



NHS Standard Contract 2019/20

Particulars (Shorter Form)

Provider:

Contract ref: **11A1920XXXXX**

NHS Standard Contract 2019/20

Particulars (Shorter Form)

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Contract Reference	11A1920XXXX
DATE OF CONTRACT	1/4/2019
SERVICE COMMENCEMENT DATE	1/4/2019
CONTRACT TERM	Two years commencing 1/4/2019 With the option of a further one year.
COMMISSIONER	West Hampshire CCG (ODS 11A) Omega House 112 Southampton Road Eastleigh Hants SO50 5PB
CO-ORDINATING Commissioner	West Hampshire CCG Omega House 112 Southampton Road Eastleigh Hants SO50 5PB
PROVIDER	[] (ODS []) Principal and/or registered office address: [] [Company number: []

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CONTRACT

This Contract records the agreement between the Commissioners and the Provider and comprises

1. these **Particulars**;
2. the **Service Conditions (Shorter Form)**;
3. the **General Conditions (Shorter Form)**,

as completed and agreed by the Parties and as varied from time to time in accordance with GC13 (*Variations*).

IN WITNESS OF WHICH the Parties have signed this Contract on the date(s) shown below

SIGNED by

Signature

**Mike Fulford, for
and on behalf of
West Hampshire CCG**

.....
Title

.....
Date

[INSERT AS ABOVE FOR EACH COMMISSIONER]

SIGNED by

Signature

**[INSERT AUTHORISED
SIGNATORY'S
NAME] for
and on behalf of
[INSERT PROVIDER NAME]**

.....
Title

.....
Date

SERVICE COMMENCEMENT AND CONTRACT TERM	
Effective Date	01/04/2019
Expected Service Commencement Date	01/04/2019
Longstop Date	N/A
Service Commencement Date	01/04/2019
Contract Term	2 years commencing 1.4.2019 or as extended in accordance with Schedule 1C
Option to extend Contract Term	YES by One Year
Notice Period (for termination under GC17.2)	3 months for the entire contract 3 months for an individual service specification within the contract (unless otherwise stated)
SERVICES	
Service Categories	Indicate <u>all</u> that apply
Continuing Healthcare Services (CHC)	
Community Services (CS)	Yes
Diagnostic, Screening and/or Pathology Services (D)	
End of Life Care Services (ELC)	
Mental Health and Learning Disability Services (MH)	
Patient Transport Services (PT)	
Service Requirements	
Essential Services (NHS Trusts only)	
Is the Provider acting as a Data Processor on behalf of one or more Commissioners for the purposes of the Contract?	NO
PAYMENT	
National Prices Apply to some or all Services (including where subject to Local Modification or Local Variation)	
Local Prices Apply to some or all Services	YES
Expected Annual Contract Value Agreed	NO

GOVERNANCE AND REGULATORY	
Provider's Nominated Individual	[] Email: Tel:
Provider's Information Governance Lead	[] Email: Tel:
Provider's Data Protection Officer (if required by Data Protection Legislation)	[] Email: Tel:
Provider's Caldicott Guardian	[] Email: Tel:
Provider's Senior Information Risk Owner	[] Email: Tel:
Provider's Accountable Emergency Officer	[] Email: Tel:
Provider's Safeguarding Lead	[] Email: Tel:
Provider's Child Sexual Abuse and Exploitation Lead	[] Email: Tel:
Provider's Mental Capacity and Deprivation of Liberty Lead	[] Email: Tel:
Provider's Freedom To Speak Up Guardian(s)	[] Email: Tel:
CONTRACT MANAGEMENT	
Addresses for service of Notices	Co-ordinating Commissioner: West Hampshire CCG Address: Omega House 112 Southampton Road Eastleigh Hants SO50 5PB Email: Chris.Stevens2@nhs.net
Provider Representative	[] Address: [] Email: [] Tel: []

SCHEDULE 1 – SERVICE COMMENCEMENT AND CONTRACT TERM

A. Conditions Precedent

The Provider must provide the Co-ordinating Commissioner with the following documents and complete the following actions:

- | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ol style="list-style-type: none">1. Evidence of appropriate Indemnity Arrangements2. Evidence of CQC registration (where required) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|

C. Extension of Contract Term

To be included only in accordance with the Contract Technical Guidance.

1. As advertised to all prospective providers during the competitive tendering exercise leading to the award of this Contract], the Commissioners may opt to extend the Contract Term by 1 year.
2. If the Commissioners wish to exercise the option to extend the Contract Term, the Co-ordinating Commissioner must give written notice to that effect to the Provider no later than 6 months before the original Expiry Date.
3. The option to extend the Contract Term may be exercised:
 - 3.1 only once, and only on or before the date referred to in paragraph 2 above;
 - 3.2 only by all Commissioners; and
 - 3.3 only in respect of all Services
4. If the Co-ordinating Commissioner gives notice to extend the Contract Term in accordance with paragraph 2 above, the Contract Term will be extended by the period specified in that notice and the Expiry Date will be deemed to be the date of expiry of that period.

