ROYAL NORWEGIAN MINISTRY
OF HEALTH AND CARE SERVICES

EFTA Surveillance Authority
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BELGIUM

Your ref	Our ref	Date
Case No 72376	21/2317-	18.06.2021

Request for information concerning the criteria for access to in-patient treatment in other EEA States

Dear Sir/Madam,

Reference is made to the EFTA Surveillance Authority's (the Authority) letter dated 7 May 2021 with request for information concerning the criteria for access to in-patient treatment in other EEA states. In the said letter the Authority refers to the Reasoned Opinion dated 20 September 2017 concerning Norway's criteria for access to in-patient treatment in other EEA States, and their compliance with Article 20 of Regulation 883/2004 and/or Article 36 EEA and/or Articles 7(6), 7(9)-7(11), 8(1), 8(3)-(5) and 9(1) of Directive 2011/24.

The Authority has in the said letter requested the Norwegian Government to provide further information and clarifications so it reaches the Authority by 7 June 2021. The Ministry has requested for an extension of the deadline to 18 June 2021 and Authority has granted the extension of the deadline as requested. The Ministry of Health and Care Services will hereby provide information and clarifications, limited to what seems appropriate at the present stage of the Procedure.

1. INTRODUCTORY REMARKS

As described in earlier letters there are, according to Norwegian legislation, three different legal grounds for publicly paid in-patient treatment abroad:

1. *Regulation 22 June 2012 No 585, incorporating Regulation (EC) No 883/2004 on social security coordination.*

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Norway has incorporated Regulation (EC) No 883/2004 on Social Security Coordination, as such, into Norwegian law, see Regulation 22 June 2012 No 585 on the incorporation of the social security into the EEA Agreement (forskrift 22. juni 2012 nr 585 om inkorporasjon av trygdeforordningene I EØS-avtalen). The obligations with regard to the incorporation of the Regulation (EC) No 883/2004 are therefore complied with. The Regulation provides an independent basis for in-patient treatment abroad. If the criteria in Article 20 of Regulation (EC) No 883/2004 are met, the patient will have a right to receive an authorisation or reimbursement in accordance with the Regulation.

2. *Regulation 22 November 2010 No 1466 on reimbursement of health care services received in another EEA State (Reimbursement Regulation)*
   Norway established 1 January 2011 a reimbursement scheme covering certain types of healthcare services received in the EEA, cf. Regulation 22 November 2010 No 1466 on reimbursement of health care services received in another EEA State (Reimbursement Regulation) to fulfil patients' rights to reimbursement according to case law. To complete our obligations according to the Patients' Rights Directive 2011/24/EU the reimbursement scheme was from 1 March 2015 extended to include expenses for in-patient treatment. The main condition to get reimbursement is that the patient would have received benefits or contributions under the National Insurance Act (Act 1997-02-28-19) or the health care would be funded by the public, if the particular health care was received in Norway, cf. Section 2 of the Reimbursement Regulation. Prior authorisation is not required for the reimbursement of expenses for in-patient treatments. Furthermore, patients who are evaluated to have a right to receive necessary healthcare according to Section 2-1 b(2) PRA may apply for advance commitment (forhåndstilsagn). The commitment will clarify whether the patient is entitled to the particular healthcare that the patient would like to receive in another EEA country and the maximum reimbursable amount. This will further facilitate access to in-patient healthcare abroad. The cost is reimbursed up to the cost of the equivalent health care services in Norway, cf. Section 7.

3. *Patient Rights Act (PRA) 2 July 1999 No 63 section 2-1b(4) and (5) (in force at the RDO deadline 20 January 2018, amended 1. March 2020, cf. PRA section 2-4 a(2) subparagraph a) with further provisions in Prioritization Regulation (PR) 1 December 2000 No 1208*
   Provided that the necessity condition in Section 2-1 b(2) PRA is met, Section 2-1 b(4) and (5) PRA (in force at the RDO deadline 20 January 2018, amended 1 March 2020) foresees two alternative situations in which patients could be entitled to publicly paid medical treatment abroad. The first only becomes active following the expiry of the time limit set pursuant to Section 2-1 b(2), entitling the patient to receive publicly paid medical treatment abroad or with a private service provider, cf. Section 2-1 b(4). The second concerns the right to receive publicly paid medical treatment abroad if there are no adequate health care in Norway, and is also applicable prior to the expiry of the aforementioned time limit, cf. Section 2-1 b(5). The intention of these provisions is

to secure that the regional health authority fulfils its obligation to provide necessary specialist health services to patients within a medical justifiable time limit. The costs of treatment abroad can be covered under the PRA provisions if there is a lack of capacity to provide necessary healthcare (until 1 March 2020) or there are no adequate medical services in Norway for the individual patient (for instance because Norway, as a relatively small country, has not developed the particular treatment). Patients has a right to get publicly paid health care abroad (not limited to the EEA area) on certain conditions. One of the conditions is that the patient has a right to receive necessary healthcare from the specialist health service, cf. Section 2-1 b(2) PRA and Section 2 of the Prioritization Regulation (PR). When it is necessary for patients to go abroad in these cases, the expenses for travel and accommodation are, in addition to the treatment cost, fully covered. This right to access to health care services and full cost coverage does, in our view, go beyond our obligations under EEA law.

The two first set of rules are incorporated into Norwegian legislation in order to fulfil our obligations according to EEA law. The third set of rules (under the PRA and PR) has a different function and character. The right to go abroad according to Section 2-1 b(4) and (5) PRA (amended 1 March 2020, cf. PRA section 2-4 a(2) subparagraph a) is intended to secure that the regional health authority fulfils its obligation to provide necessary specialist health services to patients within a medical justifiable time limit. This is further addressed in the Ministry's letter of 3 May 2016.

2. ANSWER TO QUESTION 1

1.1 At the top of page 3 of the Letter, the National Office for Health Service Appeals states that, in its view, the assessment of whether treatment can be given within a medically justifiable time limit should be made by reference to the date of the offer of treatment in Norway which the complainant was given, and when that treatment could be provided.

