

This publication was withdrawn on 2 January 2024

The guidance has been withdrawn because it is out of date.

The regulations that this guidance was based on have been revoked - [The National Health Service \(Cross-Border Healthcare\) Regulations 2013 \(revoked\)](#) were revoked on 31 December 2020 by [The National Health Service \(Cross-Border Healthcare and Miscellaneous Amendments etc.\) \(EU Exit\) Regulations 2019](#).



Department
of Health

Cross Border Healthcare and Patient Mobility in Europe

*Information to accompany the implementation of
Directive 2011/24/EU – on patients' rights in cross-
border healthcare*

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Cross Border Healthcare and Patient Mobility in Europe

Information to accompany the implementation of Directive 2011/24/EU – on patients' rights in cross-border healthcare

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EU & International Cross-border Healthcare Policy Team

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Purpose

The purpose of this information document is to explain the rights and entitlements of patients, to help all relevant parts of the NHS understand the obligations set forward by a new EU Directive on cross-border healthcare¹, (“the Directive”) and to appreciate how the broader aspects of patient mobility in Europe - under the freedom to provide services provisions of the EU Treaty - impact patients and the system as a whole.

This information document accompanies the National Health Service (Cross-Border Healthcare) Regulations 2013². These and accompanying Directions from the Secretary of State set out the obligations placed on the NHS Commissioning Board (known as and referred to in this guidance as “NHS England”), clinical commissioning groups and healthcare providers in England in relation to claims for reimbursement of treatment costs and applications from patients who seek prior authorisation for the receipt of healthcare in another EEA³ State. There is also some information for NHS providers who may receive requests from overseas patients for treatment in the UK under the provisions of the new EU Directive.

This document should be read in conjunction with the Regulations and Directions. Also relevant in terms of understanding the totality of the Directive’s obligations is the recent public consultation documentation explaining the Government’s overall approach to implementing the new Directive.

<https://www.gov.uk/government/consultations/eu-directive-on-patients-rights-to-healthcare-in-other-european-countries>

Scope

This guidance relates to managing applications for treatment within the European Economic Area (EEA). Arrangements across borders within the UK, use of the European Health Insurance Card and reciprocal arrangements with other non-EEA countries are not within the scope of this guidance.

¹ Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare (OJ No. L88, 4.4. 2011, p.45).

² S.I. 2013/2269.

³ The Member States of the European Union plus Iceland, Liechtenstein and Norway. The Directive does not apply to Iceland Liechtenstein and Norway until the Directive applies to those states in accordance with the EEA Agreement.

Introduction

General

The majority of EU citizens receive healthcare in the Member State where they live, via the health system through which they are covered or insured. However, in some instances, it may benefit the patient to obtain healthcare in another European country – for example, where there may be better expertise available, lower costs, better availability of certain highly specialised treatments or where waiting times are shorter.

EU regulations on the coordination of social security systems (Regulation (EEC) 1408/71, which were replaced by revised provisions in Regulation (EC) No. 883/2004^a with effect from May 2010) already provide certain levels of reciprocal healthcare cover to EEA citizens. These arrangements apply to tourists requiring necessary care during a temporary stay in another Member State, for example a holiday or business visit (via the European Health Insurance Card), to people living and working in Europe or, in certain circumstances those who are authorised to travel specifically to receive pre-arranged healthcare. The Regulation also covers state pensioners, as social security provisions (including those for healthcare) are transferable around the EU at state pension age.

How the Directive evolved

While these reciprocal arrangements have existed for many years, current generations of Europeans, accustomed to crossing borders with ease and being able to purchase goods and services from any part of the EU, are proving less willing to accept constraints on how and where they obtain their healthcare. This is often due to perceived advantages relating to quality, favourable cost, waiting times, the availability of different treatments or where citizens have close cultural or familial links in another country.

Over the past two decades, there have been more than a dozen high profile legal cases in which Member States' interpretation of the rules in respect of obtaining healthcare across borders in Europe has been questioned and on which the Court of Justice of the European Union (CJEU) has been asked to make a ruling. The development of this case law based on individual cases (including a ruling of particular significance in 2006 against the UK in the case of *Yvonne Watts vs Bedford PCT and the Secretary of State for Health*^b – see *text box below*), was inevitably piecemeal and could not provide a coherent overall approach to the rules surrounding patient mobility in Europe. The ruling in *Yvonne Watts vs Bedford PCT and the Secretary of State for Health* was given effect by the National Health Service (Reimbursement

^a Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems; OJ No L 166, 30.4.2004 p.1-123; corrigenda to the Regulation published in OJ No L 200, 7.6.2004 p 1-49 and OJ no L 2044.8.2007, p30. The Regulation applies to the Member States of the EEA and to Switzerland.

^b Case C-372/04 *The Queen, on application of Yvonne Watts v Bedford Primary Care Trust and the Secretary of State for Health* [2006 ECR I-4325].

of the Costs of EEA Treatment) Regulations 2010^a which amended the National Health Service Act 2006 to insert sections 6A and 6B setting out the right to reimbursement subject to certain conditions and limitations.

With so many ad hoc judgements being made in the courts, based on health systems which are very different in organisation and funding, the development of an EU-wide Directive was seen as necessary to clarify the law and the rights of citizens across the EU. This new legislation reflects existing rights under the Treaty on the Functioning of the European Union, the principles confirmed by established CJEU case law and applies best practice in providing access to these rights. Its main objectives are to:

- Clarify and simplify the rules and procedures applicable to patients' access to cross-border healthcare;
- Provide EU citizens with better information on their rights;
- Ensure that cross-border healthcare is safe and of high-quality;
- Promote cooperation between Member States.

