ROYAL NORWEGIAN MINISTRY
OF HEALTH AND CARE SERVICES

EFTA Surveillance Authority
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BELGIUM

Your ref	Our ref	Date
	20/4441-	28 September 2023

Response to reasoned opinion concerning Norway's alleged breach of Articles 7 og 9 of Directive 2011/24

Dear Sir/Madam,

1 Introduction

Reference is made to the EFTA Surveillance Authority's (hereafter «the Authority») reasoned opinion dated 5 July 2023 (hereafter «the Authority's letter») concerning legislation and administrative practices relating to the reimbursement of costs for cross-border healthcare.

In the Authority's letter the Authority concludes that:

- by maintaining in force an administrative practice whereby the reimbursement of costs related to cross-border healthcare is limited to 80% of the relevant national DRG, Norway has failed to fulfil its obligations arising from Article 7(4) of Directive 2011/24, c.f. Article 7(1) thereof.

- by maintaining in force an administrative practice whereby the national legislation's generic deadline is applied strictly to claims relating to cross-border healthcare, Norway has acted in breach of the principle of proportionality as expressed in Article 9(1) of Directive 2011/24 and the principles of equivalence and effectiveness.

The Authority requests that the Norwegian Government submits its observations on the content of their letter within two months of its receipt. The Ministry of Health and Care Services (hereafter «the Ministry») requested an extension of the deadline, and the Authority extended the deadline to 5 October 2023.

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The Ministry will hereby provide its observations regarding the Authority's assessments and conclusions.

2 Reimbursement level

2.1 Article 7 of Directive 2011/24/EU

The Directive provides a legal framework for cross-border healthcare, including provisions on the reimbursement of costs, the administrative responsibilities of the EEA States, and cooperation among national authorities.

Article 7 of the Directive is entitled «general principles for reimbursement of costs» and provides that:

> *1. Without prejudice to Regulation (EC) No 883/2004 and subject to the provisions of Articles 8 and 9, the Member State of affiliation shall ensure the costs incurred by an insured person who receives cross-border healthcare are reimbursed, if the healthcare in question is among the benefits to which the insured person is entitled in the Member State of affiliation.*
> *[…]*
>
> *3. It is for the Member State of affiliation to determine, whether at a local, regional or national level, the healthcare for which an insured person is entitled to assumption of costs and the level of assumption of those costs, regardless of where the healthcare is provided.*
>
> *4.The costs of cross-border healthcare shall be reimbursed or paid directly by the Member State of affiliation up to the level of costs that would have been assumed by the Member State of affiliation, had this healthcare been provided in its territory without exceeding the actual costs of healthcare received.*
> *[…]*
>
> *6. For the purposes of paragraph 4, Member States shall have a transparent mechanism for calculation of costs of cross-border healthcare that are to be reimbursed to the insured person by the Member State of affiliation. This mechanism shall be based on objective, non-discriminatory criteria known in advance and applied at the relevant (local, regional or national) administrative level.*
> *[…]*

2.2 Relevant national legislation

Norway established 1 January 2011 a reimbursement scheme covering certain types of healthcare services received in other EEA states. 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. Section 5-24 a of the National Insurance Act («NIA») forms, together with Regulation 22 November 2010 No 1466 on

reimbursement of health care services received in another EEA State («IR»), the legal basis under Norwegian law for the reimbursement of costs related to cross-border healthcare. A distinct administrative circular sets out how those provisions are to be applied by the national authorities.

The main condition to get reimbursement is that the patient would have received benefits or contributions under the NIA or the health care would be covered by the public, if the particular healthcare was provided in Norway, cf. Section 2 IR.

For specialized healthcare the benefit amounts to the actual expenses unless the amount exceeds the costs that would have been covered by the public, if the healthcare had been provided in Norway. In such case, the benefit is limited to an amount corresponding to the assumed costs the public would cover if the healthcare had been provided in Norway, cf. Section 7(2) IR.

2.3 The Authority's View

The Authority finds that the national DRG costs must be considered to constitute «fees for healthcare» for the purpose of reimbursement under the Directive. More generally, the Authority contends that all costs must be borne by the EEA State of affiliation, regardless of whether they emanate from the central authority, one regional authority or another regional authority that is making a guest settlement.