1.1.1 Does the Norwegian Government consider that this approach generally is in compliance with relevant EEA law set out in the RDO, in particular Regulation 883/2004 Article 20(2), which requires authorisation for treatment in another EEA State where the treatment in question is among the benefits provided for by the legislation and where "he/she cannot be given such treatment within a time limit which is medically justifiable, taking into account his/her current state of health and the probable course of his/her illness"?

A patient is entitled in accordance with Regulation (EC) No 883/2004 Article 20(2) to receive authorisation from the competent institution if the treatment in question is among the benefits provided for by the legislation in the Member State where the person concerned resides and where he/she cannot be given such treatment within a time limit which is medically justifiable, taking into account his/her current state of health and the probable course of his/her illness.

There are two conditions laid down in Article 20(2) and both must be fulfilled. The first condition requires that the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the insured person resides. The second condition requires that the treatment cannot be given within a medically justifiable time limit, taking into account the patients current state of health and the probable course of his disease. Both these conditions must be met in order to be entitled to receive authorisation in accordance with Regulation (EC) No 883/2004 Article 20.

The obligation to grant prior authorisation is consequently not present if the treatment is not among the benefits provided for by the legislation of the competent Member State, or if it indeed is and may be provided by the competent Member State within a medically justifiable time limit (see also Regulation 987/2009 article 26 (2))

In Norway entitlement to health care from the specialist health service depends on whether the patient fulfils the criteria for “entitlement to receive necessary health care” pursuant to Section 2-1 b(2) PRA and Section 2 PR.

Section 2-1 b(2) PRA read at the RDO deadline (20 January 2018)[1] as follows:

"*Pasienten har rett til nødvendig helsehjelp fra spesialisthelsetjenesten. Spesialisthelsetjenesten skal i løpet av vurderingsperioden etter § 2-2 første ledd fastsette en frist for når pasienten senest skal få nødvendig helsehjelp. Fristen skal fastsettes i samsvar med det faglig forsvarlighet krever. […]*"

Section 2 PR read at the RDO deadline (20 January 2018)[2] as follows :

"*Pasienten har rett til nødvendig helsehjelp fra spesialisthelsetjenesten etter pasient- og brukerrettighetsloven § 2-1b andre ledd, når:*

a) pasienten, med det unntaket som er nevnt i § 3 andre ledd, kan ha forventet nytte av helsehjelpen og

b) de forventede kostnadene står i et rimelig forhold til tiltakets effekt.

Med forventet nytte av helsehjelpen menes at kunnskapsbasert praksis tilsier at aktiv medisinsk eller tverrfaglig spesialisert helsehjelp kan bedre pasientens livslengde eller

[1] Unofficial translation:
The patient is entitled to receive necessary healthcare from the specialist health service. The specialist health service shall within the period of evaluation, cf. section 2-2 first paragraph, set a time limit within which the patient shall receive the necessary healthcare. The time limit shall be set in accordance with what is medically justifiable.[…]

[2] Unofficial translation:
The patient is entitled to receive necessary healthcare from the specialist health service pursuant to Section 2-1b second paragraph PRA when:

a) the patient, with the exception mentioned in Section 3 second paragraph, has an expected benefit of the healthcare and
b) the expected costs are reasonable, taking due account to the effect of the measure.

By "expected benefit of the health care" is meant that knowledge-based experience requires that active medical or multidisciplinary specialised health care can improve the patient's life expectancy or life quality with a certain duration, that the condition may worsen without healthcare or that treatment options are forfeited by postponing the health care

livskvalitet med en viss varighet, at tilstanden kan forverres uten helsehjelp eller at behandlingsmuligheter forspilles ved utsettelse av helsehjelpen."

This warrants a concrete assessment of the anticipated benefits of the health care in question seen in light of the medical condition of the patient as well as the expected costs of the treatment. There must be solid documentation that the treatment has an expected benefit.

The condition concerning anticipated benefit is clarified in Section 2 PR third paragraph (unofficial translation):
"*By "anticipated benefit of the health care" is meant that knowledge-based experience requires that active medical or multidisciplinary specialised health care can improve the patient's life expectancy or life quality with a certain duration, that the condition may worsen without healthcare or that treatment options are forfeited by postponing the health care."*

The second condition in accordance with Regulation 883/2004 Article 20 requires that the necessary treatment cannot be given within a medically justifiable time limit, taking into account the patients current state of health and the probable course of his disease. It is important, in this regard, to distinguish between the time limit justified by EEA law to assess whether effective treatment can be provided within a medically justifiable time limit domestically, and how the time limit for treatment under Norwegian law is set.

In the case there is a need for an examination or treatment in the specialist health service (hospital or other specialist treatment centre), the GP or other health care providers refer the patient to the specialist health service. Within 10 working days of receiving the referral, the specialist health service makes an individual medical assessment and decides whether the patient is entitled to necessary health care from the specialist health service. If the patient is entitled to such health care, a time limit is set for the starting point of the healthcare and must be set so that the entire course of treatment can be provided within a medically justifiable timeframe.

The time limit is to be set in accordance with professional prudence, and on the basis of the individual patient's current state of health and probable course of the illness. In addition various priority guidelines are developed for different conditions, with indicative time limits. The time limits must be set prior to the very latest time constituting the outer limit for what would give a medically justifiable timeframe. This is also clarified in Section 2-2 (2) PRA. When setting the time limit, the possibility of obtaining health care from a public provider in another health region, a private health care provider or abroad within what is justified from a medical perspective, must be taken into account. Hence, the time limit cannot be set so marginally that it will not be possible to obtain subsidiary treatment privately or abroad within a time limit which is medically justifiable. This is also emphasised in the preparatory works of the Patient's Rights Act, cf. Prop. 118 L (2012-2013) page 102-104.

Necessary health care pursuant to Section 2-1b(2) PRA and Section 2 PR will in most cases be provided by the public healthcare or private providers in Norway, but in some cases the healthcare is provided by providers abroad, cf. Section 2-1 b(4) and Section 2-1 b(5) (in force at the RDO deadline 20 January 2018, amended 1 March 2020). If the specialist health service provides the patient with necessary healthcare within the time limit set in accordance to Section 2-1 b(2), the conditions laid done in Regulation 883/2004 Article 20(2) will in our opinion not be met. As pointed out above the time limit is set with the necessary margin to ensure that the patient receive the necessary healthcare within a time limit which is medically justifiable.