The Directive sets out the information Member States must provide for patients from other states considering coming to the country to purchase healthcare. It also sets out the arrangements that a Member State must provide to allow its own citizens to access their rights to reimbursement of the costs of cross-border healthcare if they choose to seek such healthcare in another Member State.

"If you are entitled to it here, you can get it there"

Importantly, the 'home' state retains responsibility for deciding what healthcare it will fund on a cross-border basis, so the Directive is not a way for a patient to obtain reimbursement for the costs of a treatment which they obtain in another EU member State if the same or equivalent treatment would not be made available to that patient in their circumstances under their home health service. In addition, Member States are required to be clear and transparent in home legislation or administrative processes as to what entitlements to healthcare home patients have within their national health system.

All Member States of the European Union must implement the Directive by 25 October 2013. For England and Wales the main provisions are implemented by the National Health Service (Cross-Border Healthcare) Regulations 2013.

^a S.I.2010/915.

“Watts” judgement - 2006

The “Watts” judgement was a seminal moment in the development of European case law applying to cross-border healthcare and patient mobility. Ruling on the Watts case, the European Court found that:

- The application of fundamental rights under the EU Treaty applied equally to NHS-style health systems where NHS hospital treatment was provided free of charge (whereas the UK had previously argued that it applied only to insurance-based health systems)
- NHS arrangements were deficient on the criteria for the grant or refusal of prior authorisation and reimbursement of costs
- Guidance on the procedure for an applicant to follow fell a long way short of the requirement for a procedural system which was easily accessible to citizens
- A refusal to grant authorisation cannot be based merely on the existence of waiting lists to manage general clinical priorities without carrying out an objective medical assessment of the individual patient’s medical condition and circumstances. Where the delay exceeds a medically acceptable length of time authorisation cannot be refused on the grounds of the existence of those waiting lists and an alleged distortion of the normal order of priorities. Failure to grant prior authorisation contravened both Regulation 1408/71 and Article 49 of the EU Treaty.

European Regulations, existing domestic legislation & the new Directive

General

There are currently two potential routes for patients to receive planned care in another Member State at the expense of the NHS:

(a) The long-established route under Articles 20 and 27(3) of Regulation (EC) No. 883/2004 - these are reciprocal arrangements that stem from the EU-wide coordination of social security systems, including reciprocal arrangements for access to healthcare and authorisation of pre-planned treatment in another Member State (“the S2 Route”)^a. Where a patient applies for and is authorised to obtain pre-planned treatment in another Member State, the Secretary of State issues to the patient form S2 as a guarantee of payment;

(b) Directive 2011/24/EU (“the Directive Route”)^b.

Following centralisation of EU patient mobility functions from 1 April 2013, both routes are now administered by NHS England on behalf of the Secretary of State

S2 route

The key difference between the two routes is that the S2 route relates only to state-provided treatment and costs are dealt with directly between Member States, with the S2 acting as a form of payment guarantee. This means that in the majority of cases, the patient is not required to pay anything themselves.

Under the S2 route, Member States retain discretion as to whether to authorise planned treatment in another Member State except in cases where “undue delay” is relevant – i.e. where treatment cannot be provided by the NHS within a time that is medically acceptable, based upon an objective clinical assessment of the patient and their individual circumstances. Where this is the case, authorisation must be given.

The principles surrounding undue delay are discussed further on in this guidance.

^a The provisions of Regulation (EC) No. 883/2004 apply to the Member States of the EEA and to Switzerland.

^b The Directive does not apply to Iceland, Liechtenstein and Norway until the Directive applies to those states in accordance with the EEA Agreement. In this guidance the term “Directive Route” describes the provisions of the Directive implemented by the National Health Service (Cross-Border Healthcare) Regulations 2013 with effect from 25 October 2013.

The Directive

Unlike the S2 route, under the terms of the new Directive EU citizens who choose to obtain a healthcare service (including private and unplanned care) in another Member State can seek reimbursement of the costs, provided the healthcare service is the same as or equivalent to a service that would have been provided to the patient within the NHS in the circumstances of their case. The right to claim a reimbursement of costs is limited to the cost to the NHS of the same or equivalent treatment had the patient obtained that treatment from the NHS - or the actual amount paid by the patient where this is lower than the cost of the equivalent NHS treatment.

A patient may receive treatment in the state-provided sector or they may access services in the private sector under the Directive. The S2 route does not cover private sector treatment.

Under the Directive, the principle of reimbursement of costs assumes that patients will pay the overseas provider up front for their treatment and then claim reimbursement. The patient will also bear the financial risk of any additional costs arising.

Except where legislation requires the seeking of prior authorisation, a patient may obtain healthcare in another Member State under the Directive without authorisation from NHS England, whereas under the S2 route, **all** healthcare must be authorised in advance.

Directive vs S2

Coverage	S2 Route	Directive Route
EU / EEA	Yes	Yes ^a
Switzerland	Yes	No
Requires prior authorisation	Yes	Specified treatments only
Discretionary (unless undue delay applies)	Yes	Only in the 4 circumstances set out on page 16
Planned healthcare	Yes	Yes
Unplanned (emergency) healthcare	No	Yes
Treatment in state-run / contracted facilities	Yes	Yes
Treatment in private / non-contracted facilities	No	Yes
Must be granted if undue delay applies	Yes	Yes
Requires payment in full up front	No	Yes
Scope restricted to home entitlements only	No	Yes
Retrospective reimbursement (depending on circumstances)	No ^b	Yes

^a The Directive does not apply to non EU Member States of EEA namely Iceland, Liechtenstein and Norway until the Directive applies to those states in accordance with the EEA Agreement.

^b Retrospective reimbursement is available where authorisation for treatment under S2 is refused and that refusal is subsequently overturned.