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	11A1819PH1
Service	Community Dressings Primary Care Service
Commissioner Lead	Neil Hardy
Period	1 April 2019 – 31 March 2021
Date of Review	31 March 2021

1. Population Needs

1.1 General Overview

Non-prescription supply of dressings allows organisations to purchase and store a supply of dressings. It is well known that items procured via the FP10 route are the property of the patient and can only be used by or on that patient. Dressings procured via the non- FP10 route are the property of the organisation. They can be used as a 'stock' item by the nursing team and so will be immediately available to start treatment.

The decision was taken to rationalise the various non-prescription supply options which were in existence in the legacy organisations which had become West Hampshire CCG to a single on-line ordering system (ONPOS®) which is run by Coloplast. Community pharmacies were the preferred supply route.

This service covers the ordering, supply and reimbursement for the community pharmacies.

1.2 National/local context and evidence base

In July 2010 the NPC published a MeReC Bulletin *Evidence-based prescribing of advanced wound dressings for chronic wounds in primary care*. Further advice is also available in the NICE clinical guideline CG 29: Pressure ulcers: The management of pressure ulcers in primary and secondary care.

The emphasis throughout has been on the use of dressings in community and primary care services for patients with non-surgical wounds. However, there is some reference to secondary care services where there is likely to be an influence on dressing use in the community. Advice on the management of surgical wounds can be found in the NICE clinical guideline

CG74: *Surgical site infection*.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	
Domain 2	Enhancing quality of life for people with long-term conditions	
Domain 3	Helping people to recover from episodes of ill-health or following injury	X

Domain 4	Ensuring people have a positive experience of care	X
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	X

2.2 Local defined outcomes

The key outcomes that the service will provide are as follows:

- Reduction of Waste
- Rationalisation of systems
- Improved Patient Care
- Improved infection control
- Timely access to appropriate wound care products

3. Scope

3.1 Aims and objectives of service

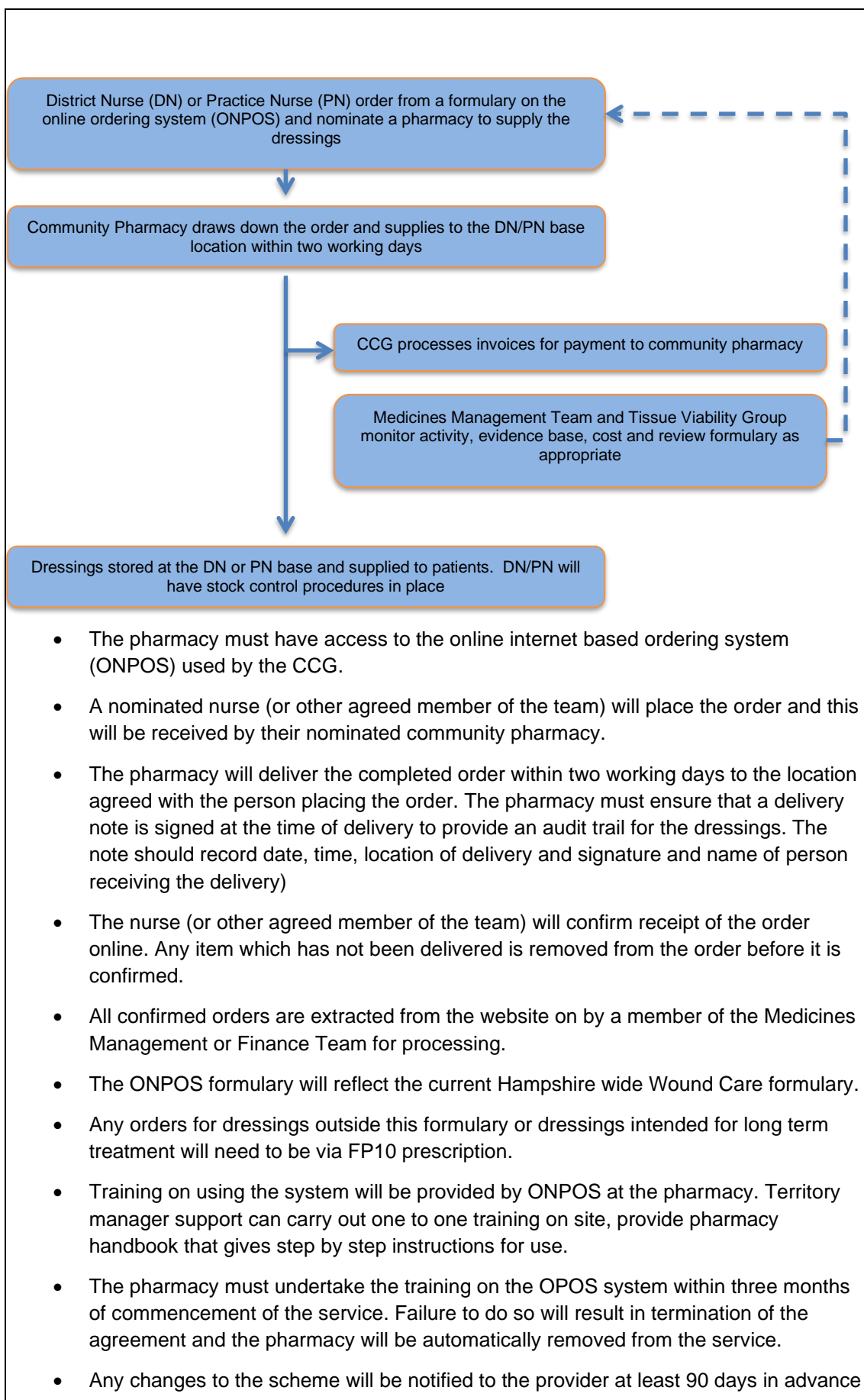
The service is the supply and delivery of dressings via an online (internet-based) ordering system called ONPOS, which has a pre-agreed formulary, through community pharmacies, to healthcare professionals authorised by West Hampshire CCG. The service ensures that patients have access to clinically appropriate dressings and that the quantities of dressings provided are sufficient to meet clinical needs but not excessive