The competent institution is only obliged to grant prior authorisation insofar the treatment in question is among the benefits provided for by the legislation in the Member State where the person concerned resides and where he/she cannot be given such treatment within a time limit which is medically justifiable. Hence; when the specialist health service makes sure that the individual patient receives necessary healthcare within a medically justifiable time limit, there is no obligation to grant prior authorisation in accordance with article 20 of Regulation (EC) No 883/2004.

1.1.2 Is it relevant for that assessment whether elements are present, such as described on page 2 of the Letter, where a surgeon in 2012, Haukeland sykehus in its letter of 23 October 2013, and Helse Bergen HF, as described by Statens Helsetilsyn on 26 August 2015, all concluded that there was no relevant treatment for the patient in question?

The Ministry is not in a position to comment on the specific case in question, but will in general claim that lack of relevant health care in Norway does not in itself oblige the competent institution to grant prior authorisation in accordance with article 20 of Regulation (EC) No 883/2004. The conditions in accordance to Article 20 of the Regulation are as described above whether the health care in question is among the benefits provided for by the legislation and whether the patient has been provided with the necessary healthcare within a medically justifiable time limit. Both conditions laid down in article 20 must to be fulfilled for the obligation in Article 20 to occure.

As explained above patients have in accordance with Section 2-1 b(5) PRA (now Section 2-4 a(2) subparagraph a), a right to go abroad if there is not adequate healthcare available in Norway. The entitlement presupposes that the conditions for the right to health care from the specialist health service are met, cf. Section 2-1 b(2) PRA and Section 2 PR. This include that it is well documentet that active medical treatment can improve the patients life expectancy or quality of life and that the anticipated costs are reasonable, taking due account to the effect of the measure.

Section 2-1 b(2) PRA, cf. Section 2 PR, implies that there is no entitlement to experimental or test treatment, neither in Norway nor abroad, as such treatment by definition lacks the necessary documentation of effects etc. The EFTA Court has held this to be compatible with EEA law, cf. Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*. The patient may

therefore be declined entitlement to a treatment that is not scientifically recognised internationally, also in cases where there is no effective medical treatment available in Norway.

1.2 At the bottom of page 3 of the Letter, the National Office for Health Service Appeals states that it wishes to underline that if there is a lack of a treatment for a particular diagnosis due to a lack of competence, the Regulation does not provide a legal basis for reimbursement, which includes reimbursement pursuant to Article 20 of Regulation 883/2004.

Given that Article 20 concerns authorisations for benefits in kind, the Directorate understands that the National Office for Health Service Appeals is in effect stating that Article 20 of Regulation 883/2004 does not give the right to reimbursement to a patient going to another EEA State to receive treatment if there is a lack of a competence to provide treatment for a particular diagnosis in Norway, even if the treatment in question is among the benefits provided for by Norwegian legislation.

Does the Norwegian Government consider that this statement of the National Office for Health Service Appeals provides the correct interpretation of Article 20 of the Regulation 883/2003, especially in light of § 2-4 a PRA?

The Ministry is of the opinion that Article 20 of Regulation 883/2004 might give reimbursement to patients going to another EEA state to receive treatment also in cases where there is lack of competence to provide treatment for a particular diagnosis in Norway. The conditions for the obligation would be that the treatment in question is among the benefits provided for by Norwegian legislation. This means that the conditions in Section 2-1 b(5) PRA and Section 3 PR, cf Section 2-1 b(2) PRA, cf. Section 2 PR must be fulfilled. Furthermore that the patient cannot be provided with such treatment within a time limit which is medically justifiable. Reference is made to the explaination above under 1.1.1. and 1.1.2 about entitlements to health care from the specialist health service. It follows from Section 4 PR that a medically justifiable time limit is to be set also for patients meeting the conditions in Section 2-1 b(5) PRA and Section 3 PR. This implies the obligation of the specialist health service to ensure that the patient receives necessary treatment within a medically justifiable time limit even when the necessary healthcare is not available in Norway. In such cases the specialist health service must arrange for treatment abroad within the time limit.

If the specialist health service makes sure that the individual patient receives necessary healthcare from a provider abroad within a medically justifiable time limit, there is no obligation to grant prior authorisation in accordance with article 20 of Regulation (EC) No 883/2004.

3. ANSWER TO QUESTION 2

The Directorate refers to the first ground in the RDO, namely that:

- *by maintaining in force legislation, such as Section 2-1b(2) PRA and Section 2 PR, which provides for a necessity test as a basis for entitlement to in-patient treatment, which does not ensure that what is accepted according to international medical science is taken into account when evaluating the expected benefit of treatment, the Kingdom of Norway has failed to fulfil its obligations under Article 20 of the Act referred to at point 1 of Chapter I of Annex VI to the EEA Agreement (Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems), as adapted to the EEA Agreement by Protocol 1 thereto and/or Article 36 EEA and/or Articles 7(6), 7(9)-7(11), 8(1), 8(3)-(5) and 9(1) of the Act referred to at point 2 of Annex X to the EEA Agreement (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), as adapted to the EEA Agreement by Protocol 1 thereto.*

The Authority observes that, by Act of 1 December 2017 No 1905, Norway amended the Prioritisation Regulation ("PR") so that, with entry into force on 1 January 2018, Section 3(1) provided (amendments in bold):

"En pasient som har rett til nødvendig helsehjelp, men som ikke kan få helsehjelp fordi behandling ikke kan utføres forsvarlig i Norge etter akseptert metode, har rett til helsehjelp i utlandet, jf. pasient- og brukerrettighetsloven § 2-1b femte ledd. Det er en forutsetning at helsehjelpen kan utføres forsvarlig av tjenesteyter i utlandet etter akseptert metode og at pasientens tilstand og den aktuelle behandlingen tilfredsstiller kravene i § 2. ***Vurderingen av pasientens nytte av behandlingen skal være individuell og ta utgangspunkt i internasjonal medisinsk vitenskap.****"*

The Authority notes that in cases to which Section 6 of the Prioritisation Regulation applied (breach of deadline), there was no corresponding amendment which ensured that the assessment of the patient's benefit from the treatment shall be individual and be based on international medical science.