Patients seeking treatment in another EEA State

General principles

From 1 April 2013, NHS England assumed responsibility for the various patient mobility and cross-border healthcare functions previously delivered locally by Primary Care Trusts. These include:

- Receiving patient applications for authorisation under Regulation EC No. 883/2004 and reimbursement under the Directive;
- Publicising information on rights, entitlements and reimbursement principles, including which services patients will be reimbursed for;
- Considering applications for prior authorisation;
- Calculating reimbursement levels and informing patients about this;
- Dealing with appeals & reviews;
- Data collection.

Patients wishing to access treatment in another EEA Member State are therefore recommended to contact NHS England in advance of travelling to discuss whether prior authorisation is required, as well as what levels of cost reimbursement will apply. Otherwise, patients may discover after treatment that they have obtained a service that they are not entitled to under the NHS and will not therefore receive a reimbursement of their costs.

Implications for patients

There are a range of other issues that patients will need to be aware of when seeking treatment in another European country – for example, there may not be the same standards of care, there may not be the same styles of treatment or of aftercare and there may be language barriers to negotiate. In seeking healthcare in another EEA State, the patient is stepping outside of NHS jurisdiction – consequently, it is the law of the country of treatment that will apply and therefore it is the patient's responsibility to be clear on who in the Member State of treatment is accountable for assuring their safety throughout the course of their treatment.

NHS clinicians and commissioners cannot be held liable for any failures in treatments organised by the patient and undertaken in another European country under the Directive. Their role is strictly limited to helping facilitate this if that is the patient's expressed wish.

The process of prior authorisation, where this is applied, is a mechanism by which individual patients can get clarity about a range of matters relating to patient care. This includes confirmation that the treatment is one the NHS offers (i.e. the patient would be entitled to reimbursement and the level of such reimbursement), which elements of the care pathway are being funded, what the patient must do if there is a problem with the treatment they receive, and so on. It also helps ensure patients are aware of all of the possible treatment options within the NHS, which may be more beneficial and convenient for the patient. However, patients cannot

be prevented from seeking treatment in Europe simply because alternative services may be available at home.

Patients also need to be aware that prior authorisation does not imply clinical approval of a patient's planned healthcare in another Member State, nor does it imply acceptance of any responsibility for that treatment. No duty of care attaches to the authorisation. These general principles help highlight the need for commissioners and/or clinical staff to remind anyone wishing to seek medical treatment in another country under the Directive to ensure that they have fully considered all aspects of the arrangements necessary - such as when they will be fit to travel home, whether they need to make any special travel arrangements, to have comprehensive medical insurance for their trip, for example to cover having to stay abroad longer than planned. The cost of insurance and other incidental costs are not reimbursable by NHS England.

Patients' rights & information: National Contact Points

A key theme of the Directive is the emphasis placed on national and local health bodies in making information on rights and entitlements publicly available and easily accessible, as well as the conditions that will apply to reimbursement and procedures for appeal and redress if patients consider that their rights have not been respected.

The Directive requires the set-up of what are termed "National Contact Points" (NCPs). These are national or sub-national bodies from which information about patients' rights and providers or services available in other Member States may be facilitated. The intention is to establish a network of NCPs around the EU, to facilitate exchange of information and help smooth the path for patients looking to access treatment in a particular Member State. The information given to patients/citizens by NCPs on quality of healthcare, patient safety and procedures to follow will help people make an informed choice on the healthcare they seek.

The National Contact Point for England also resides within a centrally coordinated function at NHS England and may be accessed in the following ways:

