

HOME OXYGEN THERAPY SERVICE: SERVICE SPECIFICATION

4.1. INTRODUCTION AND GUIDANCE NOTES FOR OFFERORS

- 4.1.1. The integrated home oxygen therapy service provides a service to patients in their own homes and also supports patients working and travelling outside the home through the provision of ambulatory oxygen.
- 4.1.2 This Contract provision is being organised on behalf of the Department of Health (England) and the National Assembly for Wales by the NHS Purchasing and Supply Agency (hereafter referred to as NHSPASA). All correspondence and questions should be addressed to NHSPASA.
- 4.1.3 The Contract is to be split into 10 separate geographical oxygen service regions covering England and one region covering Wales.
- 4.1.4 The profile of the service described may change during the life of the Contract in the light of policy changes, service review and the development of new products. Any such changes will be discussed between the Department of Health, the Assembly, NHSPASA, NHS organisations, contractors and other appropriate stakeholders to determine all the implications of any such changes and what actions need to be taken if these are to be implemented. This assessment will include any financial consequences.
- 4.1.5 For guidance purposes, usage information is provided. All figures shown are historical figures and are not a guarantee of future activity, which may be subject to fluctuation.
- 4.1.6 Throughout the period of this Contract, the systems in place will be reviewed continually for improvement. The Contractor will play an important role in the continuing development of the service specification and is expected to support this activity.
- 4.1.7 Electronic ordering, payment processes and the provision of electronic order information is to be introduced during the contract period. Contractors are required to work closely with all stakeholders to develop and implement this process to agreed timescales.
- 4.1.8 Throughout the contract, contractors will be obliged to keep NHSPASA informed of how the service will be provided and how the key elements of the supply chain that make up the totality of the service will be met. This will include information relating to
- Source and range of equipment and accessories
 - Source of medical compressed and liquid oxygen and equipment
 - How the distribution service will be provided
 - Details of the customer service and helpline/freephone provision

Any changes to any elements of the total supply chain must be submitted to NHSPASA for authorisation in accordance with the contract terms and conditions.

4.2. THE OPERATIONAL PLAN AND PROCEDURES FOR REVIEW

- 4.2.1 Within 30 days of the start of each contract year, the Contractor shall deliver a plan to the authorised officer(s) for the oxygen service region in which the Contractor provides a service setting out all relevant information on how the service is to be provided during the forthcoming year. Once agreed, the plan

is to be known as the Operational Plan. A copy of the Operational Plan should be sent to NHSPASA, for information.

- 4.2.2 The Operational Plan should indicate all those steps that the Contractor intends to undertake in order to achieve the optimum provision of an integrated oxygen service within the region during the forthcoming year.
- 4.2.3 The Parties (ie the Contractor, NHSPASA and authorised officer(s) for the oxygen service region concerned) shall conduct formal meetings, to be known as Reviews, at no less than 6 monthly intervals. At each Review, the Parties will discuss their respective levels of satisfaction in respect of the Contract and any necessary action to address areas of dissatisfaction. Each Review will have a standing agenda including, but not limited to the following items:
- All service information to be provided on a monthly or other specified period basis. The format and content of this information is to be agreed with the contractors during the pre-contract period (See Sections 4.11 and 4.12.)
 - Such other issues that may be notified by any of the Parties in writing, at least ten (10) working days in advance of the Review.
- 4.2.4 At the Review, all Parties shall ensure that they have at their disposal all information and personnel necessary for a meaningful discussion of the agenda items.
- 4.2.5 The Contractor shall make arrangements for the Reviews, including those for ensuring that there are formal minutes of Review meetings. Such minutes to be issued to all Parties for agreement and counter signature. The signed minutes shall be an authoritative record of the matters discussed and agreed, but shall not be construed as varying the terms of this Agreement in any way.

National Review

- 4.2.6 NHSPASA will invite the Contractor, together with other contractors providing a home oxygen therapy service and the Assembly to attend an annual National Review meeting to discuss
- existing service provision
 - latest service developments
 - service improvement
 - any changes in NHS policy, legislation and other related issues that impact on the contract

The Review is also to be attended by NHS representatives from each home oxygen service region.

- 4.2.7 In addition to the Reviews outlined above, 18 months following the contract start date, NHSPASA will invite all contractors and other appropriate stakeholders to include the Assembly to participate in an overall review of the service to determine how the service has developed, to assess how the specification has been implemented in practice, to review the financial impact of the service and to agree the way forward for the remaining period of the contract.

4.3. CLINICAL SERVICE SPECIFICATION

4.3.1. Introduction

- 4.3.1.1 The NHS home oxygen therapy service provides oxygen therapy to patients in their own homes and also supports patients – through the provision of ambulatory oxygen – in working and travelling outside the home. Under the arrangements to introduce an integrated service, specialist clinical staff, as well as GPs, may order oxygen therapy for patients at home. However, it is likely that specialists will take the main responsibility for assessing and ordering home oxygen therapy as they have greater expertise and access to the necessary facilities to undertake patient assessments, particularly for long term and ambulatory oxygen needs.
- 4.3.1.2 Guidelines for clinicians assessing and prescribing oxygen therapy are set out in the Royal College of Physicians' (RCP) report: *Domiciliary oxygen therapy services, clinical guidelines and advice for prescribers*, issued in 1999. These guidelines are currently being updated by the British Thoracic Society and are likely to be published in late 2004.
- 4.3.1.3 The Contractor is responsible for providing home and ambulatory oxygen systems to meet the clinical needs of the patient as set out in the order for oxygen issued by the GP or the specialist clinical team. Information provided in this section aims to support the Contractor in providing oxygen systems that deliver oxygen in a safe and effective way to meet the patient's clinical needs as set out in an order for home oxygen therapy. It should be read in conjunction with all other sections of the specification. The Contractor will also need to be familiar with the 1999 RCP guidelines on domiciliary oxygen therapy services and the updated British Thoracic Society (BTS) guidelines (see paragraph 4.3.1.2 above) when these become available later in 2004. This document reflects the BTS guidelines currently being developed.

4.3.2 Long term oxygen therapy (LTOT)

- 4.3.2.1 Long term oxygen therapy (LTOT) relates to the provision of oxygen therapy for continuous use in a patient's home. Clinicians usually prescribe LTOT where this is needed for at least 15 hours daily, including at night. For children this may be 24 hours per day, but often this will cover sleeping periods only or overnight

4.3.3 Ambulatory oxygen

- 4.3.3.1 The integrated home oxygen therapy service extends the range of ambulatory oxygen equipment (including liquid oxygen) available to patients at home. Most patients receiving ambulatory oxygen will also be using LTOT. As with LTOT, the specialist clinical team will order ambulatory oxygen therapy following appropriate patient assessment. Ambulatory oxygen therapy may be ordered for patients on LTOT who are mobile and are able/need to leave the home – for example, to attend school, to travel to work, visit family or attend rehabilitation centres and outpatient clinics.
- 4.3.3.2. When ordering ambulatory oxygen, a specialist clinician will indicate the patient's assessment category based on the patient's level of mobility, the hours of ambulatory oxygen use required and the oxygen flow rate required. This information should guide the Contractor on decisions on the equipment to be provided. Where appropriate, the Order will also indicate a "ceiling" for high usage of ambulatory oxygen. Where the patient's usage extends beyond that set out in the Order, the Contractor should inform the specialist clinical team so that the patient's oxygen needs may be reassessed, as necessary.