Norway is accordingly invited to explain:

2.1 How it ensured, at 20 January 2018 and thereafter, (by means of legal basis, circulars and in administrative practice), in cases to which Section 6 PR applies, that the assessment of the patient's benefit from the treatment shall be individual and be based on international medical science.

As explained above the necessity test is individual and assessed on the basis of international medicine and applied in accordance with international standards.

All health personnel in Norway must under the Health Personnel Act Section 4 conduct their work in accordance with the requirements to professional responsibility and diligent care that can be expected based on their qualifications, the nature of their work and the situation in

general. The requirements to professional responsibility include the responsibility to conduct their work in accordance with the requirements to professional responsibilty and diligent care. What is to be considered professional responsibilty and diligent care will alter with time due to medical development, changes in ethical values and international knowledge of best practice.

When a medical specialist is considering whether the individual patient has a right to necessary healthcare, he or she will normally base his or her consideration on national guidelines and his or her professional knowledge of treatments options available nationally or internationally.

The Norwegian Directorate of Health has a responsibility to develop national guidelines and has adopted guidelines on several several conditions. The guidelines are based on knowledge of evidence based on practice and contribute to continuous improvement of the health care services, cf. the Specialist Health Service Act Section 7-3.

The guidelines include medical recommendations on examinations, treatments and follow-ups of the patients and are based on international knowledge of best practice. To grade the quality of evidence and the strength of recommendations, and to improve communication with users of the guidelines, the Directorate of Health uses international classification systems like GRADE* (Grades of Recommendation Assessment, Development and Evaluation), which is also used by WHO and by many other international organizations. The guidelines are published online and are updated on a regular basis, www.helsedirektoratet.no/produkter .

The Knowledge Centre for the Health Services (a department within the Norwegian Institute of Public Health) contributes to quality improvement in the health services by summarising international research, promoting the use of research results, measuring the quality of health services, and working to improve patient safety. The Centre provides useful information for health professionals through the Norwegian Electronic Health Library, www.helsebiblioteket.no. It is a publicly funded e-library that provides free access to many Norwegian and international sources. In addition, the e-library is a sharing platform for Norwegian clinical practice guidelines, clinical procedures, and other materials developed in the public health care system in Norway.

The Norwegian Electronic Health Library also provides free access to international clinical resources. Through the library, all health personell in Norway have access to BMJ Best Practice and UpToDate, both evidence-based, physician-authored clinical decision support resources. In addition, the e-library provides free access to the Cochrane Library, IBM Micromedex and NHS Evidence.Through ACCESSSS (previously McMaster PLUS), the health personell can search the current best evidence research through the "knowledge pyramid", which provides one stop-access to the leading sources of pre-appraised evidence in order to find the current best evidence available to support clinical decisions. Health personell can also subscribe to updates from ACCESSSS.

By logging in, healthcare professionals and students also have free access to bibliographic databases such as CINAHL, MEDLINE and PsycINFO.

Medical doctors working in the specialist health service are provided the possibility to attend international conferences so that they are updated on the newest international research, clinical guidelines and medical practice.

To enable sustainability and to increase quality and patient safety, Norway has also established a national system for introduction of new health technologies within the specialist health service. The regional health authorities make common decisions to ensure that new technologies meet health care needs for patients in all regions and secures sustainability of the specialist health service. The system utilizes the Health Technology Assessment (HTA) tool to evaluate available international documentation on medicine efficacy, effectiveness and cost effectiveness. Also these assessments are therefore based on international medicine.

The Ministry is of the opinion that this shows that the assessment of the benefits of a treatment is based on what is documented in international medical science.

Section 6 PR applies when the patient has a right to healthcare in accordance to Section 2-1 b(2) PRA and Section 2 PR and necessary health care is available in the public healthcare domestically, but it cannot be provided within the timelimit set in accordance to Section 2-1 b(2) PRA, due to lack of capacity. In such cases the conditions in Section 2 PR are fullfilled, and the question regarding the effect of the medical treatment will not be an equally essential question as it is for treatment abroad in cases where there is no adequate treatment in Norway.

Section 2-1 b(4) gives in such cases the patients a right to receive the health care from a private health care provider in Norway, and was (until 1 March 2020) a separate legal ground for publicly paid in-patient treatment abroad.

Section 2-1 b(4) PRA was amended in december 2019 (in force 1 March 2020) and reads[3]:

> "*Dersom det regionale helseforetaket ikke har sørget for at en pasient med rett til nødvendig helsehjelp fra spesialisthelsetjenesten får den nødvendige helsehjelpen innen tidspunkt fastsatt i medhold av annet ledd, har pasienten rett til nødvendig helsehjelp uten opphold, om nødvendig fra privat tjenesteyter*."

If the specialist health service (usually a public hospital) cannot provide the necessary health care before the time limit, the specialist health service must immediately contact Helfo, cf.

[3] Unoficial translation:
If the regional health authority has not ensured that a patient who is entitled to necessary health care from the specialist health service receives such care within the time limit fixed pursuant to the second paragraph, the patient has the right to receive necessary health care immediately, if necessary from a private service provider or service provider outside the realm.

Section 6(2) PR. Helfo would in such cases find capasity in the public specialist health service in other regions of Norway or from private providers. Before the amendments Helfo also could use healthcare providers abroad, but this was very seldom necessary.

Furthermore there are other legal grounds for publicly paid treatment abroad in such cases, e.g the right to authorisation or reimbursement under Article 20 (2) of Regulation (EC) No 883/2004, and the right to reimbursement in accordance with the Reimbursement Regulation (which implements the right to reimbursement in accordance to Article 36 of the EEA Agreement and the Patients' Rights Directive). This is clarified in Section 6(4) PR.