NHS England
PO Box 16738
Redditch
B97 9PT

Tel: 0300 311 22 33

Web: www.nhs.uk/nationalcontactpoint

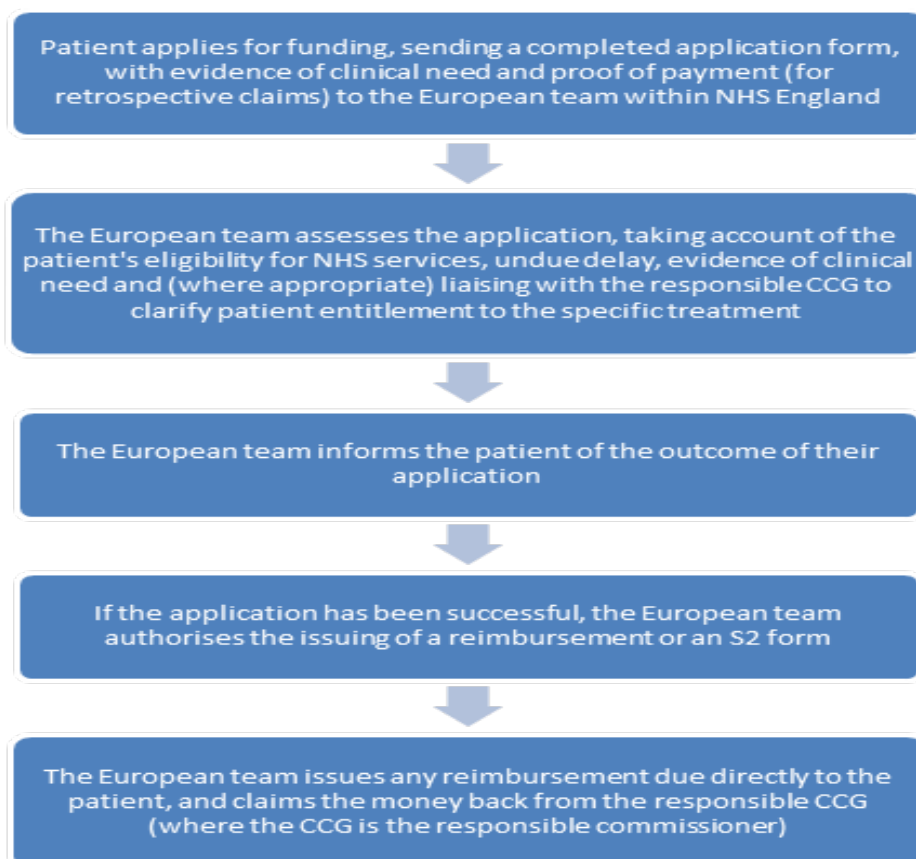
Email: england.contactus@nhs.net

The application process

NHS England is directly responsible for commissioning a range of different services - from primary care to specialised services. In addition, and by virtue of centralising the administration of cross-border healthcare, NHS England is also responsible for directly reimbursing the patient costs of other services normally commissioned by local clinical commissioning groups (CCGs). To ensure that NHS England is not disadvantaged in carrying out this role, CCGs are required to repay NHS England for patient costs reimbursed on their behalf^a.

Good links between NHS England and local CCGs are also necessary to ensure that clear information is available to patients and that each have systems in place for determining and confirming entitlements to NHS care quickly for patients seeking treatment in another Member State. In particular, there is a need to ensure that appropriate arrangements are in place to enable NHS England to confirm with the relevant CCG a patient's entitlement where that patient is already outside the UK and requiring treatment in another Member State.

The broad process for making and determining applications (under both Directive and S2 routes) is as follows:



^a Regulation 7 of the National Health Service and Public Health (Functions and Miscellaneous Provisions) Regulations 2013 (S.I. 2013/261).

Maternity care in another EEA State

The exception to this process is maternity care under the S2 route, where different arrangements apply. To apply for an S2 covering maternity care (only), the applicant should write to the Overseas Healthcare Team in Newcastle at the address below, explaining why they want care outside the UK and enclosing the following information:

- A maternity certificate (MATB1) or a letter from a UK GP or midwife showing the expected date of delivery;
- NHS number or National Insurance number;
- Date of birth, full UK address and dates of travel;
- Whether returning to the UK after giving birth and whether the applicant has already left the UK for the other country.

Contact:

Overseas Healthcare Team (Newcastle)
Room M0135, Durham House
Washington
Tyne & Wear
NE38 7SF
Tel: +44 (0)191 218 1999

Procedure for making an application

NHS England publishes information on how to make an application for reimbursement of costs and how to apply for prior authorisation (under both the Directive and S2 routes). This information includes:

- The services for which prior authorisation is a condition of reimbursement under the Directive route;
- Where to and how patients should apply for prior authorisation;
- What information the application must contain;
- What factors will be taken into account in arriving at the decision;
- The time limits within which NHS England are required to decide applications.

Following application, the information that NHS England must provide to an applicant are:

- Where authorisation is refused NHS England must inform the applicant in writing of the reasons for refusal and set out the information considered by NHS England in reaching the decision;
- A clear statement of the amount of reimbursement;
- If reimbursement is refused or full reimbursement is refused, NHS England must inform the applicant in writing of the reasons for refusal of reimbursement or refusal to reimburse in full and set out the information considered in reaching the decision;
- Where NHS England refuse authorisation or refuse reimbursement or refuse full reimbursement NHS England must inform patients of their right to request a review what steps they need to take.

Part 2 of the National Health Service and Public Health (Functions and Miscellaneous Provisions) Regulations 2013^a requires NHS England to determine applications within 20 working days, unless further information is required in which case within 10 working days NHS England must tell the applicant what further information is needed (in which case, the clock stops until the information is received).

^a S.I. 2013/261.

Prior authorisation

NHS England will need to consider each application carefully. Generally, reimbursement (or the issuing of an S2) will not usually be retrospectively authorised where the patient should have applied for prior authorisation but did not do so - unless exceptional reasons apply in a particular case, for example circumstances where it was not possible for the patient to have applied for prior authorisation before receiving the treatment or service in another EEA State.

This would be determined on a case-by-case basis, taking account of the facts of the case. Retrospective authorisation and reimbursement will be given in cases where the initial decision to refuse authorisation or reimbursement is overruled on review or appeal.

The services which require prior authorisation under the Directive are set out at Annex A.

Refusal criteria

Where prior authorisation has been requested, the Directive gives Member States the discretion to refuse only in the following four circumstances:

- a) Where the patient will, according to a clinical evaluation, be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable, taking into account the potential benefit for the patient of the sought cross-border healthcare; (e.g. from poor quality care or unproven procedures)
- b) Where the general public will be exposed with reasonable certainty to a substantial safety hazard as a result of the cross-border healthcare in question; (this might include where a patient who had a highly contagious disease wanted to go to another state for treatment or where a patient with mental health problems and a history of violence requested authorisation)
- c) Where this healthcare is to be provided by a healthcare provider that raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety, including provisions on supervision, whether these standards and guidelines are laid down by laws and regulations or through accreditation systems established by the Member State of treatment; (this would require evidence from the appropriate regulator or authority)
- d) Where this healthcare can be provided on its territory within a time-limit which is medically justifiable, taking into account the current state of health and the probable course of the illness of each person concerned (i.e. where the NHS can provide the same or equivalent treatment in a medically acceptable period of time based on an objective assessment of the individual patient's condition).

Undue delay

“Undue delay” cannot be determined simply on the basis of nationally or locally decided general waiting time arrangements for the purpose of managing pre-determined clinical priorities.

Whether the waiting time is medically justifiable must be based on an objective medical assessment of the individual patient's condition, including the patient's medical history, the extent of the patient's pain, disability, discomfort or other suffering attributable to the medical condition; whether that pain, disability or discomfort makes it impossible or extremely difficult for the patient to carry out ordinary daily tasks; and the extent to which the service would be likely to alleviate or enable alleviation of the pain, disability, discomfort or suffering.

