Department of Health & Social Care

Progress report on the National Health Service (Cross-Border Healthcare) Regulations 2013

15 November 2018

Contents

1. Executive summary

1.1 The National Health Service (Cross-Border Healthcare) Regulations 2013 implement in England and Wales the Directive 2011/24/EU of the European Parliament and the Council on the application of patients' rights in cross-border healthcare, in domestic legislation. These include provisions for reimbursement of healthcare costs, patient information and the equal treatment of visiting patients in relation to NHS charges. A review and report is a statutory requirement of the Regulations.

1.2 The report outlines the objectives of the system established by the Regulations, which include clarity on patients' rights, facilitating of the right to obtain services and support for patient choice, provision of relevant information to patients, improving patient safety and promoting cooperation between member states. It evaluates how far those objectives have been met, whether they remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation. It finds that these objectives are being met and remain appropriate that the Regulations are the most appropriate mechanism for achieving these objectives.

2. Background

2.1 The National Health Service (Cross-Border Healthcare) Regulations 2013 (CBH Regulations), which came into force on 25 October 2013, transposed elements of EU Directive 2011/24/EU on the application of patients' rights in cross-border healthcare ('the Directive') in relation to England and Wales. Similar legislation was enacted for Scotland, Northern Ireland and Gibraltar.

2.2 The Directive is separate from the Social Security Coordination Regulations (883/2004 and 987/2009) that govern reciprocal healthcare (i.e. the EHIC, S1 and S2 schemes for people who receive healthcare in the EU whose healthcare costs are the responsibility of the UK (and vice versa for EU-insured people in the UK)). The reciprocal healthcare legislation is linked to free movement of persons and covers the EU/European Economic Area (EEA) and Switzerland, the Directive is linked to free movement of services and covers the EU/EEA (not Switzerland – as it is not in the single market). Both funding routes have a separate set of criteria that need to be met.

2.3 The UK remains a Member State of the EU and will therefore continue to work with the European Commission and other Member States to comply with the

requirements of the Directive until the UK exits the EU. However, any decisions regarding the implementation of the Directive post-exit will be subject to the ongoing negotiations with the EU.

2.4 The CBH Regulations transposed specific requirements of the Directive (either directly within the Regulations or by amending existing domestic legislation) in relation to England and Wales. Some requirements of the Directive did not require transposition because they were already met by existing domestic legislation, and others were transposed into other domestic legislation. The main elements transposed by the CBH Regulations were:

2.5 Reimbursement - The Directive enables patients to receive treatment in another EU/EEA country with the costs being covered by their home country. The treatment must be one they are entitled to, and reimbursement is capped at the cost of same or equivalent treatment in their home healthcare system.

2.6 The S2 route (under Social Security Coordination Regulations) only provides for treatments under the state system paid for through state-to-state payments and it covers the EEA and Switzerland. The Directive route, by contrast, reimburses individual patients for state or private treatment in the EU/EEA (and vice versa). It does not cover Switzerland. The Directive route does not require pre-authorisation in most cases. Travel and accommodation costs are not covered in England and Wales. Patients only require pre-authorisation for a limited number of treatments; otherwise they are entitled to reimbursement without pre-authorisation. There is no right for patients to receive reimbursement for planned treatment within or between England, Wales, Scotland and Northern Ireland.

2.7 For example, a UK citizen has the right to go to France and purchase a hip replacement privately. Providing the NHS subsequently agrees the treatment was necessary and within the scope of what the NHS offers, and where all other eligibility criteria are met, it must reimburse the costs (up to the NHS tariff). There are also EEA visitors to the UK who purchase healthcare from UK NHS/Private providers and obtain reimbursement from their home member state.

2.8 Patients can currently use the S2 route for qualifying, state-provided healthcare in the EEA, rather than the Directive. Using the S2 route, they do not have to pay the costs of treatment upfront and there is no cap on the amount reimbursed (although S2 treatments are all subject to prior approval). Alternatively, patients may use the Directive to receive reimbursement for their healthcare (capped at the domestic tariff).

2.9 In 2017, 1,108 individuals from England and Wales were reimbursed for treatment under the Directive at a cost of £1.41m. Poland, Lithuania and France were among the most common destinations.

2.10 National Contact Points (NCPs) – NCPs are required to be established in each member state to provide appropriate information on essential aspects of cross-border healthcare to facilitate patients exercising their rights to that healthcare, including clarification of the rules and procedures applicable and providing information on their rights. They are required to provide a range of information such as on a provider's right to practice, quality, safety, complaints and dispute procedures and hospital accessibility for disabled people. NCPs are required to cooperate with NCPs in other MS, and the Commission, to give effect to the Directive. NCPs are also required to consult with patient organisations, health care providers and insurers so far as they consider appropriate for the purposes of giving effect to the Directive.