To give the patients a better overview of the different legal bases and schemes for access to healthcare abroad and to make the regulation more transparent, the Norwegian Parliament has passed a new provision which gathers the different legal grounds to access to healthcare abroad, and where the right to go abroad is clarified. The new provision came into force 1 March and reads[4]:

> *"§ 2-4 a Helsehjelp i utlandet*
> *Pasient har rett til å få utgifter til helsehjelp som mottas i et annet EØS-land, helt eller delvis dekket*
>
> *a) etter folketrygdloven § 5-24 a med forskrifter som gjennomfører pasientrettighetsdirektivet i norsk rett. Dette gjelder når den aktuelle helsehjelpen tilsvarer helsehjelp som pasienten hadde fått tilbud om i den offentlige helse- og omsorgstjenesten i Norge.*

[4] Unofficial translation:
Patient has the right to have expenses for health care received in another EEA country, fully or partially covered

a) pursuant to the National Insurance Act § 5-24 a with regulations that implement the Patient Rights Directive in Norwegian law. This applies when the health care in question corresponds to health care that the patient had been offered in the public health care service in Norway.

b) pursuant to Council Regulations (EC) No. 883/2004 and 987/2009, which, among other things, gives the right to be reimbursed for necessary health care during temporary stays and for planned health care in other EEA countries if the health care is not provided within a reasonable time in Norway.

Patients have the right to have expenses for health care received abroad fully or partially covered

a) if the patient is entitled to necessary health care from the specialist health service according to § 2-1 b and the necessary health care is not available in Norway or the health care abroad is documented to be more effective than the health care offered by the public health care in Norway.

b) pursuant to the National Insurance Act § 5-24 and provisions issued pursuant to it, which, among other things, gives the right to receive benefits for health services for members of the National Insurance who stay abroad over time.

Expenditure on health care that has been decided not to be introduced in Norway is not covered, cf. the Specialist Health Services Act § 4-4. However, this does not apply to health care during temporary stays pursuant to the first paragraph, subparagraph b.

The Ministry may issue regulations with further provisions on the types of health care that are covered by the expenditure coverage, conditions for having the expenses covered and the calculation of the expenditure coverage.

b) *etter rådsforordning (EF) nr. 883/2004 og 987/2009, som blant annet gir rett til å få dekket utgifter til nødvendig helsehjelp under midlertidig opphold og til planlagt helsehjelp i andre EØS-land dersom helsehjelpen ikke ytes innen forsvarlig tid i Norge.*

Pasient har rett til å få utgifter til helsehjelp som mottas i utlandet helt eller delvis dekket

a) *dersom pasienten har rett til nødvendig helsehjelp fra spesialisthelsetjenesten etter § 2-1 b og det ikke finnes et tilbud i riket eller helsehjelpen i utlandet er dokumentert mer virkningsfull enn den helsehjelpen som tilbys av det offentlige i Norge.*
b) *etter folketrygdloven § 5-24 og bestemmelser gitt i medhold av den, som blant annet gir rett til å få stønad til helsetjenester for medlemmer av folketrygden som oppholder seg i utlandet over tid.*

Utgifter til helsehjelp som er besluttet ikke innført i Norge, dekkes ikke, jf. spesialisthelsetjenesteloven § 4-4. Dette gjelder likevel ikke helsehjelp under midlertidig opphold etter første ledd bokstav b.

Departementet kan gi forskrifter med nærmere bestemmelser om hvilke typer helsehjelp som omfattes av utgiftsdekningen, vilkår for å få dekket utgiftene og beregningen av utgiftsdekningen"

The Ministry is of the opinion that the new provision Section 2-4 a gives patients a better overview over the different legal grounds for publicly paid healthcare abroad and also gives more transparency to the conditions for receiving publicly paid health care in those cases where the necessary health care is not available in Norway or the health care abroad is documented to be more effective than the health care offered by the public health services in Norway, cf. Section 2-4 a(2) subparagraph a. This will be helpful both for the patient and for the administrators of these regulations. The new provision is mainly given for informational purposes.

2.2 To what extent did this affect/change existing practice?

In the reasoned opinion, the Authority is of the opinion that the applicable Norwegian legislation does not ensure that international medical science is taken into account when evaluating the expected benefit of treatment. As explained above the necessity test shall be assessed on the basis of international medicine and applied in accordance with international standards. The Ministry is not aware of circumstances demonstrating that this rule is not generally followed by the relevant authorities and cannot see that the arguments which has been presented by the Authority call for a different conclusion.

The amendmend in Section 3(1) PR which came into force the 1st of January 2018 was made to remove any doubt that might nevertheless remain in this regard, but the Ministry does not anticipate that the change will have much impact, because we are of the opinion that international medical science has been taken into account when evaluating the expected benefit of treatment also before the amendmend.

4. ANSWER TO QUESTION 3

At the RDO deadline (20 January 2018):

- *Section 3(1) PR provided:*

  "En pasient som har rett til nødvendig helsehjelp, ***men som ikke kan få helsehjelp fordi behandling ikke kan utføres forsvarlig i Norge etter akseptert metode****, har rett til helsehjelp i utlandet, jf. pasient- og brukerrettighetsloven § 2-1b femte ledd. Det er en forutsetning at helsehjelpen kan utføres forsvarlig av tjenesteyter i utlandet etter akseptert metode og at pasientens tilstand og den aktuelle behandlingen tilfredsstiller kravene i § 2. Vurderingen av pasientens nytte av behandlingen skal være individuell og ta utgangspunkt i internasjonal medisinsk vitenskap."*4 (emphasis added)

- Section 3(4) PR provided:

  "***Manglende kapasitet i spesialisthelsetjenesten gir ikke rett til behandling i utlandet etter denne bestemmelsen****. Rett til behandling omfatter ikke forsendelse av laboratorieprøver for analyse ved utenlandsk tjenesteyter uten som ledd i behandling i utlandet.*" (emphasis added)

3.1 Norway is invited to clarify how Section 3(4) PR interacts with Section 3(1) PR, Section 2-1b PRA and Section 6PR. In particular:

3.1.1 Does Section 3(4) PR mean that, where the treatment <u>can</u> technically be performed properly in Norway due to an accepted method, but there is a lack of capacity (e.g. due to very long waiting lists), the patient is not entitled under Section 3(1) PR to medical care abroad?

In cases where the necessary health care can be performed properly in Norway due to an accepted method, but there is a lack of capacity e.g. due to long waiting lists, patients **cannot** use Section 3 PR as a legal ground for receiving medical treatment abroad.