Therefore, in a case where NHS England wished to refuse authorisation under criterion (d) above, it would need to be able to set out in full the reasons for refusing the application and explain the reasons for reaching a decision on the length of time it is reasonable to ask the patient to wait for treatment. The matters to which NHS England (on behalf of the Secretary of State) must consider in determining whether the length of any (undue) delay is medically justifiable are set out in the regulations and include:

- (a) The patient's medical history;
- (b) The extent of any pain, disability, discomfort or other suffering that is attributable to the medical condition to which the healthcare service is to relate;
- (c) Whether any such pain, disability, discomfort or suffering makes it impossible or extremely difficult for the patient to carry out ordinary daily tasks, and
- (d) The extent to which the provision of the service would be likely to alleviate, or enable the alleviation of, the pain, disability, discomfort or suffering.

When a patient requests prior authorisation for a relevant treatment under the Directive route, NHS England must first of all determine whether or not the patient meets the requirements of the S2 route. If they do, they will be granted authorisation via that process, unless the patient specifically requests to use the Directive – for example, to access the private/independent sector abroad. This will ensure that appropriate consideration occurs of patients' rights under both sets of legislation and that the relevant case law is applied effectively.

Reimbursement

A patient seeking treatment in another Member State under the Directive would need to pay the healthcare provider directly for their treatment. In cases where the treatment is not subject to the condition of prior authorisation (see Annex A), providing it is a treatment, product or intervention that the patient would be entitled to receive on the NHS in the circumstances of their case, he/she may subsequently request reimbursement from NHS England for some or all of the costs of this treatment.

In requesting reimbursement for the cost of their treatment, patients will need to complete an application form and provide NHS England with evidence of clinical need, itemised receipts and proof of payment for the treatment or service they have purchased. If the patient's receipts and supporting documentation are in a different language, then these will need to be translated. National Contact Points can play a key role in helping to facilitate this with their counterparts in other European countries.

The maximum level of reimbursement may be limited to the cost of the equivalent NHS service or the actual cost of treatment, where this is lower than the NHS cost. If the treatment for which reimbursement is being requested would normally attract a patient charge under the NHS, NHS England may deduct this from the amount due. Any additional cost is borne by the patient.

Once the reimbursement has been issued to the patient, NHS England will recover the costs from the responsible commissioner.

Determining entitlements

The Directive does not provide for reimbursement for any treatment (or drug) a patient may obtain elsewhere within the European Union. A patient is only eligible to receive reimbursement for a treatment, product or service where the same or equivalent treatment, product or service would be made available to the patient by the NHS based on their individual clinical circumstances.

To enable people to exercise their rights under the Directive, information on those services, interventions and treatment regimes that are generally available to NHS patients (and for whom a CCG or NHS England is responsible), the expectation is that there should be easily accessible published information providing appropriate clarity and transparency on NHS entitlements for patients who are considering cross-border healthcare. Patients need this information to understand whether they can access the treatment they require and then expect reimbursement of their costs. Much of this information is already produced in the NHS in terms of treatment policies, criteria and thresholds for treatment - however, this is not always easily accessible to patients and needs to be made available in easily understood formats.

To help achieve this, the NHS (Cross-Border Healthcare) Regulations 2013 place a legal requirement on both NHS England and local CCGs to provide patients with the information they need. The accompanying Secretary of State's Directions (attached at Annex B) direct NHS

England and local CCGs to publish information on health services that they make available to patients for whom they are responsible, together with information on any general policies and criteria that may apply to the provision of a particular service.

Payment of travelling expenses

NHS England does not generally refund travel or accommodation costs for healthcare funded via the S2 or Directive routes. Travel costs will only be considered where a patient would have been entitled to assistance with such costs if the treatment had been provided in England. This would be via the means-tested Healthcare Travel Costs Scheme (HTCS).

Patients from Member States seeking treatment in England under the Directive

Non-discrimination

The inflow of patients from other Member States (“visiting patients”) who wish to access treatment from NHS providers (including those contracted to the NHS in the independent sector) raises particular issues for providers. Whilst there is no specific requirement on the provider to accept any patient, there are a number of factors that need to be considered.

The Directive does not require providers to accept visiting patients for planned healthcare if this would be to the detriment of ensuring sufficient access for their own patients with similar health needs, nor to prioritise them to the detriment of other patients, for instance by increasing waiting times^a. However, given that it is possible that providers or acute trusts may be contacted in advance by either the prospective patient, his/her clinician or potentially another countries’ National Contact Point, acute trusts or other providers would need to be able to explain and evidence the lack of capacity and demonstrate that refusal is necessary and show they were not discriminating against nationals of other states on grounds of nationality if rejecting a request for treatment.

In principle, the strongest grounds for refusing a visiting patient are the lack of service capacity – however, the provider would need to consider whether the patient could be offered the option of joining the waiting list, to be treated alongside “home” patients on the basis of clinical priority. Alternatively, the patient has the option of considering a different provider.

Obligations on providers

Healthcare providers in England who are providing treatment to visiting patients under the provisions of the Directive need to observe some key requirements. They must:

- Provide patients with relevant information on treatment options and quality and safety;
- Provide clear invoices and price information;
- Apply fees in non-discriminatory manner;
- Ensure transparent complaints procedures and procedures to obtain redress;
- Apply adequate systems of professional liability insurance or similar;
- Respect privacy in the processing of personal information;
- Supply patients with a copy of the record of their medical treatment.