4.3.4 Short burst oxygen

- 4.3.4.1 Short burst oxygen therapy (SBOT) refers to oxygen provided for intermittent breathlessness in those patients assessed as not requiring long term (LTOT) or ambulatory oxygen.
- 4.3.4.2 Traditionally, SBOT has been prescribed to relieve breathlessness where a patient is at rest or following exercise. A clinician may order SBOT for episodic breathlessness that has not been relieved by other treatments for patients with severe chronic obstructive pulmonary disease (COPD), lung disease and heart failure. A clinician may also order SBOT as symptomatic relief – for example, as part of palliative care or for those patients suffering from migraine or cluster headaches. A clinician will indicate on the Home Oxygen Order where short burst oxygen is required usually providing this information as a specific flow rate with an indication of intermittent need.
- 4.3.4.3 As there is no methodology for assessing short burst oxygen needs, clinicians will take into account other causes of breathlessness and may assess patients for LTOT or ambulatory oxygen therapy, as appropriate.
- 4.3.4.4 Currently, there will be some LTOT patients who make use of short burst oxygen to relieve breathlessness- for example, before or after climbing stairs. These patients will require assessment of all their ambulatory needs. Thus there should usually be no separate requirement to provide SBOT for those patients already assessed as needing LTOT and/or ambulatory oxygen therapy.
- 4.3.4.5 There will also be some patients currently receiving an oxygen cylinder service who have yet to undertake full assessment in relation to their long term or ambulatory oxygen therapy needs. GPs are likely to continue to order short burst oxygen therapy for these patients until their referral to the specialist team for assessment.
- 4.3.4.6 Updated clinical guidelines will recommend a review of the needs of patients receiving SBOT after one year. However, the pace of patient review/reassessment will depend, initially, on the number of existing patients currently receiving a cylinder service who require specialist assessment or reassessment and the ability of local clinical specialist services to meet local assessment needs. Therefore, assessment of existing patients currently receiving short burst oxygen therapy may take some time to complete.
- 4.3.4.7 For the first two years of the Contract, those patients currently receiving short burst oxygen therapy who have not undergone specialist assessment of their long term or ambulatory needs will continue to receive this service as ordered by the clinician. Where these patients are also receiving an ambulatory oxygen service, this should continue until the local specialist team has formally assessed ambulatory needs. Following assessment, the Contractor will receive a revised Home Oxygen Order. Up until that time, the contractor should continue to meet the short burst and ambulatory needs of these patients as advised by the clinician.
- 4.3.4.8 The arrangements set out in paragraphs 4.3.4.5 to 4.3.5.7 will be reviewed as part of the arrangements outlined in paragraph 4.2.7 and arrangements for the price review at Section 4.14.

4.3.5 Non Invasive Ventilation (NIV)

- 4.3.5.1. Some LTOT patients (fairly small in number) with respiratory disease require nocturnal mechanical support to assist their breathing and may also require

additional oxygen to feed into a ventilator. The clinician will provide information on supply for these patients with an order for LTOT oxygen.

4.3.6 Palliative care

4.3.6.1 Oxygen therapy may be ordered for patients who are terminally ill (for example, those with lung cancer or heart failure). Such patients may be clinically assessed as requiring LTOT or short burst oxygen therapy to provide symptomatic relief.

4.3.7 Children

4.3.7.1. Assessment of oxygen therapy requirements for children will differ, as most of the clinical conditions seen in children are not seen in adults - although sometimes there is an overlap between older children and young adults. Nearly all children receiving LTOT also require ambulatory oxygen, unless oxygen is only used at night, as their parents need to be able to leave the home. Children requiring ambulatory oxygen will need access to lighter weight solutions. The clinician may also specify other requirements – for example, a need to fix and maintain the stability of an oxygen delivery device to a pram/pushchair or a wheelchair.

4.3.7.2. Children will require provision of a low (0.1-1 l/min) or very low (0.025-0.2 l/min) flow rate meter, compatible with the oxygen delivery device. A humidification system may be required for those on flow rates 1 l/min, although it is recognised that for an oxygen concentrator this will only be effective at flow rates of 4 l/min or above, as water blocks the tubing at lower flow rates. The specialist clinical team will set out this information, as appropriate, on the oxygen therapy Order.

4.3.7.3. As with adults, clinicians are unlikely to order short burst oxygen therapy for children assessed for LTOT and ambulatory oxygen.

4.3.8 Training for parents/carers

4.3.8.1. The Contractor is required to provide appropriate training for parents and other carers in their responsibilities for supervising children receiving oxygen therapy (see also Section 4.3.14 below). Older children will also require training in the use of their oxygen equipment.

4.3.9. Training for School Staff

4.3.9.1. There is no legal duty that requires school staff to administer medicines; this is a voluntary role. For further information, the Contractor should refer to guidance issued by the Department for Education and Skills (DfES), which schools and Local Education Authorities (LEAs) are encouraged to adopt. *Supporting Pupils with Medical Needs: A good practice guide* is available on the DfES website: www.dfes.gov.uk. In Wales, the Welsh Office issued a similar guidance document in December 1997.

4.3.9.2 Arrangements to support school attendance by children receiving oxygen therapy should be made through the School Health Service. The GP or clinical specialist team will advise the Contractor of any arrangements where school staff have agreed to support a child whilst he or she is at school. Where there is such agreement, the Contractor is required to provide any necessary information and training for the school staff concerned on the safe and effective use of oxygen equipment used by the child on school premises. Training should be provided at a time that is convenient to school staff and will need to fit with arrangements made for the child's return to school.

4.3.9.3. Parents may raise the question of arrangements to support their children when at school directly with the Contractor or staff employed by the Contractor. This is not a matter for the Contractor to resolve. The Contractor and staff employed by the Contractor should refer the child's parent or other carer to the appropriate Primary Care Trust (in Wales, the Local Health Board (LHB)) or the child's doctor.

4.3.10 Oxygen flow rates and useage

4.3.10.1. An order for oxygen therapy should clearly state the oxygen flow rate requirement for the patient, together with the rate of usage and frequency of need. It should also indicate whether this relates to oxygen therapy based within the home and/or the numbers of hours that ambulatory oxygen is required. The clinician may indicate on the oxygen Order the need for a lower flow rate for some patients – for example, older patients, those with specific clinical conditions and children. The commonest flow rate is 2l/min but lower rates may also be set (for example, less than 1l/min used for children).

4.3.11 Orders for home oxygen made by GPs

4.3.11.1 GPs will continue to order oxygen therapy for their patients. However, it is considered that most GPs will do so to meet a patient's short burst or short term needs. For example where

- a GP or out of hours service considers that a patient does not need to be admitted to hospital but has an immediate need for oxygen until such time as arrangements can be made to assess longer term requirements
- a terminally ill patient, requiring oxygen therapy as part of symptomatic relief, is being cared for at home or in a hospice (ie palliative care).
- a patient's needs can be met by short burst oxygen therapy
- a patient requires home oxygen therapy whilst awaiting specialist assessment of longer term needs.

Where a GP orders oxygen therapy, the Contractor is required to provide the equipment to meet the patient's needs within the agreed response times. (See Section 4.6.)

4.3.12 The Clinical Specialist Team

4.3.12.1. Specialist services, including follow up and review services, are commissioned by PCTs or LHBs in discussion with clinical service providers, such as hospital trusts. At present, the specialist clinical team is usually hospital based but changes in the management of patients with chronic disease or long-term medical conditions may support other arrangements. The Contractor will need to be aware of local service provision, including patient follow up arrangements, as part of developing working relationships with PCTs/LHBs and hospital trusts in the oxygen service region.

4.3.12.2. Clinical good practice guidelines recommend specialist assessment of a patient's long term and/or ambulatory oxygen needs. The specialist team may order home oxygen therapy where

- a GP has referred a patient for specialist assessment
- a patient is discharged from hospital

- a patient's needs are re-assessed as part of clinical follow up and review services.

4.3.13 Hospital discharge

4.3.13.1. The discharge planning team co-ordinates plans for a patient's discharge from hospital including, where appropriate, assessment of the patient's need for long term oxygen therapy at home and/or ambulatory oxygen.

4.3.13.2. Long term or ambulatory oxygen therapy requirements may need to be assessed or reviewed once a patient's clinical condition has stabilised. Where this does not prevent a patient's discharge from hospital, an initial order for oxygen may be given until formal assessment for LTOT and/or ambulatory oxygen therapy can be undertaken. Patients will usually be reviewed between 5 to 6 weeks later when they are more clinically stable and able to undertake formal assessment. Where on hospital discharge, and prior to formal assessment, an initial Order is given to meet a patient's immediate needs, the Contractor is required to meet the initial Order requirement the day following receipt of the Order, between 8.30am and 5.30pm. If the time of the patient's discharge is not specified on the Order, the Contractor will wish to check with the discharge planning team, when the patient is expected to return home. (See also Section 4.6.)

4.3.14. Emergency and out of hours arrangements

4.3.14.1 Where a GP, or local out-of-hours service, is called out as an emergency a decision may be taken to order home oxygen therapy to meet a patient's immediate needs if it is considered that the patient does not require admission to hospital. The patient's GP may subsequently decide that the patient should be referred to the specialist team for assessment. The Contractor is required to meet the Order requirements within 4 hours of notification (See Section 4.6.) This initial order may continue until the Contractor is advised of any changes following formal assessment of the patient's long-term or ambulatory needs or is advised that the patient does not have a continuing need for oxygen therapy.

4.3.14.2. It is important that patients and their carers (like others) make proper use of NHS emergency or out of hours arrangements, so that these services are free to respond to urgent need as a priority. Therefore, these services should not be used where patients have allowed insufficient time to order supplies to meet their needs or where the Contractor is able to respond to concerns about equipment etc. NHS clinical staff will provide information to patients and carers about accessing healthcare services as part of the patient's care education programme (see Section 4.3.17). However, the Contractor will also wish to draw patients' attention to information on ordering supplies or contacting the Contractor where supplies are required at short notice, as part of the training provided for patients and/or their carers. (See Section 4.3.17, Section 4.4.4 and Section 4.6.6).

