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Norwegian Ministry of Health and Care Services
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Dear Sir/Madam,

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

Introduction

On 20 September 2017, the EFTA Surveillance Authority ("the Authority") delivered a Reasoned Opinion ("the RDO") to the Norwegian Government, in which it found that Norway's rules for access to in-patient treatment in other EEA States, as they were in force at the time, were in breach of Article 20 of Regulation 883/2004, as well as certain provisions of Directive 2011/24/EU ("the Patients' Rights Directive") and Article 36 EEA.

Following delivery of the RDO and the Norwegian Government's reply of 19 January 2018, and further correspondence between the Authority and the Norwegian Government, the Authority has received additional information relating to the issues identified in the RDO.

The Internal Market Affairs Directorate ("the Directorate") refers in particular to documentation received from one of the complainants, namely a letter of 1 September 2020 from the National Office for Health Service Appeals (*Nasjonalt klageorgan for helsetjenesten*) to the National Insurance Court (*Trygderetten*) ("the Letter").[1]

Having considered the information in the Letter in light of its correspondence with the Norwegian Government, the Directorate considers it necessary to request the Norwegian Government to provide further information and clarifications.

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

[1] Annex: Letter of 1 September 2020 from the National Office for Health Service Appeals to the National Insurance Court (Document no: 1200102).

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*"?

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?

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?[2]

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*

[2] Introduced by Act of 20 December 2019 no 104.

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***.”[3]

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.

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

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*.”[5] (emphasis added)

[3] Unofficial translation: “*A patient who is entitled to necessary health care, but who cannot get health care because the treatment cannot be performed properly in Norway according to an accepted method, is entitled to medical care abroad, see the [PRA] § 2-1 fifth paragraph [now Section 2-1b(5)]. It is a prerequisite [for this provision to apply] that the health care can be performed properly by the service provider abroad according to accepted method and that the patient's condition and the treatment in question satisfy the requirements of § 2 [PR].* The assessment of the patient's benefit from the treatment shall be individual and be based on international medical science.”

[4] Unofficial translation: “*A patient who is entitled to necessary health care,* ***but who cannot get health care because the treatment cannot be performed properly in Norway according to an accepted method****, is entitled to medical care abroad, see the [PRA] § 2-1 fifth paragraph [now Section 2-1b(5)]. It is a prerequisite [for this provision to apply] that the health care can be performed properly by the service provider abroad according to accepted method and that the patient's condition and the treatment in question satisfy the requirements of § 2 [PR].* The assessment of the patient's benefit from the treatment shall be individual and be based on international medical science.”

[5] Unofficial translation: *“****Insufficient capacity in specialist health services does not render patients eligible for treatment abroad under this provision****. Right to treatment does not include shipment/sending of laboratory samples for analysis with a foreign service provider if it is not part of treatment abroad.*”

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 can 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?
>
> 3.1.2 If there is a lack of capacity to perform treatment, in the sense e.g. of not enough qualified specialists *available* 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?
>
> 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 2-1b PRA and Section 6 PR refer? Is for example there a mechanism for ensuring that waiting lists and times are monitored?

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."*[7]

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

[6] Unofficial translation: *[5.] If the regional health enterprise cannot provide health care for a patient who is entitled to necessary health care,* ***because there are no adequate medical services in the realm,*** *the patient has the right to receive necessary health care from a service provider outside Norway within the time limit fixed pursuant to the second paragraph."*

[7] Unofficial translation: "*A patient who is entitled to necessary health care, but who cannot receive health care because it is not offered in Norway or where the health care abroad is documented to be more effective than the health care offered by the public in Norway, is entitled to health care abroad, cf. The Patient and User Rights Act § 2-4, second paragraph, letter a. It is a prerequisite that the health care can be performed properly by the service provider abroad according to accepted method and that the patient's condition and the treatment in question satisfies the requirements of Section 2. The assessment of the patient's benefit from the treatment shall be individual and be based on international medical science."*

effective than the health care offered in Norway, given that no cross-reference is provided to e.g. PRA §2-4 a first paragraph.

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

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.

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."***[8]

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:

[8] Unofficial translation: "[2] *If the specialist health services cannot provide the patient with a commencement date for the medical examination or treatment which is before the deadline for when necessary medical care at the latest should be provided, or the appointment time must be amended so that the deadline cannot be met, or if the deadline is exceeded, the health specialist shall immediately contact HELFO, cf. Section 2-1b(4). If the deadline is exceeded the patient can also contact HELFO.[3] HELFO shall promptly provide the patient a service from public service provider or, if necessary, from a private service provider in the kingdom or, if necessary, abroad. The patient cannot freely choose the service provider."*
[4] ***Regardless of whether the deadline has been breached, the patient may apply for reimbursement of costs for health services received in another EEA country in accordance with the regulation on aid for health services received in another EEA country [understood to be FOR-2010-11-22-1466 as amended]. The patient may also be entitled to reimbursement for costs for health services in other EEA countries in accordance with the terms of Council Regulation (EC) No 883/2004. Applications for reimbursement under the regulations on benefits received in another EEA country or prior approval under Council Regulation (EC) No 883/2004 is processed by HELFO.***"

4.1 If the deadline cannot be met or has expired, must the patient contact HELFO before going 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;

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?

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?

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).

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.

The Norwegian Government is invited to submit the above information, as well as any other information it deems relevant to the case, so that it reaches the Authority by *7 June 2021*.

Yours faithfully,

Jónína Sigrún Lárusdóttir
Director
Internal Market Affairs Directorate

This document has been electronically authenticated by Jonina S. Larusdottir.

Annex: Doc No 1200102