2.11 Equal Treatment – Directive 2011/24/EU requires non-discriminatory pricing for services provided to EEA nationals or that this is calculated on a non-discriminatory basis. This means that EEA residents who receive qualifying treatments in the UK cannot be charged differently to UK residents purely because they do not reside in the UK. The CBH Regulations transposed this requirement.

2.12 The main aim of the CBH Regulations was to comply with the obligations under EU Directive 2011/24/EU. More specifically to:

- clarify 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 was safe and of high-quality; and
- to promote cooperation between Member States.

3. Evidence to support progress

Information

3.1 The UK set up NCPs in each UK territory to provide information on patients' rights, provider information and complaints procedures. In England, the NCP is NHS England and in Wales it is the National Contact Point Wales. This has increased the availability of information to patients, and clarified their rights, as codified by the Directive.

Clarification, simplification and awareness

3.2 NCPs in the UK offer a centralised service through which patients can obtain relevant information and/or make reimbursement or pre-authorisation requests. This simplifies the process. In England, the European Cross Boarder Healthcare Team processes application forms and makes reimbursements and the NCP provides information. However, both teams sit within NHS England.

3.3 The UK aims to determine applications within 20 working days. The maximum processing times adopted by England and Wales are 20 and 10 working days respectively for pre-authorised treatments. For reimbursements (without pre-authorisation) these are 20 working days for both England and Wales. In 2017, the average processing times for pre-authorised treatments were 15 working days in England and 8.6 working days in Wales. For reimbursements (without prior authorisation) this was 22 working days for England and 8.1 working days for Wales.

3.4 The rules on reimbursement are clear and transparent in the UK under the CBH regulations. They clearly state objective criteria for reimbursement. In addition to this, the UK does not have extensive limitations on reimbursement. As a result, people are generally not restricted from obtaining qualifying treatments in accordance with the Directive rights. NCPs (or the European Cross Border Healthcare Team for England) in the UK also provide for reimbursement up to the level of public provision domestically.

3.5 The rules for pre-authorisation are also clear and transparent. In both England and Wales, the requirement for pre-authorisation of treatments under the CBH Regulations is confined to specialised treatments. The treatments that require prior authorisation are clearly listed on the NCP websites along with the rationale for their inclusion in the list.

3.5 It is likely that patients' awareness of their rights under the Directive has increased. The numbers of people receiving reimbursement for treatments in other EEA countries under the Directive is small, but the numbers have steadily risen over time, suggesting that awareness has increased, which may be attributable to the wider availability of information.

3.6 The number of treatments authorised or reimbursed by England and Wales is given in table 1 below.

Table 1 – The number of pre-authorised treatments and reimbursements provided by England and Wales

	Pre-authorised Treatments				Reimbursements (without pre-authorisation)			
Year	**England**	**% change**	**Wales**	**% change**	**England**	**% change**	**Wales**	**% change**
2017	75	67	16	167	1006	13	11	57
2016	45	-6	6	-63	892	-14	7	0
2015	48	37	16	78	1034	71	7	75
2014	35	N/A	9	N/A	604	N/A	4	N/A

3.7 Table 1 shows that the number of pre-authorised treatments under the Directive rose by 114% in England from 35 to 75 between 2014 and 2017 and the number rose by 78% in Wales from 9 to 16 in the same period.

3.8 The number of reimbursements (without pre-authorisation) for treatments under the Directive rose by 67% in England from 604 to 1006 between 2014 and 2017 and the number in Wales rose by 175% from 4 to 11 in the same period.

3.9 While the CHB Regulations does not relate to Northern Ireland or Scotland, these figures are provided for comparison in table 2 below.

Table 2 – The number of pre-authorised treatments and reimbursements provided by Northern Ireland and Scotland

	Pre-authorised Treatments				Reimbursements (without pre-authorisation)			
Year	**N.I.**	**% Change**	**Scotland**	**% Change**	**N.I.**	**% Change**	**Scotland**	**% Change**
2017	230	248	0	-100	27	-36	29	-44
2016	66	120	3	200	42	100	52	79
2015	30	1400	1	-50	21	91	29	107
2014	2	N/A	2	N/A	11	N/A	14	N/A

3.10 The number of pre-authorised treatments authorised by Northern Ireland under the Directive rose from 2 to 230 between 2014 and 2017, but they fell in Scotland from 2 to 0 in the same period.

3.11 The number of reimbursements for treatments under the Directive rose in Northern Ireland from 11 to 27 between 2014 and 2017 and the number in Scotland rose from 14 to 29 in the same period.

3.12 Table 3 below shows the total cost of treatments reimbursed in England and Wales (for both pre-authorised and reimbursed (without prior authorisation)).