4.3.15 Patients receiving home oxygen therapy in other settings

4.3.15.1. Some patients receiving home oxygen therapy may be cared for in settings other than their own home. For example, the patient may live within a residential care home or nursing home, or be admitted to a hospice for care and treatment at the end stages of his or her life. A patient may be admitted to a care home or hospice temporarily to provide a period of respite for his/her family or carer. Or it may be decided, as part of hospital discharge plans, that a patient should be transferred to residential, nursing home or hospice care rather than returning home. In these circumstances, the

patient's GP or a member of the clinical specialist team should inform the Contractor of any changes in the patient's address.

4.3.16 Oxygen equipment

4.3.16.1. To ensure best use is made of developing technologies and the Contractor's expertise and experience, an Order for home oxygen will not usually indicate specific requirements as to the mode of delivery and associated oxygen equipment. However, in some circumstances, the clinician may indicate the following requirements:

- Use of a conserving device. Individual patient assessment will include the use of such equipment and, in some cases, the clinician may decide that this is not required. However, it may be assumed that a conserving device could form part of delivery unless contraindicated in the Order.
- Use of a specific type of nasal cannulae or mask. For example, where the clinician is aware of any sensitive reactions of individual patients (eg dermatitis) and young children
- The need for a humidifier

4.3.17 Information for patients and carers

4.3.17.1. The clinical specialist team will provide patients with some training in the use of equipment, as part of the care education programme (see below). However the Contractor must ensure that arrangements are in place to provide patients and their carers with appropriate information and training in the use and maintenance of equipment provided at home. Where home oxygen therapy is ordered for children, the Contractor is required to ensure that information and training is provided for the child and his/her parents and other carers on the use of oxygen equipment.

Information provided by clinicians: the patient/carer education programme

4.3.17.2. Clinical good practice guidelines highlight the need for information for patients (and carers) about their clinical condition and the provision of oxygen therapy as part of their care plan. Thus, those treating patients will develop a patient and carer education programme that is likely to include:

- an explanation of the requirements and principles supporting LTOT and ambulatory oxygen
- discussion and assessment of the patient's individual needs and abilities
- discussion of the installation of oxygen equipment in the patient's home
- a warning as to the dangers of smoking
- the dangers presented by open and gas fires
- the need for the patient or carer to inform house and car insurance of the use of oxygen
- the need for the patient to inform the fire brigade that oxygen equipment is used within the home

- contact telephone numbers for the clinical team
- Information on ordering supplies and emergency arrangements
- advice on travel
- an assessment of the parents' ability, with training, to support a child receiving oxygen therapy at home

Patient/Carer Information and Training to be provided by the Contractor

4.3.17.3. The Contractor is required to provide information and appropriate training to patients and their carers on the use of oxygen equipment provided or installed in the patient's home or other setting (eg nursing home or hospice). This should include

- written instruction, supported by appropriate training in the safe and effective use of the oxygen equipment provided, particularly the dangers of smoking and the potential hazards presented by open and gas fires
- discussion of the installation of oxygen equipment in the patient's home
- a warning as to the dangers of smoking
- the dangers presented by open and gas fires
- the need for the patient or carer to inform house and car insurance of the use of oxygen
- the need to inform the fire brigade that oxygen equipment is within the home in the event of a fire
- advice on the use of any instruction manual(s) or other service information provided
- information on ordering supplies and arrangements for contacting the contractor in an emergency (eg machine failure)
- a manned 24 hour/7 days a week free phone contact number
- advice on travel

4.3.17.4. The Contractor will need to ensure that, as far as possible, the advice and information provided to patients and carers is consistent with, and complementary to, the advice and information provided by the clinical specialist team or the patient's GP.

Language and other needs

4.3.17.5. The Contractor should offer written information to meet the main language needs within the oxygen service region – other than English. The Department of Health, the Assembly and the NHS recognise that all patients should be

able to access NHS services in a way that recognises their cultural and information needs. Most PCT's, LHB's and NHS trusts provide health information in a number of languages. The contractor should consult PCTs/LHBs within the region on local requirements. Within Wales the Contractor shall supply information and training in Welsh and/or English depending on the patients' needs (including but not limited to information referred to in Clauses 4.3.9.2, 4.3.17.1, 4.3.17.3, 4.4.2.7, 4.4.3.2, 4.4.4, 4.6.4.3 and 4.7.5). Information and training should also be provided in a way that meets the needs of visually impaired patient and those with a hearing disability.

4.3.17.6. In developing information for services users, the Contractor may wish to take into account advice provided in the Toolkit for Producing Patient Information that is available on www.nhs.uk/nhsidentity. The British Lung Foundation provides support to people living with lung disease, and their carers, in hospital and in their homes. As such, it can provide advice on developing patient information. Their address is:

The British Lung Foundation
73-75 Goswell Street
LONDON EC1V 7ER

And the website is: www.britishlungfoundation.com

4.3.18 Patient follow-up and review

4.3.18.1 Primary Care Trusts/Local Health Boards commission local patient follow-up and review services. The Contractor should check local arrangements for the provision of these clinical services with the PCT/LHB.

4.3.18.2. However, the Contractor should also be aware of clinical good practice guidelines on the periodic review of a patient's oxygen needs. These recommend

- A home visit made by a member of the local respiratory care services team between 2 and 4 weeks after an initial oxygen order and subsequent visits at 6 monthly intervals
- A review undertaken by the clinical specialist team 3 months after an initial order to assess the patient's condition, make any necessary changes to the order and to review the continuing need for oxygen therapy.
- Short burst oxygen therapy. All patients receiving short burst oxygen therapy should be seen at least once a year by the hospital specialist or GP to review continuing need.

4.3.18.3 Following clinical review of a patient's home oxygen needs the GP or clinical specialist team may issue a revised Order for oxygen therapy or may decide that the patient no longer requires oxygen therapy. Where a Contractor is already providing a service to a patient, this should continue unless he receives a revised Order for that patient or is advised that equipment may be removed from the patient's home (see Section 4.3.19 and Section 4.6.5).

4.3.19. Discontinuing home oxygen therapy

4.3.19.1. Where continuing patient clinical assessment and review indicates that a patient no longer requires oxygen therapy, or a patient has died, the Contractor will be informed, with reasonable time given for the removal of oxygen equipment from the patient's home (see Section 4.6.5).

TECHNICAL SPECIFICATION

4.4.1 Introduction

- 4.4.1.1. The home oxygen therapy service covers the provision of a medical oxygen service, including ambulatory oxygen, to patients at home.
- 4.4.1.2. It is the responsibility of the Contractor to provide home and ambulatory oxygen systems in a way that ensures a safe and effective supply of medical oxygen to patients.
- 4.4.1.3. The Contractor is required to have in place safe and effective systems and procedures to supply and support the use of oxygen in the home, including the installation, use and maintenance of equipment within the proposed location and for ambulatory use. As part of the service, written, user-friendly, guidance supported by necessary training should be available to clinicians ordering oxygen, the patient and his/her nominated carer to ensure that any risks associated with the use of the equipment are minimised.
- 4.4.1.4. The Contractor is required to put in place a formal record and review system covering all aspects of the initial installation of any oxygen equipment, including arrangements for each installation to be signed off by the Contractor and the patient/carer.
- 4.4.1.5. To meet the above requirements all Contractors should have in place a risk assessment policy for their home oxygen therapy service. This should include a system for monitoring and reporting adverse incidents involving equipment used by patients, carers and clinical staff (See Section 4.11) and that also takes account of guidance set out in the Domiciliary Oxygen Safety Group report ***Domiciliary Oxygen Risk Assessment***.
- 4.4.1.6. All Contractors are required to ensure that the home oxygen therapy service provided meets the standards set out in the following European Industrial Gases Association documents:

Safe use of medical oxygen systems for supply to patients with respiratory disease: IGC Document 89/02/E

Safe supply of transportable medical liquid oxygen systems by healthcare service providers: IGC Document 98/03/E

- 4.4.1.7 All Contractors take account of the Hospital Technical Memorandum HTM20/22 Chapter 8 – Storage and handling of cylinders.
- 4.4.1.8. The systems and procedures put in place by Contractors must as a minimum include effective arrangements to cover the following:
- Hazards and safety precautions with oxygen therapy supply systems
 - Installation set up of oxygen therapy supply systems
 - Medical oxygen incidents
 - Maintenance of oxygen therapy supply systems and equipment

- Medical oxygen cylinder supply in relation to storage, handling, use and transportation
- Medical liquid oxygen supply in relation to storage, handling, use and transportation
- Oxygen concentrator supply systems in relation to installation and use
- Provision of appropriate patient/carer documentation
- Provision of written guidance, supported by appropriate training for patient and their carers
- the management of the oxygen supply to the patient to ensure that the patient does not run out of oxygen, whether this be the primary or secondary source (eg back-up cylinder)
- a system for monitoring and reporting adverse incidents involving patients, carers or healthcare professionals.