- **Reduction of waste.** Any dressings supplied via FP10 are the property of the patient to whom they were prescribed. Any unused dressings have to be destroyed, as they cannot be reused for other patients, which can result in a significant amount of waste. Allowing health care professionals to order non patient specific stock will allow more flexible supply of dressings to patients thus reducing waste
- **Rationalisation of systems.** The service will ensure one clear method of supply, within a timely manner, throughout West Hampshire CCG and a method of accurately assessing usage and expenditure for the CCG by using formulary compliance
- **Improved patient care.** By not using FP10 prescriptions, it allows the rational ordering of dressings and a small stock stored at the point of care for short term or initial supply to the patient. This can significantly reduce time between patient's assessment and application of appropriate dressing. For long term treatment dressings should be supplied on FP10 for that individual patient
- **Ensure formulary compliance**

A single formulary has been adopted across the county using the Hampshire Wound Formulary. This ensures that only evidence-based dressings, that are clinically effective, are available for use.

3.2 Service Description

As diagram below:



3.3 Interdependence with other services/providers

The Provider shall ensure that effective and clear communication is maintained with Patients, GP surgeries and Nursing Teams.

There is an overarching wound formulary which has been developed between a number of local stakeholders. The wound formulary group membership includes representatives from community providers (Southern Health and Solent), acute providers (Hampshire Hospitals, Portsmouth Hospitals and University Hospital Southampton) and the five commissioning groups (Fareham & Gosport CCG, North East Hampshire & Farnham CCG, North Hampshire CCG, South Eastern Hampshire CCG and West Hampshire CCG) plus podiatry and practice nurse representation. It has been agreed the group will be a sub-committee of the Basingstoke, Southampton and Winchester District Prescribing Committee and other prescribing committees will ratify the recommendations. The group reviewed the formulary and it was re-launched in October 2016.

3.4 Eligibility

- Patients registered with a GP within the NHS West Hampshire CCG area
- Pharmacies within the NHS West Hampshire CCG area.

3.6 Population covered

This service should be provided within the existing skillset of the community pharmacy to meet the needs of the population, improve health and wellbeing, reduce health inequalities and support the provision of care closer to home.

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

In 2010 the NPC was asked by the Department of Health to undertake the production of guiding principles for the procurement and supply of appliances as listed in Part IX of the Drug Tariff. There was a particular need to develop guiding principles for the prescribing and supply of dressings, especially in primary care. In order to improve the quality and productivity of patient care the guiding principles consider the whole patient care pathway rather than focusing solely on the products prescribed.

In April 2011, the National Prescribing Centre integrated into the National Institute for Health and Clinical Excellence (NICE). However, the guiding principles do not constitute formal guidance of the National Institute for Health and Clinical Excellence.

5. Applicable quality/performance requirements

Applicable quality requirements (See Schedule 4 Parts A-D)

Not applicable

Only Performance Indicators are appropriate for this service:

Performance Indicator	Indicator	Threshold	Method of measurement	Frequency of monitoring
<p>Complaints Strengthen where appropriate complaints process to include:</p> <ul style="list-style-type: none"> • Acknowledgement letter within 3 working days • Final response within 25 working days 	Complaints records	100%	Audit	Quarterly
Service user Audit	ONPOS and Community pharmacies to Measure order turn around, formulary compliance and delivery time to Nursing Teams		survey	Quarterly
The provider will notify the CCG of the number of incidents, organisational learning and direct action taken in response to any incidents.	By exception	100%	Report	Monthly (by exception)