Charging

The Directive requires healthcare providers to provide visiting patients with clear information on prices and clear invoices. Pricing must be non-discriminatory; providers cannot make up a price

^a See recital 21 and Article 4(3) of the Directive.

or seek to charge more simply because the person is a visiting patient seeking treatment under the Directive. Healthcare providers must therefore apply the same scale of fees for healthcare to visiting patients as for domestic patients. If there is no comparable price for domestic patients, the price must be based on objective, non-discriminatory criteria. The NHS (Cross-Border Healthcare) Regulations 2013 provide that where a visiting patient receives an NHS service for which a charge can be made, the visiting patient must not be charged more than the amount that an NHS commissioner would have been charged if that service had been provided to an NHS patient.

If providers (including providers from the independent sector contracted to deliver NHS services) accept a visiting patient for treatment, they must not assume that such patients wish to be considered as private patients. Providers must ensure that they explain to the visiting patient the choice of private care and NHS care. This is because although the patient is independent of the NHS system and is not referred formally by their state health system, they are exercising their rights under the Directive and may themselves receive reimbursement from their state system for eligible costs under the provisions of the Directive (i.e. turning around the reimbursement process outlined in this guidance).

Similarly, primary care providers should not assume that a visiting patient can, or should be treated as a private patient – at the same time, patients who specify from the outset that they *do* wish to be treated privately may be charged in the same way as at the equivalent cost to private patients resident in England.

In terms of how these requirements are met, for secondary care provided by the NHS, relevant NHS bodies should recover the full cost of the treatment given to a visiting patient under the Directive. Member States must have a transparent mechanism for the calculation of costs for cross-border healthcare and this must be based on objective, non-discriminatory criteria known in advance. To calculate the NHS cost, trusts should use the latest mandatory tariff or published national average reference costs at:

www.dh.gov.uk/paymentbyresults

For GP and GP out of hours services, if a visiting patient is treated as an NHS patient (as they should be unless they specifically request to be treated on a private basis), then that treatment / consultation is currently free of charge, regardless of nationality. Charges are, however levied for medication dispensed via community pharmacies.

Charges for NHS dental services differ, in that they relate to average costs by treatment band for courses of treatment – that is, on the basis of a contract value, which is delivered through an agreed number of units of dental activity.

Providers will need to ensure systems are in place for dealing with requests for treatment from visiting patients. This includes processes for seeking more information about the patients' condition and diagnoses where this is not initially available, systems for dealing with payment direct from the patient, clear information about the services they provide and the terms of treatment.

“Emergency brake” provisions

It is possible that the inflow of patients from other EEA States may, over time create a demand exceeding the capacities existing in the NHS for certain treatments - or there may be a need to control costs relating to the planning or funding of services. Therefore, the Directive allows Member States to retain the possibility, in exceptional cases, to adopt measures controlling access to treatment where this is necessary and proportionate to ensure sufficient and permanent access to healthcare for domestic citizens.

Should such a situation arise, this would be a matter for the Secretary of State. Any decision by the UK Government to exercise this provision in the Directive could not be arbitrary, nor a policy of first resort and would need to be supported by clear evidence on the effects of cross-border healthcare on the home system. If such circumstances arise, NHS England should provide the Department of Health with any such evidence.

Additional information & enquiries

For patient / citizen enquiries arising from this information document, please contact the National Contact Point for England:

NHS England
PO Box 16738
Redditch
B97 9PT

Tel: 0300 311 22 33

Web: www.nhs.uk/nationalcontactpoint

Email: england.contactus@nhs.net

Enquiries on the detail of the governing European legislation may be made to the Department of Health Cross-border Healthcare mailbox:

eucross-borderhealthcare@dh.gsi.gov.uk

ANNEX A

List of services subject to prior authorisation

Adult ataxia telangiectasia services
Adult congenital heart disease services
Adult highly specialist pain management services
Adult highly specialist respiratory services
Adult highly specialist rheumatology services
Adult secure mental health services
Adult specialist cardiac services
Adult specialist eating disorder services
Adult specialist endocrinology services
Adult specialist intestinal failure services
Adult specialist neurosciences services
Adult specialist ophthalmology services
Adult specialist orthopaedic services
Adult specialist pulmonary hypertension services
Adult specialist renal services
Adult specialist services for patients infected with HIV
Adult specialist vascular services
Adult thoracic surgery services
Alkaptonuria service
Alström syndrome service
Ataxia telangiectasia service for children
Autoimmune paediatric gut syndromes service
Autologous intestinal reconstruction service for adults
Bardet-Biedl syndrome service
Barth syndrome service
Beckwith-Wiedemann syndrome with macroglossia service
Behcet's syndrome service
Bladder exstrophy service
Blood and marrow transplantation services
Bone anchored hearing aid services
Breast radiotherapy injury rehabilitation service
Child and adolescent mental health services – Tier 4
Choriocarcinoma service
Chronic pulmonary aspergillosis service
Cleft lip and palate services
Cochlear implantation services
Complex childhood osteogenesis imperfecta service
Complex Ehlers Danlos syndrome service
Complex neurofibromatosis type 1 service
Complex spinal surgery services
Complex tracheal disease service