4.4.1.9. Each Contractor must provide the NHSPASA, with the name and contact details of their nominated Qualified Person/Responsible Person or other nominated member of the management team who will be directly responsible and accountable for all safety issues.

4.4.1.10. Within 3 months of the Contract start date, each Contractor is required to notify all local fire authorities within the geographical oxygen service area to discuss with these authorities any local protocols to be adopted. The results of these discussions must be provided to the NHSPASA, within 6 months of the Contract start date.

4.4.2. Equipment

4.4.2.1. General

- Medical oxygen, in liquid or compressed gas form, must be supplied under an appropriate marketing
- Any equipment used in the provision of the home oxygen service must be CE marked and comply with the requirements of the Medical Devices Directive 93/42/EEC or be covered by a marketing authorisation for medical oxygen as above
- The Contractor shall determine the mode of supply, specifically whether liquid, cylinder or concentrator and, where there is no contraindication, the provision of a conserving device.
- The Contractor is responsible for ensuring that the equipment supplied is suitable to meet the needs of the patient as set out in the home oxygen Order.
- The medical oxygen supply shall be connected to a domiciliary piped distribution system unless the patient or his/her representative refuses consent for this work to be undertaken. Where consent is withheld, the Contractor must obtain the patient's or his/her representative's written agreement that the work to install a distribution system should not be carried out.

- All equipment provided must be disability friendly. Where reasonable, all a patient's disabilities should be taken into account, including the supply of appropriate alarm systems that take account of a patient's disability.
- Any proposals for change to the equipment to be supplied or used within the home oxygen service must initially be submitted to the NHSPASA for consideration. Introduction will require prior written approval from the NHSPASA.

4.4.2.2. Cylinders

- Cylinders provided with ambulatory oxygen systems must be supplied with an integral regulator/flowmeter from the Contract start date.
- For a period of 2 years from the Contract start date, the Contractor may continue to provide a cylinder with a valve and separate regulator in the following circumstances:
 - To meet short burst oxygen requirements
 - Emergency cylinder use
- For the full term of the Contract, the Contractor may continue to provide a cylinder with a valve and separate regulator in the following circumstances:
 - Back up cylinder supply, where a patient is using a concentrator
 - Low flow (0.025 to 0.2 litres per minute) paediatric needs requiring special low flow headsets on non-integrated cylinders
- Where non-integrated cylinders are supplied, each cylinder must be provided with its own regulator /flowmeter which has been fitted by the Contractor. Patients and their carers should not fit regulators to cylinders. It is unacceptable for the Contractor to place a requirement on a patient or his/her carer to fit a regulator on any cylinder supplied by the Contractor.
- The number of cylinders held by each patient at any one time will be dependant on the order for oxygen therapy, the frequency of deliveries and the constraints of the patient's home. However, storage of empty and full cylinders in normal use at any private home should not exceed a maximum of 8 cylinders in any one location. The Contractor will be required to undertake a risk assessment for the use of more than 8 cylinders in use in a private homes, residential care homes, nursing homes, hospices, etc to determine the appropriate level of cylinder storage
- The provision of conserving devices is optional. These may be provided at the discretion of the Contractor unless contraindicated in the Order.
- The transfilling of compressed medical oxygen cylinders is not permitted. The filling of cylinders in the patient's home

with either compressed medical oxygen or oxygen-enriched air is also not permitted.

4.4.2.3. Concentrators.

The oxygen concentrator provided must:

- Meet **BS EN ISO 8359:1997 Oxygen concentrators for medical use: safety requirements**
- Be connected to an existing 230V AC power outlet that has been checked for suitability prior to installation. If the electricity testing shows faults in the electrical supply, the prescribing authority and the householder are to be notified and an alternative system of supply agreed with the patient and prescribing authority. Where an alternative supply is required until such time as faults in the electrical supply can be rectified, the Contractor should seek agreement from the appropriate PCT/LHB on whether this is to be regarded as an ongoing emergency supply, with costs submitted on that basis.
- Be subject to routine visits, made at least every 6 months, to each installation to check the overall performance of the installation, oxygen concentration, pipelines and all associated accessories according to the manufacturer's guidelines.
- Be capable of fully meeting the patient's oxygen therapy needs set out in the home oxygen Order.
- Incorporate a non re-settable hours elapsed meter calibrated in hours to determine the time the machine has been run
- Be fitted with an appropriate visual and/or audio alarm

4.4.2.4. Concentrator - Back up supply

- When the Contractor provides a concentrator, the Contractor must ensure that a back up supply equivalent to 8 hours of oxygen at the prescribed flow rate is available at all times for use in the event of concentrator failure or electricity supply failure.
- Back up oxygen supply should include any accessories, written instructions for use and any training required by the patient and his/her carer.
- A stand may be provided where requested by the clinician ordering oxygen therapy or where it is considered to be essential during the Contractor installation of equipment in the patient's home.
- The back up supply should receive regular 6 monthly maintenance checks to ensure that a full supply continues to be available for the patient's use.

4.4.2.5. Ambulatory oxygen provision

- Ambulatory oxygen provision must fully meet the needs of the patient as set out in the home oxygen Order
- Ambulatory oxygen provision must be supplied with either a back pack or side holster pack
- Weight – standard provision: cylinder with a minimum capacity of 400 litres, regulator, carrying pack and oxygen not to exceed 4.0 kg. If a conserving device is added the total weight must not exceed 4.5 kg
- Weight – lightweight provision (for example, for use by a child, adult with slight build or those with physical frailty): the cylinder with a minimum capacity of 250 litres, regulator, carrying pack and oxygen should not to exceed 3.0 kg. If a conserving device is added the total weight must not exceed 3.5 kg
- Alternatives to the back pack or side holster pack must be available for patients with particular needs or who find the back pack or side holster pack difficult to wear

4.4.2.6. Liquid oxygen

- The liquid oxygen supply system should consist of a base unit and a portable unit that can be filled from the base unit for ambulatory use. The portable unit will only be required where there is a need for ambulatory oxygen supply
- The Contractor should determine the method of filling/exchange of the liquid oxygen storage vessel.

4.4.2.7. Conserving device

- The use of a conserving device is optional. This may be provided at the discretion of the Contractor unless contraindicated in the Order. Where a device is provided, the Contractor must ensure that the patient and/or carer have appropriate information about its use.

4.4.2.8. Oxygen distribution system

The oxygen distribution system should meet the following requirements:

- The provision of 3/16" fir tree terminal outlets
- The use of anti-kink piping
- The securing of piping normally by means of fixing to the walls within the house. Piping should be fixed at least every 500mm for straight runs. Where a patient or his/her representative expresses a wish that piping should not be secured, he or she must support this request with a written statement confirming their position. Otherwise, fixed piping should be installed.

- The provision of firebreak mechanisms as an integral part of all new installations. Firebreaks must be incorporated within existing installations at the first visit after the start of the contract.
- A maximum length of piping including the fixed piping from oxygen device to the patient of 15 metres
- The routing of the piping should be in accordance with the patient's requirements, as far as is practicable, but should avoid sources of heat or other situations which may compromise the safety, integrity or effectiveness of the system
- The provision of robust, gas tight pipeline connections
- The installation of terminal outlets, located in accordance with the patient's requirements. A terminal outlet must be provided at each domiciliary pipeline outlet. Normally, each installation should have two terminal outlets, but between one and four outlets may be provided at the patient's request.
- Terminal outlets that contain an integral switch must be wall mounted and form a connection to the nasal cannulae or facemask or to a humidifier. In addition, these must be easy to operate and give a clear visual indication of both the on and off position.

4.4.2.9. Accessories

The following accessories shall be provided:

- An appropriate length of crush resistant tubing to meet the patient's requirements.
- A face mask, suitable for use with the installation, where requested in the Order
- A humidifier, where requested in the Order. A new humidifier must be supplied for each installation. This should be positioned as close as possible to the nasal cannulae or face mask.
- Neonatal flowmeters at the flow rate requested on the Order
- Under normal circumstances, a patient will require one mask/cannula per month. The initial supply should be sufficient to meet the patient's needs until the next planned visit

All accessories provided (such as nasal cannulae and distribution tubing) shall be new for each installation.