Service Specification No.	11A1819PH02	
Service	On Demand availability of Drugs for Palliative Care Primary Care Service	
Commissioner Lead	Neil Hardy	
Provider Lead		
Period	1 April 2019 – 31 March 2021	
Date of Review	31 March 2021	
1. Population Needs		
1.3 General Overview		
<p>The End of Life Care Programme emphasizes that 'the care of all dying patients must improve to the best level in all healthcare settings'. In relation to medicines, there are a number of issues that require consideration to facilitate symptom control in those patients who choose to live and die in the place of their choice and to reduce inappropriate admissions in the last weeks of their life. These include:</p> <ul style="list-style-type: none"> • Anticipatory prescribing - ability to access commonly used drugs in palliative care via Community Pharmacy 		
1.4 National/local context and evidence base		
2. Outcomes		
2.1 NHS Outcomes Framework Domains & Indicators		
Domain 1	Preventing people from dying prematurely	
Domain 2	Enhancing quality of life for people with long-term conditions	
Domain 3	Helping people to recover from episodes of ill-health or following injury	X
Domain 4	Ensuring people have a positive experience of care	X
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	X
2.2 Local defined outcomes		
<ul style="list-style-type: none"> • To improve access for people to these specialist medicines when they are required by ensuring prompt access and continuity of supply. • To support people, carers and clinicians by providing them with up to date information and advice, and referral where appropriate. 		

3. Scope

3.1 Aims and objectives of service

Service Aim

This service is aimed at the supply of specialist medicines for palliative care, the demand for which may be urgent and/or unpredictable.

The pharmacy contractor will stock a locally agreed range of specialist medicines and will make a commitment to ensure that users of this service have prompt access to these medicines at all times agreed with West Hampshire CCG.

The pharmacy will provide information and advice to the user, carer and clinician, in line with locally agreed palliative care guidelines. They may also refer to specialist centre's support groups or other health and social care professionals where appropriate.

This will aim to provide an equitable service to all patients in all settings and to reduce the need for out of hours drugs, with the ultimate aim of providing the best level of End of Life care.

The service involves two elements which will provide comprehensive availability of palliative care drugs across NHS West Hampshire: These are described below with a brief summary of each service area:

3.2 Service Description

On Demand Availability of Palliative Care Drugs through Community Pharmacies

- An Enhanced Service for Community Pharmacy based on the national template service specification for 'On Demand Availability of Palliative Care Drugs.
- pharmacies across NHS West Hampshire CCG, with extended opening hours and good accessibility / parking

Service outline:

- a. The pharmacy holds the specified list of medicines required to deliver this service and will dispense these in response to NHS prescriptions presented. The pharmacist should be prepared to telephone suppliers to confirm delivery of stock if necessary (or delegate this task appropriately). The pharmacist must keep patients or their representatives fully informed regarding supplies of medicines (or delegate this task appropriately).
- b. If a participating Community Pharmacist is not able to fill the prescription in the time available then he/she needs to find another Community Pharmacy who is able to fill the prescription. This should be done by telephoning another Community Pharmacy, it should not be assumed that just because a Community Pharmacy is on the palliative care list they can supply on every occasion.
- c. The pharmacist should co-ordinate with the prescriber to plan in advance for increased medication demand, particularly weekends and public holidays, when this is appropriate
- d. The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service have relevant knowledge and are appropriately trained in the operation of the service.
- e. The pharmacy should maintain appropriate records to ensure effective ongoing service delivery and audit.
- f. The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service are aware of and operate within local protocols. This includes all locum pharmacists.

- g. The pharmacy provides details of on-call contacts who will meet the commitment to have prompt access to the agreed list of medicines at all times agreed with the CCG.
- h. In the event of long-term availability problems, the pharmacy should liaise with their local palliative care team to arrange for suitable alternatives to be kept in stock.
- i. The CCG will provide locally agreed induction training for participating pharmacies.
- j. The CCG should arrange at least one contractor meeting per year to promote service development and update the knowledge of pharmacy staff.
- k. The CCG will agree with local stakeholders the medicines formulary and stock levels required to deliver this service. The CCG will regularly review the formulary to ensure that the formulary reflects the availability of new medicines and changes in practice or guidelines.
- l. The CCG will reimburse participating pharmacies to compensate for date expired medicines in the formulary. Pharmacists are requested to submit a list of expired stock annually.
- m. The CCG will provide a framework for the recording of relevant service information for the purposes of audit and the claiming of payment.
- n. The CCG & Local Pharmacy Committee will disseminate information on the service to other pharmacy contractors and health care professionals in order that they can signpost patients to the service.

Planning and Communication

It is recommended that wherever possible, when a palliative care patient is being cared for in the community setting, early warning to Community Pharmacies from the Palliative Care Consultant, GP, District Nurse or Palliative Care Nurse about the type and volume of drugs the patient is using would enable all Community Pharmacies to be prepared for any prescriptions.