In such cases there are other legal grounds for publicly paid treatment abroad; the right to authorisation or reimbursement under Article 20 (2) of Regulation (EC) No 883/2004, and the right to reimbursement in accordance with the Reimbursement Regulation (which implements the right to reimbursement in accordance to Article 36 of the EEA Agreement and the Patients' Rights Directive).

3.1.2 If there is a lack of capacity to perform treatment, in the sense e.g. of not enough qualified specialists <u>available</u> to perform treatment, does this mean that a patient would only

be eligible for treatment abroad if the lack of capacity/availability led to timing issues under Section 2-1b(2) PRA and Section 6(2) and (3) PR?

If the specialist health service (usually a public hospital) cannot provide necessary health care before the time limit, because there is a lack of capacity, in the sense e.g. of not enough qualified specialist available to provide such health care, the specialist health service must immediately contact Helfo, cf. Section 6(2) PR. Helfo shall in such cases find a provider in the public specialist health service in other regions of Norway or from private providers. Before the amendments Helfo also could use healthcare providers abroad. Patients could not choose the provider abroad.

The Ministry would like to point out that the right to get publicly paid healthcare abroad in accordance to Section 2-1 b (4) and (5) (until 1 March 2020) are supplementary to Article 20(2) of Regulation 883/2004 which is incorporated into Norwegian law by Regulation 22 June 2012 No 585 and the right to reimbursement in accordance with the Reimbursement Regulation (which implements the right to reimbursement in accordance to Article 36 of the EEA Agreement and the Patients' Rights Directive). This is clarified in Section 6 PR (4) which refers to other possible legal grounds for publicly paid healthcare abroad. Patients can therefore also apply for authorisation in accordance with Article 20 (2) of the Regulation (or reimbursement if the conditions in Article 20 (2) is met) or get reimbursed in accordance with the Reimbursement Regulation as additional routes.

As explained above under the introductory remarks prior authorisation is not required for the reimbursement of expenses for in-patient treatments in accordance to the Reimbursement Regulation. This means that a patient can choose to receive health care in another EEA country and does not have to wait for the time limit under Section 2-1 b (2) PRA to expire. The main condition is that health care would be funded by the public, if the particular health care was received in Norway.

3.1.3 Please explain how, in the circumstances described in 3.1.2 above, Norway ensures that treatment from a private service provider, or from providers abroad, is secured in accordance with the time-limits to which Section 2-1 b PRA and Section 6 PR refer? Is for example there a mechanism for ensuring that waiting lists and times are monitored?

As mention under the introductory remarks the regional health authority has the obligation to provide for necessary specialist health services to patients residing in their region, cf. the Specialist Health Service Act Section 2-1 a. In Norway most of the specialized health care is provided by public hospitals. The regional health authority may also enter into agreements with private providers (in Norway or abroad) to fulfil its obligations to supply specialized health care to the patients residing in the region.

All public hospitals and other health institutions who deliver specialised health services on behalf of the regional health authority are obliged to keep track of waiting time lists for patients where a referral is evaluated and it is decided that the patient has the right to

examination or treatment within the specialist health services in the course of a specific time period, cf. forskrift 12, juli 200 nr, 1233 om ventelisteregistrering Section 1 and Section 3. All health institutions who deliver specialist health services on behalf of the regional health authorities, use digitised health record systems and administrative systems that allow them to monitor waiting times and other related indicators electronically. Health professionals are required to register e.g. the date of which a referral is received and evaluated, when the planned medical care is scheduled to take place, the date of the time limit set in accordance to Section 2-1 b(2) PRA, and the date when the medical care in fact takes place. These indicators are monitored regularly. This information is reported monthly to the Directorate of Health. The Directorate publishes monthly reports on waiting times, the number of patients on waiting lists, the number and share of patients who have waited longer than their individual time limit, and other related indicators, see here www.helsedirektoratet.no/statistikk/statistikk-fra-npr/ventetider-og-pasientrettigheter .

The publication solution provides this information on a national, regional, local, and unit level, as well as distributed on the different medical specialities. The monitoring system within the electronical health record systems enables the health institutions to take measures if patients are approaching the time limit set in accordance to Section 2-1 b (2) PRA, and also to notify Helfo in advance if they are not able to provide the scheduled medical care within the time limit.

3.2 The Authority observes that, at the RDO deadline, Section 3(1) PR was worded as set out above and Section 2-1b(5) PRA was worded as follows:
"Dersom det regionale helseforetaket ikke kan yte helsehjelp til en pasient som har rett til nødvendig helsehjelp fordi det ikke finnes et adekvat tilbud i riket, har pasienten rett til nødvendig helsehjelp fra tjenesteyter utenfor riket innen den frist som er fastsatt etter annet ledd."6 (emphasis added)

Since the RDO deadline, we note that, by law of by law of 20 December 2019 no 104, Section 2-1b(5) PRA has been repealed, and that Section 3 PR has been amended to provide as follows:

"En pasient som har rett til nødvendig helsehjelp, men som ikke kan få helsehjelp fordi det ikke finnes et tilbud i riket eller helsehjelpen i utlandet er dokumentert mer virkningsfull enn den helsehjelpen som tilbys av det offentlige i Norge, har rett til helsehjelp i utlandet, jf. pasient- og brukerrettighetsloven § 2-4a annet ledd bokstav a. Det er en forutsetning at helsehjelpen kan utføres forsvarlig av tjenesteyter i utlandet etter akseptert metode og at pasientens tilstand og den aktuelle behandlingen tilfredsstiller kravene i § 2. Vurderingen av pasientens nytte av behandlingen skal være individuell og ta utgangspunkt i internasjonal medisinsk vitenskap."

Norway is requested to clarify:
3.2.1 What is the relationship between the provisions of Section 3 PR and PRA § 2-4 a, second paragraph, subparagraph a, given that they both refer to the

fact that there is no service in the country or health care abroad being more effective than the health care offered in Norway, given that no crossreference is provided to e.g. PRA §2-4 a first paragraph.

Section 3 PR complements Section 2-4 a(2) subparagraph a PRA. The statutory provision Section 2-4 a(2) PRA will take precedence over the regulatory provision Section 3 PR, if a conflict between the provisions arises.