4.4.3 Installation

4.4.3.1. General

On receipt of the Order, the Contractor shall undertake an initial risk assessment to determine how the Order can be dispensed safely. The Contractor shall ensure that:

- Arrangements are put in place for the correct installation of a safe and reliable system to provide a medical oxygen supply that meets the needs of the patient as set out in the home oxygen Order.
- The medical oxygen supply is installed in a suitable location in the patient's home.
- The medical oxygen supply is located in agreement with the patient.
- The patient and/or carer receives written instructions, together with any necessary training, in the use of the equipment provided so that the patient is able to comply with the clinical assessment of his or her oxygen needs and all safety procedures
- The patient and/or carer are aware of any ongoing maintenance and hygiene processes required to be undertaken by the patient/carer to ensure that the equipment operates safely and effectively.
- The patient and/or carer are aware of arrangements for ordering supplies and contacting the Contractor in an emergency (eg machine failure).

4.4.3.2. Training and guidance

The written guidance provided and any training required by the patient and/or carer should include, but not necessarily be restricted to:

- The hazards associated with using the equipment. In particular, smoking in the vicinity of the oxygen supply, the need for adequate ventilation, the need to avoid contamination of the equipment with oils and greases and the need to handle the equipment with clean hands
- Any additional hazards that are associated with the particular equipment that has been supplied to the patient
- The provision of appropriate information and documentation to ensure that the patient and/or carer is adequately trained to use the equipment in an effective, correct and safe manner from delivery of the equipment to the patient's home to its eventual collection or removal by the Contractor
- Full written information to be provided to the patient and/or carer of the steps to be taken in the event of an adverse incident with the oxygen supply

- The general principles to be applied for the safe storage and handling of the equipment to be supplied
- The precautions to be taken if the equipment is to be used and/or transported in a vehicle
- Full written information to be provided to the patient and/or carer on the steps to be taken in the event of using the equipment outside the patient's home (eg office, school, cinema, shopping etc).

4.4.4. Documentation

The Contractor shall provide a range of documentation to advise and inform clinicians ordering oxygen therapy, the patient and/or carer on the safe and effective use of the equipment provided. This must include:

- Guidance in the form of Patient User Training Cards for each method of supply of oxygen, with clear, user friendly information on its safe use within a home environment
- A Patient User Instruction Card that may be used as a reference card for the safe use and operation of the equipment provided
- Information on the potential hazards associated with the use of medical oxygen supply with particular emphasis on the dangers of smoking, open or gas fires and other safety issues
- The provision of User Instruction Manuals for the equipment installed. These should provide detailed instructions – in a user-friendly way - on the safe, effective, use and maintenance of the equipment provided
- A list of all the equipment provided at installation, together with information on obtaining additional supplies and arrangements for contacting the Contractor in an emergency (eg machine failure)
- Advice on the steps to be taken where an adverse or other incident affects the patient's oxygen supply
- Advice on the safe and appropriate method of handling the equipment provided
- Information on the use of oxygen equipment in vehicles
- All equipment provided should clearly and prominently display basic operating instructions, essential warning notices and details of service and emergency telephone numbers.
- A contact telephone number to arrange collection or removal of oxygen equipment (for example, where a patient has died).

4.4.5 Quality assurance

Contractor activity under this Contract must comply with a recognised quality assurance system that covers operational systems and procedures, such as BS EN 13485:2003 Medical Devices – Quality Management Systems- Requirements for Regulatory Purposes or ISO9001 or their equivalent

4.5. TRANSITIONAL PERIOD: PRE AND POST CONTRACT START DATE

4.5.1. Introduction

4.5.1.1. The Contractor is required to work with all Parties to secure the effective management of changes in service delivery with minimal disruption of the home oxygen therapy service to existing and new patients. This should include effective and collaborative working with outgoing contractors currently providing a home oxygen cylinder or concentrator service.

4.5.1.2. The Contractor is also required to work, as necessary, with outgoing and incoming contractors in adjoining oxygen service regions. (For example, where a patient lives on the borders of one oxygen service region but may currently receive an oxygen cylinder service from a pharmacy located in an adjoining region.)

4.5.2. The transitional period

4.5.2.1. A period of time will be agreed with the incoming Contractor to be known as the transitional period. This will have two stages:

- **A pre-contract period** in which the Contractor is required to make all necessary preparations to deliver an integrated home oxygen therapy service from the Contract start date. The pre-contract period will commence with the date of the notification of award of the Contract and end on the agreed Contract start date.
- **A post contract start date period** to allow the Contractor to complete arrangements for the delivery of the service to those patients whose needs are being met by outgoing contractors. This second stage of the transitional period will commence with the Contract start date and continue for a period of 6 calendar months

4.5.3. Pre contract period

4.5.3.1. In this period, the Contractor is required to put in place comprehensive systems for the provision of a safe, effective, and reliable home oxygen therapy service. In doing so, the Contractor should ensure that service delivery plans are developed in discussion with other stakeholders. These include

- Primary Care Trusts (PCTs) and Local Health Boards (LHBs), which have responsibility for commissioning healthcare services in their localities. Within the oxygen service region, PCTs/LHBs will lead and manage the introduction locally of the new integrated home oxygen therapy service.

- Strategic Health Authorities, which will co-ordinate the introduction of service changes across the oxygen service region(s).
- GPs ordering oxygen therapy for their patients
- NHS Trusts. From the contract start date, clinical staff working in the hospital service can order oxygen therapy for patients living at home
- The Prescription Pricing Authority (PPA) - England. The Contractor is required to submit invoices for service payment to the PPA. See section 4.15.
- Health Solution Wales and the Business Services Centre. For Wales, invoices should be submitted to Health Solutions Wales (HSW) and service management information to the Business Services Centre.
- Pharmacies currently providing an oxygen cylinder service
- NHSPASA which will be maintaining an overview of progress across all regions

4.5.3.2. In preparing to deliver the required service from the Contract start date the Contractor should take into account current arrangements for the home oxygen therapy service. The patient's requirements are set out by the GP on the FP10 or WP10 (in the case of Wales) prescription form.

4.5.3.3. During this period, GPs will continue to use these arrangements for both existing and new patients. The FP10/WP10 may cover the provision of oxygen for a period of time that may straddle the Contract start date. The Contractor is required to ensure that working arrangements developed with PCTs/LHBs and outgoing contractors providing a cylinder or concentrator service take account of the need to maintain a reliable service for patients for the period specified on the FP10/WP10 form where this overlaps with the Contract start date.

Local Arrangements for Cylinder Oxygen (Community Pharmacies) and Concentrators

4.5.3.4. The Contractor should develop timely and effective working partnerships with PCTs/LHBs in the oxygen service region. In this way he will be aware of local PCT/LHB arrangements with community pharmacies for the delivery of an oxygen cylinder service and arrangements with the contractor providing the existing oxygen concentrator service in the region.

Arrangements to maintain cylinder oxygen supply

4.5.3.5. Within 3 months of the start of the pre-contract period, a meeting will be held with representatives of all Parties to discuss and agree a continuing cylinder supply chain to meet the needs of patients in each oxygen service region.

The transfer of patients receiving a concentrator service from outgoing contractors

4.5.3.6. The Contractor should discuss and agree plans with relevant stakeholders in the oxygen service region for the transfer of existing patients receiving a

concentrator service from outgoing contractors. The transfer of existing patients to the incoming contractor should be achieved within six (6) months of the Contract start date. Plans should include arrangements agreed between incoming and outgoing contractors to reduce or avoid unnecessary disruption to existing patients that may be caused by the removal and replacement of installations. These arrangements may include mutual written agreements (including reimbursement of costs) between incoming and outgoing contractors to transfer the delivery of a concentrator service to an existing patient or a new patient to the incoming contractor prior to the contract start date. Where there are such agreements, the delivery of a concentrator service to patients will remain the responsibility of the outgoing contractor until the new contract start date.

4.5.4. Post contract start date period

4.5.4.1. During this second stage, the Contractor is required to continue to work with stakeholders (see section 4.5.4) and outgoing contractors providing a cylinder or concentrator service to implement local service delivery plans. Action taken should include agreement reached on managing the oxygen cylinder supply chain (see paragraph 4.5.3.5. above).

4.5.4.2. The Contractor is required to provide a monthly progress report to the PCTs/LHBs within the oxygen service region on progress made in providing an integrated home oxygen service to patients living within the region. As a minimum, this should include:

- the number of new patients provided with a cylinder, concentrator or ambulatory oxygen service
- the number of existing patients that have transferred to the Contractor's integrated service. and are provided with an oxygen concentrator and /or oxygen cylinder service
- the number of existing patients still receiving a service from community pharmacies or the outgoing concentrator service contractor(s)
- a brief summary of progress against plan, including any problems that remain to be resolved
- details of any complaints made by patients or carers during the month and any action taken to resolve these to the satisfaction of the patient.