Table 3 – The total cost of treatments reimbursed by England, Wales, Scotland and Northern Ireland (Pre-authorised and without prior authorisation (£m))

Year	England	Wales	Scotland	Northern Ireland
2017	1.33	0.08	0.05	0.71
2016	1	Not available. Total for pre-authorised is 0.04	0.07	0.31
2015	0.96	0.08	0.05	0.13
2014	0.89	0.04	0.02	0.02

3.13 The average cost of treatment per application is provided in table 4 below for England, Wales, Scotland and Northern Ireland.

Table 4 – The average cost of treatments reimbursed by England, Wales, Scotland and Northern Ireland (Pre-authorised and without prior authorisation (£m))

Year	England	Wales	Scotland	Northern Ireland
2017	1,230	3,122	1,645	2,758
2016	1,068	Not available. Average for pre-authorised treatment was 6,744	1,304	2,832
2015	886	3,690	1,507	2,524
2014	1,385	2,788	1,540	1,255

3.14 Table 5 shows the top 10 destinations for treatments by year from 2015-2017 for the UK.

Table 5 – Top 10 destinations for treatments by year from 2015-2017

2015		2016		2017	
Country	**No. of Treatments**	**Country**	**No. of Treatments**	**Country**	**No. of Treatments**
Poland	444	Poland	408	Poland	429
Lithuania	140	Lithuania	150	Ireland	220
France	114	France	84	Lithuania	198
Germany	102	Ireland	72	France	115
Spain	66	Spain	62	Spain	70
Hungary	37	Germany	55	Germany	56
Ireland	33	Czech Republic	37	Latvia	56
Slovakia	32	Greece	32	Slovakia	34
Latvia	30	Latvia	30	Hungary	31
Czech Republic	28	Slovakia	27	Italy	30

3.15 The number of information requests to NCPs concerning Cross-Border Healthcare (for the UK as a whole) fell from 8,471 in 2015 to 5,495 in 2016. This, in conjunction with the increased number of citizens receiving treatment abroad under the Directive, could suggest that increased availability of information on NCP websites has reduced the number of patient requests.

3.16 Table 6 below shows the proportion of successful requests relative to the number of applications. This has fallen from 95% to 52% for both pre-authorised treatment and reimbursements (without pre-authorisations) in England and has risen from 50% to 53% for pre-authorised treatment and from 40% to 73% for reimbursement (without pre-authorisation) in Wales between 2014 and 2017. The main reasons for refusal of applications requiring pre-authorisation in the UK in 2017 included the healthcare not being among the national healthcare benefits of the Member State of affiliation and the treatments being available domestically within a medically justifiable time-period, which are objectively justifiable reasons provided for by the legislation. When considered alongside the increased numbers receiving treatment abroad under the Directive, as mentioned above, the objective of facilitating the right to obtain services and support for patient choice continues to be met.

Table 6 – Number of authorised requests relative to the number of applications (%)

	Pre-authorised		Reimbursed	
Year	**England**	**Wales**	**England**	**Wales**
2017	52	53	52	73
2016	38	21	55	58
2015	76	40	65	47
2014	95	50	95	40

Safety of treatment and cooperation

3.17 It is a requirement under the Directive for member states to ensure systems of professional liability insurance, or equivalent provision, and ensure that information on the right to practice of health professionals is made available to authorities in another MS. The former is given effect through a suite of measures including regulator guidance and the latter is a requirement of the cross-border cooperation provisions in the CBH regulations. NCPs can provide patients with the details of NCPs in other EEA countries.

3.18 NCPs also perform a function of facilitating the sharing of information with the Commission and other EU member states and consult with patient organisations, health care providers and insurers.

4. The appropriateness of the CBH Regulations

4.1 Transposition of elements of the Directive in the CBH Regulations meant that the rights and duties were clearly set out and enforceable. As such, many of the provisions do not to lend themselves to non-regulatory solutions.

5. Continuity of CBH Regulations

5.1 The UK will continue to meet its obligations while a Member State of the European Union until the UK exits the EU. Therefore, the provisions made by the CBH Regulations remain appropriate for meeting the obligations under EU legislation. In the absence of these provisions the UK, would not be at risk of non-compliance

with EU legislation which could cause diplomatic harm and lead to legal risk and potentially significant financial penalties.

6. Conclusion

6.1 The CBH Regulations have met their objectives and continue to do so and ensure that the UK remains compliant with EU legislation in relation to England and Wales. NCPs were set up to provide a range of information to patients about their rights and entitlements, to support cooperation on standards and guidelines on safety and quality and to facilitate the sharing of information between themselves, the Commission and other member states, which they do effectively. They also provide clear and transparent information and objectively handle patient reimbursement requests, thus successfully facilitating the right to obtain services and supporting patient choice. While the UK remains part of the EEA, and subject to the obligations of the Directive, the CBH Regulations remain an appropriate vehicle for ensuring adherence to its binding requirements.

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