Section 2-4 a (2) subparagraph a PRA will give more transparency to the conditions for receiving publicly paid healthcare in those cases where the necessary health care is not available in Norway or the health care abroad is documented to be more effective than the health care offered by the public health care in Norway. This might be helpful both for the patient and for the administrators of this regulations.

3.2.2 To what extent this entails a change in law or practice compared with the legislation in force at the RDO deadline.

The Ministry believe that Section 2-4 a PRA and the new wording in Section 2-4 a (2) subparagraph a PRA which replaces the earlier Section 2-1 b (5) PRA will not lead to major changes in the practice as the new wording is essentially in line with previous practice. However, it cannot be ruled out that some cases might have a different outcome with the new wording compared with the earlier wording.

3.2.3 How is, under Section 3 PR, the assessment of the effectiveness of the health care in Norway compared with the health care abroad carried out (by reference to which criteria etc.), especially in light of the facts mentioned in the Letter.

The assessment of effectiveness of the health care in Norway compared with the effectiveness of the health care abroad is performed on an individual basis taking into account the specific medical situation of the patient. The assessment is based on information on documented effectiveness from several sources (see below) and based on the individual factors with the patient, such as comorbidity and adverse reaction on previous treatment. For instance there are several examples of cases where the patient has a common diagnosis where a standard treatment normally is given to patients with this diagnoses with god effect. But some, very few, patients has an additional condition or variation that make them not responsive of the standard treatment. If a different treatment/method exists abroad and it is documented that this method will have the necessary effect on the patient, this treatment will be covered.

The sources of information on effectiveness most used is:
1) international publications of effectiveness of the treatments in question, preferably high quality research with research questions close to the question of compared effectiveness that

we are to answer, and publications on effectiveness on patients comparable to the patient in question, for example in age, comorbidity or previous treatment failure
2) international guidelines where these exist, and national guidelines in other countries as for example NICE (UK NHS)
3) information from other international treatment centers on their view of the methods and the effectiveness, indications, advantages etc.

The documentation on effectiveness is evaluated by medical advisors that are medical doctors with research experience, but not necessarily specialized in the condition in question. We then often search additional advise from medical doctors specialized on treatment of the patients condition, in Norway or abroad. The effectiveness, and thus the difference in effectiveness, must be scientifically documented and internationally recognized as proven. Information about the casehandling can be found here, https://oslo-universitetssykehus.no/dine-rettigheter/utenlandsbehandling#saksbehandlingen

5. ANSWER TO QUESTION 4

At the RDO deadline (20 January 2018), Section 6 PR provided (amendments at 1 January 2018 shown in bold):

" [*1] Det regionale helseforetaket i pasientens bostedsregion skal sørge for at pasienter som har rett til nødvendig helsehjelp etter § 2, eller har rett til helsehjelp i utlandet etter § 3, får tilbud om helsehjelp fra spesialisthelsetjenesten innen den fristen som er fastsatt i medhold av § 4 eller § 4a.*
[2] Dersom spesialisthelsetjenesten ikke kan gi pasienten et tidspunkt for oppstart av utredning eller behandling før fristen for nødvendig helsehjelp senest skal gis, eller tidspunktet senere må endres slik at fristen ikke kan overholdes, eller dersom fristen er oversittet, skal spesialisthelsetjenesten umiddelbart kontakte HELFO, jf. pasient- og brukerrettighetsloven § 2-1b fjerde ledd. Dersom fristen er oversittet kan også pasienten kontakte HELFO.
[3] HELFO skal uten opphold skaffe pasienten et tilbud fra offentlig tjenesteyter eller om nødvendig fra privat tjenesteyter i riket eller om nødvendig i utlandet. Pasienten kan ikke fritt velge tjenesteyter.
[4] ***Uavhengig av om det foreligger fristbrudd kan pasienten søke om å få refundert utgifter til helsetjenester mottatt i et annet EØS-land i samsvar med forskrift om stønad til helsetjenester mottatt i et annet EØS-land. Pasienten kan også ha rett til å få dekket utgifter til helsetjenester i andre EØS-land etter vilkårene i rådsforordning (EF) nr. 883/2004. Søknad om refusjon etter forskrift om stønad mottatt i et annet EØS-land eller forhåndsgodkjenning etter rådsforordning (EF) nr. 883/2004 behandles av HELFO***."

Norway is requested to provide further details of how the procedure relating to HELFO operates, and how section 6(4) PR as amended/introduced is intended to operate. In particular:

4.1 If the deadline cannot be met or has expired, must the patient contact HELFO beforegoing abroad?

4.2 If so, please explain how the process works (administrative procedure, how this is made known to patients etc) and the reasons why contacting HELFO is a necessary step;

If the specialist health service (usually a public hospital) cannot provide necessary health care before the time limit, because there is a lack of capacity, the specialist health service must immediately contact Helfo, cf. Section 6(2) PR. Helfo shall in such cases find a provider in the public specialist health service in other regions of Norway or from private providers. Before the amendments, Helfo also could use healthcare providers abroad. Patients can also in such cases contact Helfo, in order to get Helfo to find a provider who can deliver the necessary healthcare. As explained above under 3, the intention of this regulation is to secure that the regional health authority fulfils its obligation to provide necessary specialist health services to patients within a medical justifiable time limit. In such cases the expenses for travel and accommodation are, in addition to the treatment cost, fully covered. This right to access to health care services and full cost coverage does, in our view, go beyond our obligations under EEA law.

The right to get all the costs covered in these cases is supplementary to the right to get authorisation (or reimbursed) in accordance with Regulation (EC) No 883/2004 on Social Security Coordination Article 20 or the right to get reimbursed in accordance with Regulation 22 November 2010 No 1466 on reimbursement of health care services received in another EEA State which incorporates the Patients' Rights Directive and Article 36 of the EEA Agreement.