4.5.4.3. At the end of this six (6) month calendar period, the Contractor is required to submit a final report to each PCT/LHB in the oxygen service region. This should confirm whether or not the Contractor is providing a service to all patients receiving home oxygen therapy prior to the Contract start date, together with details of such patients. Where necessary, the Contractor should also provide the PCT/LHB with an action plan to complete the transfer of any patients that continue to receive a service from outgoing contractors.

4.5.4.4. From the Contract start date, GPs and other clinicians should make use of a separate Home Oxygen Order (ie not form FP10/WP10) when ordering oxygen for their patients on or after that date. The Home Oxygen Order form will set out the patient's clinical needs. The Contractor will be kept informed of action to bring the Home Oxygen Order into use during the pre contract transitional period.

4.5.5 Responsibilities of the Contractor providing an integrated oxygen service in accordance with the specification and terms of this Contract, where the Contractor has been unsuccessful in tendering for renewal of the Contract in 2010 (ie he is an outgoing contractor).

- 4.5.5.1. Subject to the provisions of paragraph 4.5.5.2-4.5.5.4, the Contractor, if required, shall continue to provide all the services specified in this Contract in accordance with the specification and the terms of this Contract for a period not exceeding 9 months beyond the expiry date of this Agreement. The Contractor will continue to be entitled to receive in respect of those services the sums set out in the Contract as if this Contract had not expired. The overall period during which the Contractor may be required to continue the provision of the specified services shall be determined by no later than one month before the expiry date of this Contract.
- 4.5.5.2. The Contractor shall not provide any services specified in this Contract to any patient for whom a clinician has prescribed oxygen after the expiry date. However, the Contractor may be required to provide all the services laid down in this Contract to any patient for whom a clinician has prescribed oxygen on or before the expiry date. In doing so, the Contractor shall be entitled to receive in respect of those services the sums set out in the Contract, irrespective of the date on which the service is provided, including completion of any installation.
- 4.5.5.3. Following determination of the specific period during which the Contractor shall continue to be responsible for the provision of services, the Contractor shall complete a schedule containing the names and addresses of patients to whom he is currently providing those services. The schedule shall be submitted to the relevant PCT(s)/LHB(s) and to the Prescription Pricing Authority or Health Solutions Wales not later than 6 weeks before the expiry of that period.
- 4.5.5.4. On receipt of such a schedule, the PCT/LHB shall send a copy to the Contractor's successor. The Contractor shall make such arrangements as are necessary with the Contractor's successor to ensure that responsibility for the provision of the services to each of the patients named in that schedule is transferred to the Contractor's successor by the final date of the period determined. The arrangements made shall ensure that there is no hiatus in the provision of those services to those patients.

4.6 SERVICE AND RESPONSE TIMES

4.6.1. Long term and ambulatory oxygen therapy

- 4.6.1.1. Where a patient has long term oxygen and/or ambulatory oxygen therapy needs, as set out in the clinical service specification, an authorised member of the specialist clinical team or the GP practice will issue a home oxygen Order to the Contractor. The Order should include details of the patient's name, address (including postcode) and telephone number, his/her GP and the patient's oxygen therapy requirements.
- 4.6.1.2. Within **24 hours of receipt** of the Order, the Contractor should provide the authorised member of the specialist team or GP practice with written confirmation of the arrangements being made directly with the patient to provide and/or install the most appropriate oxygen therapy modality in the patient's home. This written confirmation should be copied to a named individual at the appropriate PCT/LHB.

- 4.6.1.3. Within **3 working days of receipt** of the Order, the Contractor shall provide the patient with the oxygen modality required, including completion of any necessary installation, and meet any training needs.
- 4.6.1.4. Following clinical assessment for long-term oxygen and/or ambulatory oxygen therapy, the Order may indicate that the patient requires immediate provision of oxygen. Where this is required, the Contractor shall ensure that suitable oxygen provision to meet the patient's immediate needs is delivered to the patient's home the day following receipt of the Order, between 8.30am and 5pm. Such provision should continue until the Contractor is able to provide the oxygen modality required within the specified 3 working days.
- 4.6.1.5. Hospital Discharge: A patient may be discharged from hospital but considered to be not yet well enough to undertake full oxygen therapy assessment. However, where oxygen therapy is required to meet a patient's immediate needs prior to full assessment, the Contractor shall ensure that suitable oxygen provision is delivered the day following receipt of the Order, between the hours of 8.30am and 5pm. This provision should continue until the Contractor receives a revised Order, following full assessment of the patient's oxygen needs.
- 4.6.1.6. Where an Order is issued for emergency oxygen provision, this should be delivered within 4 hours of receipt of the Order.

4.6.2 Short burst oxygen therapy

- 4.6.2.1. An authorised member of the specialist team or the GP practice ordering short burst oxygen for a patient will provide the Contractor with an Order setting out the patient's name and address, post code, telephone number, details of his/her GP and details of his/her short burst oxygen requirements. The Contractor should ensure that suitable provision for the supply of oxygen is made, including any information or training requirements, the day following receipt of the Order between the hours of 8.30am and 5pm. Where this is ordered in an emergency, oxygen should be provided within 4 hours of receipt of the order.
- 4.6.2.2. Within 48 hours of receipt of the Order for SBOT, the Contractor should provide the authorised member of the specialist clinical team or general practice and a named person at the relevant Primary Care Trust/Local Health Board, with written confirmation of completed arrangements for the provision of oxygen.

4.6.3 Orders made by the specialist clinical team

- 4.6.3.1. Clinical good practice recommends assessment by a specialist for patients with long term or ambulatory oxygen therapy needs. A GP may refer his/her existing patients receiving oxygen therapy to a specialist for re-assessment and review and any new patients for assessment. When ordering home oxygen therapy, a member of the specialist clinical team should send a copy of the Order to the patient's GP to ensure that the GP is kept informed of how the patient's care needs are being met..

4.6.4 Delivery and/or Installation of Oxygen Therapy Equipment

- 4.6.4.1. The Contractor should request the patient or his/her representative to sign the Contractor's home oxygen service installation record in order to verify that the service has been delivered. The Contractor should provide a copy to the patient and submit the signed record when claiming payment, even where the majority of Order processing is undertaken electronically.
- 4.6.4.2. Within 7 working days of installing home oxygen therapy equipment, the Contractor should provide the authorised member of the specialist team or GP practice and the named person at the relevant PCT/LHB with a copy of the Contractor's home oxygen therapy service installation record
- 4.6.4.3. On installation of the home oxygen service required, the Contractor shall instruct the patient, and any authorised representative of the patient, in the safe and effective operation of the system(s), and action to be taken in any emergency. The Contractor shall also provide the patient or his/her representative, with user manual(s) together with instruction on their use and any other written information provided.

4.6.5 Removal of Equipment

- 4.6.5.1. At any time during the Contract period, an authorised person may instruct the Contractor to remove a specified home oxygen therapy installation from a patient's home. An authorised person includes a named person at the PCT/LHB, the patient's GP or a member of the patient's clinical specialist team. Equipment may need to be removed for a number of reasons. For example, the death of a patient or where, following consultation with a patient, a clinician advises that oxygen therapy is no longer required for a patient.
- 4.6.5.2. Where the Contractor is requested to remove equipment, the Contractor shall make appropriate arrangements with the patient, or his/her representative, for the removal of the home oxygen therapy installation from the patient's home. Such removal shall be completed between 3 and 14 working days of the date on which the Contractor is advised that equipment is no longer required or on a date specified by the authorised person. On completion of removal, the Contractor shall obtain a brief, signed, and dated statement from the patient or his/her personal representative (as appropriate) to confirm that the removal has been completed. The Contractor should inform the PCT/LHB and the PPA/HSW of the date of removal of equipment from the patient's home. (See also Section 4.3).

4.6.6 Emergency response

- 4.6.6.1. The Contractor is required to provide a back up service in the event of a power or machine failure (see Section 4.4.). However, a patient or carer may also seek help from the Contractor in relation to oxygen supplies or oxygen equipment provided or installed in the home. In doing so, a patient may request attendance as an emergency or the Contractor may consider from information provided by the patient that an urgent response is required. The Contractor must put in place clear procedures to ensure attendance at a patient's home in an emergency, within 4 hours of notification of the emergency. (This requirement is irrespective of whether notification has been made via a manned or unmanned telephone number).