For those Pharmacies involved in this service, it is vital for them to keep aware of any changes in prescribing patterns to allow them to monitor and get feedback on the service they are providing.

Drugs Available

The Community Pharmacies will guarantee to stock an agreed formulary of the commonly prescribed drugs. These drugs have been agreed by the service providers and are considered to cover the majority of “urgent” requests. These drugs do not cover all eventualities but it is important to note that most Community Pharmacies can usually order supplies of a prescribed drug for the same day delivery if ordered before 11.30 am and for the following morning if ordered before 5.00pm. (Monday to Friday)

The palliative care drugs list will be circulated to all primary care prescribers, including the out of hours services, District Nurses, Palliative Care Nurses, Community Pharmacies, Hospital Pharmacists and Palliative Care Consultants so that all the appropriate health care professionals are aware of what is reasonable to expect to be available both in and out of hours.

Access to the Service

Details of the Pharmacies will be circulated to all community based Palliative Care Nurses and District Nurses and to other Community Pharmacies. During working hours, it is anticipated that in the first instance, prescriptions should be presented at any local community pharmacy, and the “palliative care” Pharmacies used mainly in an emergency situation, where the drugs cannot be obtained by the local Community Pharmacy within an appropriate timescale.

3.3 Interdependence with other services/providers

The Provider shall ensure that effective and clear communication is maintained with Patients and GP surgeries

3.4 Eligibility

- Patients registered with a GP within the NHS West Hampshire CCG area
- Pharmacies within the NHS West Hampshire CCG area

3.5 Exclusions

Patients who are not registered with a GP within the NHS West Hampshire CCG area

3.6 Population covered

This service should be provided within the existing skillset of the community pharmacy to meet the needs of NHS West Hampshire CCG population, improve health and wellbeing, reduce health inequalities and support the provision of care closer to home.

4. Applicable Services Standards

4.1 Applicable national standards (e.g. NICE)

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

4.3 Applicable local standards

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

Not applicable

6. Location of Provider Premises

The Provider's Premises are located at:

See contract.

B. Indicative Activity Plan

Palliative Care
There is no indicative Activity Plan

Dressings
There is no indicative Activity Plan

D. Essential Services (NHS Trusts only)

Not Applicable

G. Other Local Agreements, Policies and Procedures

Not Applicable

J. Transfer of and Discharge from Care Protocols

Not applicable

K. Safeguarding Policies and Mental Capacity Act Policies

Providers must have their own comprehensive Safeguarding and Mental Capacity Act policies in line with national guidance

SCHEDULE 3 – PAYMENT

A. Local Prices

Dressings:

The Pharmacy will be reimbursed for each dressing supplied at the prices listed on the online ordering system, at the time of ordering, plus VAT at the current rate.

Palliative Care:

The Pharmacy will be paid an annual honorarium of £250 for the provision of the service.

The Pharmacy will be reimbursed on an annual basis for the cost of the expired medicines from the specified formulary.

B. Local Variations

Not Applicable

C. Local Modifications

Not Applicable

F. Expected Annual Contract Values

Not Applicable

SCHEDULE 4 – QUALITY REQUIREMENTS

A. Operational Standards and National Quality Requirements

Ref	Operational Standards/National Quality Requirements	Threshold	Guidance on definition	Consequence of breach	Timing of application of consequence	Applicable Service Category
	Duty of candour	Each failure to notify the Relevant Person of a suspected or actual Notifiable Safety Incident in accordance with Regulation 20 of the 2014 Regulations	See CQC guidance on Regulation 20 at: https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour	Recovery of the cost of the episode of care, or £10,000 if the cost of the episode of care is unknown or indeterminate	Monthly	All

SCHEDULE 4 – QUALITY REQUIREMENTS

C. Local Quality Requirements

Quality Requirement	Threshold	Method of Measurement	Consequence of breach	Timing of application of consequence	Applicable Service Specification
Not Applicable					

SCHEDULE 4 – QUALITY REQUIREMENTS

D. Commissioning for Quality and Innovation (CQUIN)

The Commissioners have applied the small-value contract exception set out in CQUIN Guidance and the provisions of SC38.8 therefore apply to this Contract.