Congenital hyperinsulinism service
Craniofacial service
Cryopyrin associated periodic syndrome service
Cystic fibrosis services
Diagnostic service for amyloidosis
Diagnostic service for primary ciliary dyskinesia
Diagnostic service for rare neuromuscular disorders
Encapsulating peritoneal sclerosis treatment service
Epidermolysis bullosa service
Extra corporeal membrane oxygenation service for adults
Extra corporeal membrane oxygenation service for neonates, infants and children with respiratory failure
Ex-vivo partial nephrectomy service
Fetal medicine services
Gender identity development service for children and adolescents
Gender identity disorder services
Heart and lung transplantation service (including bridge to transplant using mechanical circulatory support)
Highly specialist adult urinary and gynaecological surgery services
Highly specialist allergy services
Highly specialist colorectal surgery services
Highly specialist dermatology services
Highly specialist metabolic disorder services
Highly specialist pain management services for children and young people
Highly specialist palliative care services for children and young people
Highly specialist services for adults with infectious diseases
Hyperbaric oxygen treatment services
Insulin-resistant diabetes service
Islet transplantation service
Liver transplantation service
Lymphangiomyomatosis service
Lysosomal storage disorder service
Major trauma services
McArdle's disease service
Mental health service for deaf children and adolescents
Middle ear implantable hearing aid services
Neurofibromatosis type 2 service
Neuromyelitis optica service
Neuropsychiatry services
Ocular oncology service
Ophthalmic pathology service
Osteo-odonto-keratoprosthesis service for corneal blindness
Paediatric and perinatal post mortem services
Paediatric cardiac services
Paediatric intestinal pseudo-obstructive disorders service
Pancreas transplantation service

Paroxysmal nocturnal haemoglobinuria service
Positron Emission Tomography – Computed Tomography services
Primary ciliary dyskinesia management service
Primary malignant bone tumours service
Proton beam therapy service
Pseudomyxoma peritonei service
Pulmonary hypertension service for children
Pulmonary thromboendarterectomy service
Radiotherapy services
Rare mitochondrial disorders service
Reconstructive surgery service for adolescents with congenital malformation of the female genital tract
Retinoblastoma service
Secure forensic mental health service for young people
Severe acute porphyria service
Severe combined immunodeficiency and related disorders service
Severe intestinal failure service
Severe obsessive compulsive disorder and body dysmorphic disorder service
Small bowel transplantation service
Specialist burn care services
Specialist cancer services
Specialist cancer services for children and young people
Specialist dentistry services for children and young people
Specialist ear, nose and throat services for children and young people
Specialist endocrinology and diabetes services for children and young people
Specialist gastroenterology, hepatology and nutritional support services for children and young people
Specialist genetic services
Specialist gynaecology services for children and young people
Specialist haematology services for children and young people
Specialist haemoglobinopathy services
Specialist immunology services for patients with deficient immune systems
Specialist mental health services for deaf adults
Specialist morbid obesity services
Specialist neonatal care services
Specialist neuroscience services for children and young people
Specialist ophthalmology services for children and young people
Specialist orthopaedic surgery services for children and young people
Specialist paediatric intensive care services
Specialist paediatric liver disease service
Specialist perinatal mental health services
Specialist plastic surgery services for children and young people
Specialist rehabilitation services for patients with highly complex needs
Specialist renal services for children and young people
Specialist respiratory services for children and young people
Specialist rheumatology services for children and young people

Specialist services for children and young people with infectious diseases
Specialist services for complex liver, biliary and pancreatic diseases in adults
Specialist services for haemophilia and other related bleeding disorders
Specialist services for severe personality disorder in adults
Specialist services to support patients with complex physical disabilities
Specialist surgery for children and young people
Specialist urology services for children and young people
Spinal cord injury services
Stem cell transplantation service for juvenile idiopathic arthritis and related connective tissue disorders
Stickler syndrome diagnostic service
Vein of Galen malformation service
Veterans' post traumatic stress disorder programme
Wolfram syndrome service
Xeroderma pigmentosum service

NATIONAL HEALTH SERVICE, ENGLAND

NATIONAL HEALTH SERVICE (CROSS-BORDER HEALTHCARE) (ENGLAND) DIRECTIONS 2013

The Secretary of State for Health gives these Directions in exercise of the powers conferred by section 6D of the National Health Service Act 2006(a).

Application, commencement and interpretation

—(1) These Directions may be cited as the National Health Service (Cross-Border Healthcare) (England) Directions 2013 and shall come into force on 25th October 2013.

These Directions are given to the National Health Service Commissioning Board and every clinical commissioning group (b).

These Directions apply to the provision of information to and consideration of applications made by resident patients in the exercise of the rights and entitlements mentioned in Directive 2011/24/EU of the European Parliament and of the Council of 9th March 2011 on the application of patients' rights in cross-border healthcare (c).

In these Directions—

1. "the Board" means the National Health Service Commissioning Board established under section 1H of the NHS Act(d) (the National Health Service Commissioning Board and its general functions);
2. "CCG" means a clinical commissioning group established under section 14D of the NHS Act (e)(effect of grant application);
3. "the Cross-Border Healthcare Regulations" means the National Health Service (Cross-Border Healthcare) Regulations 2013 (f);
4. "the Directive" means Directive 2011/24/EU of the European Parliament and of the Council of 9th March 2011 on the application of patients' rights in cross-border healthcare;
5. "the NCP" means the national contact point for England designated under regulation 2 of the Cross-Border Healthcare Regulations;
6. "the NHS Act" means the National Health Service Act 2006(g);
7. "Regulation (EC) No 883/2004" means Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29th April 2004 on the coordination of social security systems(h);
8. "resident patient" means an individual for whom the United Kingdom is the Member State of affiliation within the meaning of Article 3(c) of the Directive (definitions).

(a) 2006 c. 41. Section 6D was inserted by the Health and Social Care Act 2012 (c.7), section 19.

(b) The Directions apply to England only by virtue of section 271(1) of the National Health Service Act 2006.

(c) O.J. No L88, 4.4.2011, p45.

(d) Section 1H was inserted by the Health and Social Care Act 2012, section 9(1).

(e) Section 14D was inserted by the Health and Social Care Act 2012, section 25(1).

(f) S.I. 2013/2269.

(g) 2006 c.42.

