions and meet the net zero carbon objective?
* How do we enable more sustainable waste management practices

No action is currently required on the full re-procurement at this stage, however, further updates will follow over the course of the next 6 months.

3.5 **Waste Segregation**

One of the objectives of the Direct Awards is to operationalise a change to typical use of tiger-striped bags (Offensive waste) rather than orange bags (Infectious waste) in general practices. Existing clinical waste contracts stipulates orange bags as the main waste stream despite most waste generated in these settings not being typically infectious. There will also be a strong perception that all waste is infectious, which is also untrue, and general knowledge about waste management will vary greatly across all practices.

As part of the COVID-19 vaccine programme, NHS England introduced tiger-striped bags as the main waste type on sites and provided all sites with guidance on different waste types to start improving knowledge of waste producers. We now need to repeat this across all Primary Care Sites. To do this we are developing, with the national team:

* Guidance and resources for general practice sites to anticipate the transition to tiger-striped bags
* Guidance and resources for community pharmacy sites – in development
* Mandatory training on waste management for all staff – in development
* Webinars – we hope to present some webinars from clinical leaders to help promote best practice of waste management – Dates and times to be confirmed
* Health Technical Memorandum (HTM) 07-01 is being updated – led by NHS Estates team.
* Operational/practical supplementary guidance summarising HTM 07-01 to specific PC sites (i.e. summary of HTM bespoke for audience).
* Socialising updates through local commissioners and IPC leads

Currently, there is no specific action other than to note the above. Commissioners will be notified when we need to circulate the guidance and resources with GP practices sites. Should anyone wish to, we welcome any feedback on the current Waste Management guidance.

1. **Funding Implications**

4.1 **Direct Award**

Based on recent procurements and other ad hoc arrangements put in place to support the vaccine programme, the national team were initially seeing significant variation in prices in excess of 30 to 60% on current costs. This was largely due to a view by current clinical waste contractors that contracts are unsustainable and hence a perception that this is a correction rather than an increase. However, this has not materialised, and we will be able to progress with the direct award contracts under the existing price structure which will already be accounted for in CCGs delegated budgets.

By facilitating a direct award process nationally, it is believed this can improve management of the incumbent providers from ‘playing’ different commissioners/areas against each other, and provide benchmarking across areas and providers, as well as applying some due diligence centrally, to strengthen the ability to negotiate more affordable rates. As a result, current estimate of increased cost is in line with inflation.

4.2 **Managing Agent**

There will also be an additional cost associated to the managing agent, however, the aim of the agent is to reduce the overall cost of the clinical waste service by challenging invoices and reducing unnecessary waste. In addition to any potential costs or savings generated from a managing agent, there is also the potential benefit in reducing the burden for commissioners and freeing staff resources to focus on other issues. The estimated costs associated for the respective CCG are shown in the table below.

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| --- | --- | --- | --- |
| **ICS / STP / CCG area** | **Core MA services costs @ £87.08 per site (CCG)** | **Practice audits @ additional £42.85 per site (CCG)** | **Total Cost** |
| North East Lincs CCG | 2,090 | 1,028 | 3,118 |

Whilst there is no guarantee, CCGs who currently use a managing agent have estimated average savings of 10% on the cost of clinical waste provision. Therefore, any savings will remain with the CCG to offset the additional cost as a result of the direct award.

1. **Recommendation and Next Steps**

5.1 As the delegated responsibility for Clinical Waste remains with the CCG, the Primary Care Commissioning Committee is asked to review the information in the report and confirm if they are happy for NHS England to

* Proceed with the 12-month Direct Award with the incumbent Clinical Waste Provider
* Proceed with the addition of a Managing Agent to oversee the management of the clinical waste contract

5.2 In addition, the CCG Primary Care Commissioning Committee is also asked to note the following:

* The redesign and progression of the full clinical waste re-procurement programme for August 2022 onwards, with further information to be updated as the workstream progresses.
* The communication in relation to guidance on waste segregation and provide any feedback as appropriate