4.6.7 Patients' Telephone Costs

4.6.7.1. The Contractor shall make arrangements to ensure that the full costs of any telephone calls made by the patient and/or his/her family are borne by the Contractor through provision of a manned 24 hour/ 7 days a week "Free Phone " number.

4.7 HOLIDAY AND OTHER PROVISION OUTSIDE THE PATIENT'S HOME

- 4.7.1. A clinician may request the provision of oxygen outside the patient's home. For example, where a patient wishes to take a holiday, attend his/her workplace or school. For patients requiring oxygen in the workplace or school, these locations are likely to be within the same oxygen service region (except where a child may be attending boarding school in a different oxygen region). UK holidays are likely to be taken away from the home oxygen service region.
- 4.7.2. Where a patient requires the provision of home oxygen outside his or her main residence, the patient's GP or the specialist team will issue a second oxygen order for the separate location. In addition to information about the patient's home address and GP practice, the order should include details of the patient's location at work or school or temporary location on holiday.
- 4.7.3. Where a patient attends work, school or takes a holiday within the UK at locations outside the "home" oxygen service region, the Contractor is required to ensure continuing provision of a service under reciprocal arrangements with Contractors providing a service in other oxygen service regions. The service provided to the patient should continue to meet the patient's oxygen requirements, although it may not be necessary to match identically the oxygen modalities provided by the "home" Contractor.
- 4.7.4. The cost of providing an oxygen service in a location other than the patient's home (ie a secondary location) will be borne by the PCT/LHB in which the patient's GP practice is located (see paragraph 4.9.1.2). Where a patient receives a service in a secondary location outside the "home" oxygen service region, the Contractor providing the service should submit claims for payment by the appropriate PCT/LHB.

Holidays in the UK and Abroad

- 4.7.5. A patient's GP or a member of the clinical specialist team will provide clinical information and advice but patients will also look to the Contractor for advice, including information on:
- the need to seek medical advice prior to travel
 - the steps to be taken if the patient falls ill whilst on holiday
 - the availability of oxygen modalities and the arrangements that need to be made to ensure adequate supply
 - the need to allow sufficient time to plan and make arrangements for holiday needs, including accommodation and travel options
 - useful telephone numbers and contacts
- 4.7.6. The Contractor should make such information available as part of reciprocal arrangements with other Contractors, as set out in paragraph 4.7.3.

- 4.7.7. Where patients enquire about oxygen supplies in relation to overseas holidays, the Contractor should refer them to the Department of Health leaflet *Health Advice for Travellers*. Orders for more than 10 copies of this leaflet should be addressed to

Department of Health
PO Box 777
LONDON SE1 6XH

Or via e-mail: dh@prolog.uk.com

This information is also available on CEEFAX pages 460-464 and on the Internet: www.dh.gov.uk/travellers

Oxygen supplies can be supplied as emergency healthcare in all European Economic Areas (EEA) countries and Switzerland under the E111 arrangements. There are over 40 additional countries around the world with which the United Kingdom has reciprocal health agreements that entitle UK citizens to emergency medical care. Patients will need to make prior arrangements with the destination country to ensure availability of supplies, particularly in remote areas. Further information on oxygen supplies abroad may be obtained by telephoning 020 7210 5318.

Taking Equipment Abroad

- 4.7.8. This agreement applies to the provision of home oxygen services to patients who are residents or visitors in England and Wales. However, it is recognised that patients may need to maintain an oxygen supply whilst travelling to their destination outside the United Kingdom. A patient will need to check with their holiday company and other organisations on arrangements for travelling with portable concentrators or oxygen cylinders, including insurance arrangements. The Contractor is not obliged to meet a patient's holiday needs in travelling to a holiday or other destination outside England and Wales. However, a Contractor is free to provide a service supporting travel outside the UK that he may wish to offer patients living within the oxygen service on the basis of an agreement between the Contractor and the patient concerned.

Oxygen Patients from Abroad visiting the United Kingdom

- 4.7.9. As with UK citizens, oxygen supplies can be provided under the E111 arrangements with European Economic Area (EEA) states and Switzerland. Citizens of these countries are entitled to free or reduced cost emergency medical treatment. The Department of Health leaflet, *Advice for Travellers*, also lists those countries outside the EEA with reciprocal health care agreements with the UK. To receive oxygen supplies whilst visiting England and Wales, those covered by these reciprocal agreements should make prior arrangements with the NHS – for example, a hospital, GP practice, PCT or LHB. Where the Contractor provides an oxygen service for a non-UK national under these arrangements, the Contractor should submit a claim to the appropriate PCT/LHB in which the GP practice or trust concerned is located.

4.8 PATIENTS' ELECTRICITY COSTS

- 4.8.1. In accordance with the following provisions of this paragraph, the Contractor shall make arrangements to pay the whole of each patient's electricity costs that are wholly attributable to each patient's proper use of each oxygen concentrator installed in accordance with this service.

4.8.2. In calculating the amount to be paid in respect of each patient, the Contractor shall have regard to:

- the reading as agreed with each patient on the non-resettable hour elapsed meter since the last reading was made in respect of the last chargeable period (if any), for which payment was made by the Contractor
- the unit cost chargeable by the appropriate electricity provider

4.8.3. The Contractor shall make no payment in respect of any patient's electricity standing charge or any part thereof.

4.8.4. The arrangements entered into by the Contractor in relation to the electricity charges shall be such that all charges due from each patient in respect of electricity used in operating each oxygen concentrator shall be paid to the appropriate charging authority or where appropriate direct to the patient on a quarterly basis.

4.8.5. Where a concentrator is installed in a patient's home, the Contractor must inform the appropriate electricity supplier that the patient is an essential user of electricity to ensure that the patient is given priority if there is a breakdown in the electricity supply. In doing so, the Contractor will need to seek the consent of the patient or his/her representative to transfer personal data to the utility company. The Contractor must also inform the electricity supplier when a concentrator is removed from a patient's home.

Reimbursement of Patient Electricity Charges to the Contractor

4.8.6. The reimbursement of patient electricity charges to the contractor will be incorporated in the per diem charge and should not be subject to separate accounting procedures.

4.9 HOME OXYGEN SERVICE REGIONS: ENGLAND AND WALES

4.9.1 England and Wales

4.9.1.1. A Contract will be let for each of the 10 home oxygen service regions within England, with a single contract for Wales. Each region covers an average population of 5 million patients, with the exception of the North-East and Wales regions, which have smaller populations.

4.9.1.2. The basis for payment for the home oxygen service will be the location of the patient's main GP practice (ie the practice postcode), not a branch surgery.

4.9.1.3. To support these arrangements, the new oxygen service regions in England have been aligned with Strategic Health Authority (SHA) and PCT administrative boundaries

4.9.2 Prison Health

4.9.2.1. In 2000, a formal partnership was launched between the NHS and the Prison Service to modernise health services for prisoners. In 2003, the Department of Health and the National Assembly for Wales assumed overall financial responsibility for these services with the transfer of full responsibility for commissioning health services for

prisoners transferred to PCT's and LHB's for Wales by April 2006. Some PCTs assumed this responsibility from 1 April 2004.

- 4.9.2.2. The home oxygen therapy service is a primary care service and, like other NHS primary care services, will be made available within the prison itself. There will be very few prisoners with oxygen needs and the majority of these are likely to be short-term requirements, often provided as part of emergency treatment by a GP. However, there may also be a small number of prisoners (for example, older prisoners serving long sentences) who may have long-term oxygen or ambulatory needs. As with other patients, any long-term or ambulatory oxygen needs should be assessed by a specialist.
- 4.9.2.3. The delivery of an oxygen service to a patient in prison will need to take into account the prison environment. Therefore, where a prison is located within a PCT or LHB area, the Contractor should liaise with the prison's healthcare manager on arrangements for delivery of the service to the prison(s) concerned. The majority of patients within the prison environment will have needs that may be met by the provision of a cylinder service. However, where the Contractor considers that a more appropriate solution should be offered, he should discuss this with the prison healthcare manager before delivery is made.
- 4.9.2.4. Where the Contractor provides oxygen equipment to a patient in prison, he should also make arrangements with the prison healthcare manager to provide information and training to the patient on the safe and effective use of equipment. Where necessary, the Contractor is also required to provide information and training to prison staff.

4.9.3 Cross Border Services

- 4.9.3.1. The Contractor will be informed of agreements between the Department of Health, the Scottish Executive and the Assembly on arrangements for patients living on the borders of England and Wales and England and Scotland.

4.10 PATIENT STATISTICS

- 1.10.1 All information that is supplied to offerors as part of the procurement exercise is supplied in good faith. However, offerors must satisfy themselves as to the accuracy of such information and no responsibility is accepted for any loss or damage of whatever kind or howsoever caused arising from the use by the offerors of such information, unless such information has been supplied fraudulently.