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

A. Reporting Requirements

	Reporting Period	Format of Report	Timing and Method for delivery of Report
National Requirements Reported Centrally			
1. As specified in the DCB Schedule of Approved Collections published on the NHS Digital website at https://digital.nhs.uk/isce/publication/nhs-standard-contract-approved-collections where mandated for and as applicable to the Provider and the Services	As set out in relevant Guidance	As set out in relevant Guidance	As set out in relevant Guidance
National Requirements Reported Locally			
1. Activity and Finance Report (<i>note that, if appropriately designed, this report may also serve as the reconciliation account to be sent by the Provider under SC36.22</i>)	Dressings: Monthly Palliative Care: Annually	Via ONPOS system Invoice	Monthly via ONPOS Annually
2. Service Quality Performance Report, detailing performance against Operational Standards, National Quality Requirements, Local Quality Requirements, Never Events and the duty of candour	Monthly	Reported via the Friends & Family Test and NRLS	In line with national guidance.
3. CQUIN Performance Report and details of progress towards satisfying any Quality Incentive Scheme Indicators, including details of all Quality Incentive Scheme Indicators satisfied or not satisfied	N/A	N/A	N/A
4. Complaints monitoring report, setting out numbers of complaints received and including analysis of key themes in content of complaints	Annually	Reported via central Data collection	In line with national guidance
5. Summary report of all incidents requiring reporting	Annually	Report	Monthly (by exception)
Local Requirements Reported Locally			
Dressings: Service User Audit	Quarterly	Audit	As per specification

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

C. Incidents Requiring Reporting Procedure

Procedure(s) for reporting, investigating, and sharing lessons learned from: (1) Significant Events (2) Patient Safety Incidents (3) Serious Incidents

1.0 Serious incidents in Primary Care are rare, but it is acknowledged that all systems and processes have weaknesses and that adverse events will inevitably happen from time to time. A good practice will recognise harm and the potential for harm and will undertake swift, thoughtful and practical action in response to incidents, without blaming individuals.

Investigating all incidents enables practice teams to learn from events and ‘near misses’ and to highlight and learn from both strengths and weaknesses in the care they provide. Sharing learning from incidents also helps others in the system to avoid potential harm.

The involvement of the Clinical Commissioning Group in incident reporting is to support practices to report, investigate and learn from all incidents (regardless of seriousness or level of harm), advance a culture of patient safety across Primary Care and to disseminate learning within the system to benefit patients, staff and practices. Incidents are not a performance management tool and incident reporting should never become punitive. The principles of incident management are shown in figure one.

1.1 The provider shall comply with all national guidance and best practice on the management and reporting of Serious Incident Requiring Investigation (SIRI) in association with the Care Quality Commission (CQC) Registration requirements and in accordance with, but not limited to the following, as amended from time to time: The NHS England Serious Incident Framework – Supporting Learning to Prevent Recurrence March 2015 (as included in this schedule or subsequent updates as issued by NHS England and accessed via their website <https://www.england.nhs.uk/patientsafety/serious-incident/>

Never Events List Latest version as issued by NHS England and accessed via their website

<https://www.england.nhs.uk/patientsafety/never-events/>

Reporting a patient safety incident:

<http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/>

Being Open framework (CAS Reference NPSA/2009/PSA003; issue date 19th November 2009 DH gateway reference 13015):

<http://www.nrls.npsa.nhs.uk/beingopen/?entryid45=83726>

Checklist Guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation V5.1 – 29th May 2015

<https://www.igt.hscic.gov.uk/resources/HSCIC%20SIRI%20Reporting%20and%20Checklist%20Guidance.pdf>

Working together to safeguarding children (2015)

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/419595/Working_Together_to_Safeguard_Children.pdf

[The Care Act 2014. Care and support statutory guidance - safeguarding](#)

<https://www.gov.uk/government/publications/care-act-statutory-guidance/care-and-support-statutory-guidance#safeguarding-1>

NHS England Safeguarding accountability assurance framework

<https://www.england.nhs.uk/wp-content/uploads/2015/07/safeguarding-accountability-assurance-framework.pdf>

Notifying the HTA of a serious untoward incident (SUI) in the post mortem sector:

[Reporting an incident or concern | Human Tissue Authority](#)

Delivering a Single Operating Model for investigating mental health Homicide for the NHS in England. NHS England. April 2013

<https://www.england.nhs.uk/publications/reviews-and-reports/invest-reports/#report>

Mental Capacity Act 2005

<http://www.legislation.gov.uk/ukpga/2005/9/contents>

The Deprivation of Liberty Safeguards (DoLS)

<http://www.scie.org.uk/publications/ataglace/ataglace43.asp>

Managing Serious Incidents in National Screening Programmers:

<http://www.screening.nhs.uk/>

<http://www.screening.nhs.uk/quality-assurance>

[NPSA \(2008\) A risk matrix for risk managers – available via:
http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=60149](http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=60149)

[NHS England \(2016\) External Clinical Harm Review Handbook
http://www.londonstate.nhs.uk/wp-content/uploads/2016/01/External-Clinical-Review-Handbook.pdf](http://www.londonstate.nhs.uk/wp-content/uploads/2016/01/External-Clinical-Review-Handbook.pdf)

Seven steps to Patient Safety

<http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/>

2.1 Serious Incident Requiring Investigation (SIRI)

2.1.1 In broad terms, *serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare*

There is no definitive list of events/incidents that constitute a SIRI as this can lead to inconsistent or inappropriate management of incidents.

The national definition below sets out circumstances in which a serious incident must be declared. Every incident must be considered on a case-by-case basis using the description below. Inevitably, there will be borderline cases that rely on the judgement of the people involved.