(h) OJ No. L 166, 30.4. 2004 p.1-123; corrigenda to the Regulation published in OJ No. L 200, 7.6.2004 p.1-49 and OJ No. L 204, 4.8. 2007, p 30.

Administration

The Board in the exercise of its functions under regulation 3 of the National Health Service and Public Health (Functions and Miscellaneous Provisions) Regulations 2013 (exercise of functions)(**a**) must have regard to the matters set out in Article 9 of the Directive (administrative procedures regarding cross- border healthcare), that is to say —

- procedures and criteria for reimbursement must be based on objective and non-discriminatory criteria that are necessary and proportionate;
- information about administrative procedures must be publicly available and easily accessible;
- each application must be dealt with objectively and impartially; and
- decisions on applications must be properly reasoned.

Consideration of applications for prior authorisation

—(2) When considering an application for prior authorisation under section 6BB of the NHS Act (prior authorisation for the purposes of section 6BA) the Board must take account of the specific medical condition, the urgency and the individual circumstances of the patient to whom the application relates(**b**).

When considering an application for prior authorisation the Board must—

- consider whether the conditions for authorisation under Regulation (EC) No 883/2004 are met; and
- if the conditions are met, the Board must—
 - ask the patient if the patient wishes to be granted authorisation under the Regulation (EC) No 883/2004; and
 - unless the patient objects, grant authorisation under Regulation (EC) No 883/2004.

Duty to publish information about healthcare services subject to prior authorisation

—(3) For the purpose of enabling resident patients to exercise their rights and entitlements mentioned in the Directive, the Board must publish free of charge information identifying services that fall within section 6 BA(6)(a) of the NHS Act (reimbursement of the cost of services provided in another EEA state where expenditure incurred on or after 25th October 2013) as services for which prior authorisation is required in accordance with section 6BB(4)(b) of that Act (prior authorisation for the purposes of section 6BA).

The information must, so far as practicable, describe the services using terms that are easily understood without specialist knowledge.

The information may be provided by whatever means the Board thinks is appropriate but must be—

- easily accessible;
- available by electronic means; and
- made available in a manner that is compatible with the performance by the NCP of its functions under the Cross-Border Healthcare Regulations.

Duty to publish information about the range of NHS healthcare services generally available

—(4) For the purpose of enabling resident patients to exercise the rights and entitlements mentioned in the Directive, the Board and each CCG must publish free of charge information that enables patients to find out the range of healthcare services that are generally made available or are generally not made available (as the case may be) to patients for whom the Board or the CCG is responsible for making services available under or by virtue of the NHS Act.

- (2)The information must include any criteria, clinical thresholds or exceptions that apply to a particular service.
- (3)The information must, so far as practicable, describe the services using terms that are easily understood without specialist knowledge.
- (4)The information may be provided by whatever means the Board or the CCG thinks appropriate but must be—
 - easily accessible;

^(a) S.I.2013/261.

^(b) See the National Health Service and Public Health (Functions and Miscellaneous Provisions) Regulations 2013 (S.I. 2013/261) which specifies the time within which the Board must determine an application .

available by electronic means; and

made available in a manner that is compatible with the performance by the NCP of its functions under the Cross-Border Healthcare Regulations.

CCG duty to provide information to patients

—(5) For the purpose of complying with regulation 9 of the Cross-Border Healthcare Regulations (information on rights and entitlements) each CCG must make publicly available information giving the contact details of the person or team at the CCG to whom a resident patient may address a request for information on their rights and entitlements as mentioned in Article 5(b) of the Directive.

On receipt of a request from a resident patient for information on their rights and entitlements mentioned in Article 5(b) of the Directive, the CCG must provide such information as it considers appropriate for the purpose of giving effect to Article 5(b) of the Directive.

The CCG must provide the information referred to in paragraph (2) promptly, taking into account the patient's specific medical condition, the urgency and the patient's individual circumstances and in any event no later than 10 working days from the day on which the CCG received the patient's request for information.

The information referred to in paragraphs (1) and (2) may be provided by whatever means the CCG thinks appropriate but it must be—

easily accessible;

available by electronic means; and

made available in a manner that is compatible with the performance by the NCP of its functions under the Cross-Border Healthcare Regulations.

The Board's duty to provide advice and assistance

7—(1) For the purpose of complying with regulation 9 of the Cross-Border Healthcare Regulations (information on rights and entitlements) and assisting resident patients to exercise their rights and entitlements under the Directive the Board must—

(a) establish a service for the purpose of providing information, advice and assistance to resident patients on their rights and entitlements under the Directive; and

(b) make publicly available information giving the contact details of that service.

(2) On receipt of a request from a resident patient for information on their rights and entitlements mentioned in Article 5(b) of the Directive the Board must provide such information as it considers appropriate for the purpose of giving effect to Article 5(b) of the Directive.

(3) The Board must provide the information referred to in paragraph (2) promptly, taking into account the patient's specific medical condition, the urgency and the patient's individual circumstances and in any event no later than 10 working days from the day on which the Board received the patient's request for information.

(4) The information, advice and assistance referred to in paragraphs (1) and (2) may be provided by whatever means the Board thinks appropriate but it must be—

(a) easily accessible;

available by electronic means; and

made available in a manner that is compatible with the performance by the NCP of its functions under the Cross-Border Healthcare Regulations.

Meaning of “working day”

8. In these Directions the expression “working day” means any day except a Saturday, a Sunday, Christmas day, Good Friday or a day which is a bank holiday in England under section 1 of the Banking and Financial Dealings Act 1971(a) and any request received on a day that is not a working day is to be treated as having been received on the next working day.

Signed by authority of the Secretary of State for Health

(^a) 1971 c.80.

[Date]

[Name]
Member of the Senior Civil Service
Department of Health