4.11 PERFORMANCE MANAGEMENT

4.11.1 Reporting

- 4.11.1.1. Two service review meetings per annum will be held with the Contractor together with appropriate NHS representatives from within the service region. (See section 4.2)
- 4.11.1.2. The Contractor is to provide quarterly reports on response times to each of the PCT's/LHB's within the oxygen service region. The reports should compare actual performance with specified response times, provide an explanation where responses were made outside the specified times and action taken to improve performance.

4.11.2 Complaints

- 4.11.2.1. Under the terms and conditions of service, the Contractor is required to comply with the National Health Service complaints procedure. New guidance is being developed to support the NHS (Complaints) Regulations 2004 in relation to England. Meanwhile, information is available at www.dh.gov.uk/policyandguidance/organisationpolicy/complaintspolicy
In the case of Wales, the Contractor shall comply with such complaints procedure as may be notified to it from time to time by the Assembly (Complaints procedures are currently being drafted for Wales).
- 4.11.2.2. The Contractor is required to provide quarterly reports on any complaints about the service made by clinicians ordering home oxygen or by patients and carers. The quarterly report is to be made to each PCT/LHB as appropriate within the oxygen service region. Each report should include a summary of the complaints received during the quarter, together with details of response times and action taken to resolve complaints to the satisfaction of the complainant.
- 4.11.2.2. Where a Contractor is unable to resolve a complaint or where the complaint relates to the clinical service received by a patient, the Contractor should inform the appropriate PCT/LHB that the complainant has been advised to take this up with the PCT/LHB complaints manager.

4.11.3 Patient/Public Involvement

- 4.11.3.1. The Contractor is to provide the appropriate PCT/LHB, as required, with information to support steps taken by the PCT's/LHB's to monitor patient satisfaction and seek information from those using the home oxygen service on how this might be improved further. This

may take a number of forms, including independent patient surveys and local patient forums. The approach taken will be subject to consultation with the Contractor and appropriate NHS representation from within the oxygen service region. It may also include consultation with patient groups and/or wider public involvement.

4.12 SERVICE MANAGEMENT INFORMATION

4.12.1. The Contractor shall provide reports, on a quarterly basis to NHSPASA and to the PCT's/LHB's concerned. Each report should include:

- the total number of installations provided within the period for new patients and existing patients, the type of oxygen modality provided and the period of service provision for each patient (ie under or over 12 months since first provision of oxygen service)
- Acceptance testing reports for each installation during the period signed by the patient or other authorised signatory. These should be sent to the appropriate PCT/LHB for record keeping purposes and to support the service audit process.
- Details of emergency call outs made during the period, including showing the number of calls to patients, the reason for the call-out and action taken.

4.13 HOME OXYGEN THERAPY SERVICE AUDIT

4.13.1. The home oxygen therapy service will be subject to an audit of the home installations and the Contractor's operational activities.

4.13.2. The audit will be undertaken by the NHS PASA and MHRA on behalf of the Department of Health, the Assembly and PCT's/LHB's or any other body designated by the Department of Health and/or the Assembly.

4.13.3. An audit covering each geographical oxygen therapy service region will be undertaken at 2-yearly intervals. During the 5-year contract period, each region is likely to be subject to two service audits.

4.13.4. Each home installation audit is likely to cover 1 or 2 working days and will necessitate visiting up to 5 patient installations. Each patient will be chosen randomly from the Contractor's patient database and permission to attend at the patient's home obtained in advance

4.13.5. Each operational audit is likely to cover 1 working day

4.13.6. The cost of the audit of the home installations is anticipated to be £400 per day. There will be no cost for the operational audit.

4.13.7. Additional allowances should be made for any expenses incurred in undertaking the audit of the home installations eg travel and overnight accommodation

4.13.8. The audit cost should be covered within the offer (each audit is likely to cost in the region of £1,000 per audit)

4.13.9. The precise details of the audit will be agreed with all the successful tenderers prior to the commencement of the contract but is likely to include:

- Details of the equipment and installation provided in meeting the prescription
- Confirmation that the equipment and installation provided meet the specification and all the appropriate standards eg CE marking
- Confirmation that the patient and/or carer has received appropriate training and guidance in the safe use of the equipment
- Confirmation that the patient and/or carer has received appropriate documentation in the use of the equipment
- An inspection of all aspects of the installation to ensure it meets all safety standards, is suitably located and meets the needs of the patient/carer

4.14 CONTRACT PRICE AND PRICE REVIEWS

- 4.14.1. Subject to the provisions of this paragraph and those relating to the price review mechanism, the Prescription Pricing Authority/Business Services Centre for Wales shall pay, on a claim being made in accordance with arrangements made under the Regulations, to the Contractor for the provision of the service the agreed £ per diem rate for each category of patient. Each per diem sum will cover all costs associated with the service including but not restricted to the installation, maintenance, subsequent removal of all equipment within each patient's home and where appropriate the making good of any damage. Each per diem sum will include the cost of electricity.
- 4.14.2. The Contractor and/or the NHSPASA will be able to seek formal price reviews after 18 months, 30 months and 42 months from the Contract start date and at 60 months if an extension to the contract is granted.
- 4.14.3. To enable the NHSPASA to consider applications for a price review, the Contractor shall specify in writing the grounds on which the application is made and make this available to the NHSPASA:
- (a) a specification of all the costs, in writing, for each element (including staff, transport, electricity and equipment) in providing the servicing of each category of patient -
 - (aa) as at the time that the tender was submitted, and
 - (ab) as at the time of the application
 - (b) on request of NHSPASA, all the Contractor's books, records and accounts whatsoever, in legible form, which contain information relating to the Contractor's costs in providing the services
- 4.14.4. Contract price reviews will be based on movements in the cost price indices specified in Section 4.14.7 from the start of the contract at the 1 October 2005 for the review at 18 months and from the previous allowable review date for all other reviews, together with the cost breakdown schedules provided within the tender documents. The review date index will be the index published 3 months prior to the review date.
- 4.14.5. Price reviews that, based on the cost price indices specified in Section 4.14.7, indicate an overall cost reduction of any magnitude or an increase in cost of less than 5% will be implemented.

4.14.6 The Contractor may apply to demonstrate at the review dates that the costs incurred by the Contractor in providing the home oxygen therapy service exceed by more than 5 percent the contracted per diem rates per patient category. If the NHSPASA is satisfied with the evidence of additional costs provided by the Contractor, the Contractor may submit a request for a price review based on the actual costs incurred for consideration by NHSPASA.

4.14.7. The indices to be used in reviewing the contract prices are:

- (a) Staffing: Average Earnings Index – main industrial sectors – whole economy - ONS
- (b) Equipment and materials (excluding fuel) – Producer prices - Materials purchased by manufacturing industry – Office of National Statistics (ONS)
- (c) Fuel: John Hall Fuel Price Index for derv based on the average of the index over the previous 12 months
- (d) Administration and overheads: Retail Price Index excluding mortgages – ONS
- (e) Electricity – Retail Price Index – Electricity – DOBX -ONS

4.15. INVOICING AND PAYMENT

4.15.1. Contractors are required to submit monthly invoices for the provision of services to the Prescription Pricing Authority in England. For Wales, invoices should be sent to the Business Services Centre. Payment will be made against invoices submitted and direct to the contractor by the Prescription Pricing Authority (England) or the Business Services

HOME OXYGEN THERAPY SERVICE: CONTRACT SERVICE REGIONS

| Region: | SHAs |
|---|---|
| 1. North West | Cheshire & Merseyside Cumbria & Lancashire Greater Manchester |
| 2. North East | Co Durham and Tees Valley Northumberland, Tyne and Wear |
| 3. Yorkshire & Humberside | West Yorkshire N & E Yorks and N Lincolnshire South Yorkshire |
| 4. East Midlands | Leicestershire, Northants & Rutland Trent |
| 5. West Midlands | Birmingham & Black Country Shropshire & Staffordshire West Midlands South |
| 6. Eastern England | Bedfordshire and Herts Essex Norfolk, Suffolk and Cambs |
| 7. SW London, Thames Valley, Hants & Isle of Wight | South West London Hampshire & Isle of Wight Thames Valley |
| 8. SE London, Kent, Surrey & Sussex | Kent & Medway South East London Surrey & Sussex |
| 9. London North | North Central London North East London North West London |
| 10. South West | South West Peninsula Dorset and Somerset Avon, Glos and Wiltshire |
| 11. Wales | |

Gives average population of 5 million patients, with the exception of north east region and Wales.