2.1.2 Serious Incidents in the NHS include:

- Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:
 - Unexpected or avoidable death of one or more people. This includes
 - suicide/self-inflicted death; and
 - homicide by a person in receipt of mental health care within the recent past;
 - Unexpected or avoidable injury to one or more people that has resulted in serious harm;
 - Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:—
 - the death of the service user; or
 - serious harm;

- Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:
 - healthcare did not take appropriate action/intervention to safeguard against such abuse occurring; or
 - where abuse occurred during the provision of NHS-funded care. This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident
- A Never Event - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death. <https://www.england.nhs.uk/patientsafety/never-events/>
- An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:
 - Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues;
 - Property damage;
 - Security breach/concern;
 - Incidents in population-wide healthcare activities like screening and immunisation programmes where the potential for harm may extend to a large population;
 - Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
 - Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/unit closure or suspension of services); or
 - Activation of Major Incident Plan (by provider, commissioner or relevant agency)
- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation.

Where it is not clear whether or not an incident fulfils the definition of a serious incident, Practices and the Clinical Commissioning Group must engage in open and honest discussions to agree the appropriate and proportionate response.

2.2 Near Misses

2.2.1 *A Near Miss is an unplanned event that did not result in injury, illness, or damage – but had the potential to do so. Only a fortunate break in the chain of events prevented an injury, fatality or damage; in other words, a miss that was nonetheless very near*

- It may be appropriate for a ‘near miss’ to be classed as an SIRC, depending on the potential severity of harm that could be caused should the incident (or a similar incident) occur again
- Deciding whether or not a ‘near miss’ should be classified as an SIRC is based on an assessment of risk that considers:
 - The likelihood of the incident occurring again if current systems/process remain unchanged; and
 - The potential for harm to staff, patients, and the organisation should the incident occur again

2.2.2 Upon the occurrence of a Serious Incident Requiring Investigation (SIRC) the Provider will be required to comply with the provisions of this Schedule. In the event that the Provider fails to comply and is in breach of one or more provisions set out below, the Commissioning Organisation (on behalf of any Associate Commissioner(s)) shall apply the relevant provisions in SC33 (Service Conditions), and General Condition 9 (Contract management) as it sees fit.

2.2.3 The provider will understand and apply reporting and liaison requirements with regard to other agencies such as the police, Public Health England, Health and Safety Executive (HSE), Coroner, Education Partners, Local Midwifery Supervising Authority or Medicines and Healthcare products Regulatory Agency (MHRA) (see 1.2).

3.0 Reporting A SIRC

3.1 Evidence of compliance with the NHS England Serious Incident Framework will be monitored by CCGs. This evidence will, in part, be provided via the Strategic Executive Information System (SEIS), from receipt and review of the full root cause analysis investigation reports, from Serious Incident Requiring Investigation (SIRC) panels, and monthly submission of the quality scorecards/reports. The SIRC panel will complete the local CCG Serious Incident summary tool post CCG SI panel. The provider will share their SIRC performance and learning with their practice.

3.2 The practice will report SIs onto Datix under the Significant Event reporting system as soon as the incident comes to light. If the incident meets the SIRC threshold, the practice must **telephone the CCG Quality Team to notify them of the event on 023 8062 2741**. The CCG will report the SI onto SEIS on behalf of the practice within 2 working days:– the 2 working days standard for reporting an incident on SEIS is from the date at which the incident is

identified For this purpose the date the incident is identified is considered day zero.

3.3 The CCG will support the practice in developing a Terms of Reference for investigation and support the practice to provide a quality investigation report within 60 working days. A panel will be held chaired by the CCG with practice representation to determine the learning and outcome of the SIRI; this is determined by achievement of all the elements included in the quality SI checklist (appendix A) developed from the requirements in the SI framework (March 2015).

It is recognised that in some exceptional circumstances the completion and submission of SI reports may take longer than 60 working days, for example, where external multi-agency, Human Resource/Safeguarding and/or post-mortem/coroner input is required. It is expected that the provider will escalate these cases to the commissioner in good time and where these cases are agreed and understood, they will be excluded from contractual penalties. In such cases, the commissioner and provider will agree a suitable extension date for review of progress; this may or may not be extended depending on the circumstances.

The SIRI panel will actively identify and agree areas of learning that can be shared with other providers to promote quality improvement in the wider system, for example via the CCG newsletter or other routes.

3.4 In addition to complying with the Duty of Candour, providers will evidence through the root cause analysis report that patients, families and carers have been offered the opportunity to:

- Inform the terms of reference
- Be interviewed as part of the investigation
- Review a draft report

3.5 The Provider will ensure that clinical staff are appropriately trained in confidentiality including understanding what information can and cannot be shared, delivering duty of candour and developing the skills of empathy, openness and honesty to support this.