4.3 How is Section 6(4) PR intended to operate, and to interact with the rest of Section 6 PR, as well as the rights accorded to patients under Regulation 883/2004 and the Patients Rights' Directive? In particular:

4.3.1 Is Section 6 PR (and/or section 3 PR) intended as a prior authorisation system under Regulation 883/2004? (see wording of Section 6(4) PR which refers to "prior approval" under Regulation 883/2004 being processed by HELFO) Are these sections intended to (also) operate as prior authorisation systems under the Patients' Rights Directive?

Section 6 PR (and/or Section 3 PR) is **not** intended as a prior authorisation system under Regulation 883/2004. Regulation 883/2004 is incorporated nationally "as is", and is not further regulated by national legislation. In Section 6(4) PR it is only referred to other legal grounds which might give patients a right to get healthcare publicly paid. This is for information purpose only and does not imply any restrictions on the right to authorisation (or reimbursement) in accordance with Regulation 883/2004 on social security coordination Article 20 or the right to get reimbursed in accordance with Regulation 22 November 2010 No 1466 on reimbursement of health care services received in another EEA State (which implements the Patients' Rights Directive and Article 36 of the EEA Agreement).

These sections are neither intended to nor operate as a prior authorisation system under the Patients' Rights Directive. Norway has not adopted a system of prior authorisation in accordance with the Patients' Rights Directive. The main condition to get reimbursement is that the patient would have received benefits or contributions under the National Insurance Act (Act 1997-02-28-19) or the health care would be funded by the public, if the particular health care was received in Norway, cf. Section 2 of the Regulation 22 November 2010 No 1466 on reimbursement of health care services received in another EEA State (Reimbursement Regulation).

Helfo is given the task to give authorisation (or reimbursement) if the conditions in Regulation 883/2004 on social security coordination Article 20 is met. Furthermore Helfo is given the task to reimburse patients if the conditions in Reimbursement Regulation is fulfilled.

4.3.2 Is the 'reimbursement', to which the first sentence of Section 6(4) PR refers, reimbursement under the Norwegian law implementing the Patients' Rights Directive?

"Reimbursement', to which the first sentence of Section 6(4) PR refers to reimbursement under the Norwegian Regulation 22 November 2010 No 1466 on reimbursement of health care services received in another EEA State (which implements the Patients' Rights Directive and Article 36 of the EEA Agreement).

4.3.3 How can a patient know what his/her reimbursement rights are and which criteria must be fulfilled – whether under the national law, Regulation 883/2004 or the Patients' Rights Directive? (this does not appear from the text of Section 6(4) PR).

The patient can find the conditions for authorisation or reimbursement in accordance with Article 20 in the Regulation No 883/2004 on social security coordination and the conditions for reimbursement in the Regulation 22 November 2010 No 1466 on reimbursement of health care services received in another EEA State. This regulation can be found on the website: https://lovdata.no/

There is also information about the right to receive publicly paid healtcare abroad on the website Helsenorge.no, see here: www.helsenorge.no/behandling-i-utlandet/behandling-i-spesialisthelsetjenesten-i-utlandet/

The Norwegian Directorate of Health has also provided a circual on health care abroad, www.helsedirektoratet.no/rundskriv/pasient-og-brukerrettighetsloven-med-kommentarer/rett-til-helse-og-omsorgstjenester-og-transport/-2-4a-helsehjelp-i-utlandet

Information about the Regulation (EC) No 883/2004 on Social Security Coordination (health services, including planned treatment according to Article 20), can also be found on Nav's website: Hovednr. 45 – Rundskriv til EØS-avtalens bestemmelser om trygd - Lovdata

In Norway Helfo issues authorisation (or reimbursement) in accordance with Article 20 in the Regulation (EC) No 883/2004 on social security coordination and reimbursement in accordance with the Regulation 22 November 2010 No 1466 on reimbursement of health care services received in another EEA State. Patients can contact Helfo for information about the conditions that have to be met.

6. ANSWER TO QUESTION 5

Article 8(3) of the Patients' Rights Directive provides:

> *"With regard to requests for prior authorisation made by an insured person with a view to receiving cross-border healthcare, the Member State of affiliation shall ascertain whether the conditions laid down in Regulation (EC) No 883/2004 have been met. Where those conditions are met, the prior authorisation shall be granted pursuant to that Regulation unless the patient requests otherwise."*

In light of the above questions and more generally, please explain how this requirement was met by the deadline to comply with the RDO, as a matter of Norwegian law and practice.

As explained above under 5**,** Norway does not requests prior authorisation for reimbursement in accordance with Norwegian Regulation 22 November 2010 No 1466 on reimbursement of health care services received in another EEA State (which implements the Patients' Rights Directive and Article 36 of the EEA Agreement).

At the deadline to comply with the RDO Section 7 (9) in the Regulation 22 November 2010 No 1466 on reimbursement of health care services received in another EEA State reads[5]:

> *"Et medlem som oppfyller vilkårene for dekning av utgifter til helsetjenester etter trygdeforordningene, skal få dekket utgiftene i samsvar med bestemmelsene i trygdeforordningene, med mindre medlemmet vil få dekket en større andel av utgiftene etter forskriften her."*

Helfo must in accordance with Section 7(9) of the Reimbursement Regulation give reimbursement in accordance with the Regulation (EC) No 883/2004 if the conditions in the Regulation 883/2004 are met, unless the reimbursement in accordance with Regulation 22 November 2010 No 1466 on reimbursement of health care services received in another EEA State will give the patient a better payoff (higher reimbursement). As mentiond under 5 Helfo administer both authorisation (or reimbursement) in accordance with Article 20 in the Regulation No 883/2004 on social security coordination and reimbursement in accordance with the Regulation 22 November 2010 No 1466 on reimbursement of health care services received in another EEA State. The casehandlers in Helfo are therefore supposed to be

[5] Unofficial translation:
"A member who meets the conditions for covering expenses for health services in accordance with the Social Security Regulations shall be reimbursed for the expenses in accordance with the provisions of the Social Security Regulations, unless the member will be reimbursed a larger share of the expenses in accordance with the regulations here."

familiar with conditions laid down in both these legal grounds for publicly paid healthcare abroad and the rules for reimbursement that follows from the two different sets of rules.

Yours sincerely

Geir Helgeland
Deputy Director General

Pia Grude
Senior Adviser

This document is signed electronically and has therefore no handwritten signature