APPENDIX A

Commissioner SIRI Closure Checklist

All elements need to be present to enable closure of the investigation

**STEIS
NUMBER:**

**CCG PANEL
DATE:**

CLOSED/NOT CLOSED
(circle one)

Phase of investigation	Element	Present: Y / N	Comments
1. GATHERING AND MAPPING	a) Was the appropriate evidence used (where it was available) i.e. patients notes/records, written account?		
	b) Were interviews conducted?		
	c) Is there evidence that those affected (including patients/staff/victims/perpetrators and their families) were involved and supported appropriately?		
	d) Has Duty of Candour been met?		
	e) Has a timeline of events been produced?		
	f) Are good practice guidance and protocols referenced to determine what should have happened?		
	g) Are care and service delivery problems identified?		
2. ANALYSING INFORMATION	a) Is there evidence that the contributory factors for each problem have been explored?		
	b) Is there evidence that the most fundamental issues/ or root causes have been considered?		
	c) Have appropriate lessons been identified for learning?		
	d) Are there clear procedures for effective communication to facilitate sharing of learning across the organisation(s)?		

Phase of investigation	Element	Present: Y / N	Comments
3. GENERATING SOLUTIONS	a) Is there an action plan?		
	b) Does the action plan reflect all recommendations?		
	c) Is there a responsible person identified for each action?		
	d) Is there as timeframe for completion?		

APPENDIX B

EXTERNAL REPORTING in addition to reporting to Coordinating Commissioner

Incident type	Organisation receiving reports	Information reported
Central Alerting System CAS	Department of Health	Details of actions taken to address issues relating through alert
Child Protection	Local Authority: Local Safeguarding Children Board	Details of child protection related incident
Communicable disease outbreaks and other public health issues	Health Protection Agency (HPA)	Infection control and other public health incidents with details of spread of disease, contact etcetera.
Data losses and Caldicott contraventions	Information Commissioner	Description of contravention e/g/ patient details disclosed inappropriately.
Death certification: If doctor cannot give a proper death certificate of death: if the death occurred during an operation; if the death was due to industrial disease; if the death was unnatural or due to violence, or in other suspicious circumstances.	HM Coroner	Details about patient and full circumstances of death
Environment related incidents e.g. waste disposal	Environment Agency	Information on incidents e.g. type of waste and hazards
Fire related incidents. Estate related incidents	NHS Estates (NHSME)	Details of fire incident Injuries/death cause Type/quantity loss

Incident type	Organisation receiving reports	Information reported
Insurance claims and incidents	NHS Litigation Authority (NHSLA)	Details and cost of loss/claim.
Medical device related incidents	MHRA	Comprehensive details related to devices involved in incident including manufacture date, expiry date.
Medicine/blood related incidents	Medicines and Healthcare Products Regulatory Agency (MHRA)	Comprehensive details of incidents related to adverse drugs reactions. From 8 November 2005 it is mandatory to report a serious adverse event or reaction related to blood or blood components to the MHRA.
Mental Health Act: incident involving a patient detained under the MHA	Care Quality Commission	Details of the individual, type of section, occurrence
National Confidential Enquiries	Confidential Enquiry panels	E.g. for National Confidential Enquiry into Peri-operative deaths (NCEPOD) – details of death
Patient safety incidents	NRLS	All patient safety incidents including near-miss events
Post mortem – related incidents	Human Tissue Authority (HTA)	All serious incidents that occur at establishments in the post mortem sector holding an HTA licence.
Screening incidents: Diabetic retinopathy Abdominal Aortic Aneurysm Foetal Anomaly Infectious diseases in pregnancy Sickle Cell & Thalassaemia Newborn Blood Spot	Regional Director of Public Health Regional Quality Assurance Lead for the relevant programme Director of the relevant national screening programme Director of UK National Screening Committee	All incident information Comprehensive report with RCA and learning

Incident type	Organisation receiving reports	Information reported
Newborn Hearing Newborn & Infant Physical Examination		
Radiation related incidents	Environment Agency HSE Care Quality Commission (CQC)	All incident information. Quantity/type of radioactivity to comply with Ionising Radiation Medical Exposure Regulation (IRMER)
Residential/Nursing Care incident involving individual in a registered care home with or without nursing	Care Quality Commission	Details of individual, occurrence
RIDDOR incidents	Health & Safety Executive (HSE)	Injuries from work based accidents. Details of incident and persons involved.
Serious Adverse Blood Reactions and Events (SABRE)	MHRA	Details of incident including initial findings
Vulnerable adults	Local Authority Local Safeguarding Adults Board	Details of incident
Foundation Trust	Monitor	Details of incident including initial findings, final investigation report and outcome

Monitor:

Please note that some external reporting requirements are dependent on set criteria e.g. data loss and requirements to report to ICO. Reporting is required when meeting these criteria

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

F. Provider Data Processing Agreement

Not Applicable

SCHEDULE 7 – PENSIONS

Not Applicable

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