The Authority observes that the provision contained in Article 7(1) of the Directive is centered on the duty of the EEA State of affiliation to ensure that «the costs incurred by an insured person who receives cross-border healthcare are reimbursed». Thus, while the expenditure-component is directly joined with the costs sustained by the healthcare recipient, the limitation of the EEA State of affiliation's responsibilities relates to what treatments are available in its territory.

In light of the above considerations, the Authority concludes that the Norwegian practice at issue amounts to a breach of Article 7(4) of the Directive, c.f. Article 7(1).

2.4 The Ministry's view

The Directive states in Article 7(4) that cross-border healthcare shall be reimbursed up to the level of costs that would have been assumed by the Member State of affiliation, had this healthcare been provided in its territory without exceeding the actual costs of healthcare received.

The wording of Article 7(4), cf. Article 7(1) in the Directive, as well as the purpose and the context of the mentioned articles indicate that the EEA State shall not incur higher expenses as a result of cross border healthcare. This is also supported in the judgement by the European Court of Justice in Veselības ministrija[1], in which it held that:

[1] Case C-243/19, A vs. Veselibas ministrija, para 74-77

> *(74) The reimbursement provided for by Article 7 of Directive 2011/24 may, therefore, be subject to a twofold limit. First, it is calculated on the basis of the fees for healthcare in the Member State of affiliation. Secondly, if the cost of the healthcare provided in the host Member State is lower than that of the healthcare provided in the Member State of affiliation, that reimbursement does not exceed the actual costs of the treatment received.*
>
> *(75) Since reimbursement of that healthcare under Directive 2011/24 is subject to that twofold limit, the healthcare system of the Member State of affiliation is not liable to be faced with a risk (…) of additional costs linked to the assumption of the cross-border healthcare costs.*
>
> *(76) That interpretation is indeed supported by recital 29 of Directive 2011/24, which expressly states that assumption of costs cannot have any significant effect on the financing of the national healthcare systems.*
>
> *(77) Accordingly, in the context of Directive 2011/24, and by contrast with situations governed Regulation No 883/2004, the Member State of affiliation will not, as a rule, be exposed to any additional financial costs with respect to cross-border healthcare.*

In the said judgement it is emphasized that since reimbursement of the Directive is subject to a twofold limit, the healthcare system of the Member State of affiliation is not liable to be faced with a risk (…) *of additional costs* linked to the assumption of the cross-border healthcare. In the opinion of the Ministry the rationale behind Article 7(4), cf. Article 7(1) in the Directive is that the EEA State of affiliation shall not be burdened with higher expenses as a result of cross border healthcare.

Norway reimburses cross-border somatic health care up to the level of 80 percent DRG. The Ministry does not agree with the Authority that the Norwegian practice is in conflict with Article 7(4) of the Directive, c.f. Article 7(1).

The rationale behind our practice is that the estimated average DRG-cost is assumed to be higher than the marginal cost of treatment. DRG is used as a basis for the calculation of refunds for all somatic healthcare in the hospitals. The DRG-costs are calculated as average expenses on a public hospital level, and includes the hospital sector's administrative expenses, preparedness expenses, emergency costs, educational costs etc. Reimbursement rates that are based on the DRG-system as such are average costs that also will contain expenses that are not solely related to the treatment of individual patients.

The reimbursement is also based on the same calculation of costs for hospital treatment (DRG-system) as used within Norway. The pricing mechanism of 80 percent DRG corresponds with pricing for «guest-patients» within Norway. For patients treated in other regions there is a «guest settlement» between the regional health authorities where the

payment is 80 percent of estimated DRG-costs. The rationale behind this practice is that 80 percent of the DRG-costs is the level that will compensate the additional assumed expenses by the region treating the patient.

In this regard, the Ministry also refers to an analysis done by professor Terje P. Hagen, University of Oslo, on contracts between the regional health authorities and private hospitals. The analysis shows that the contract prices are lower than the average DRG-cost. The study found that these prices where about 65 percent of DRG-costs in 2010–2011.

The Ministry concludes that the Norwegian practice of reimbursing 80 percent DRG is in accordance with Article 7(4) of the Directive, c.f. Article 7(1).

The Ministry has presented its view for the Authority in our response on the formal notice. The Ministry notes that the Authority in the reasoned opinion maintains its conclusion that the Norwegian practice of reimbursing 80 percent DRG amounts to a breach of Article 7(4) of the Directive, c.f. Article 7(1). Based on an overall assessment and for the sake of expediency the Ministry has decided to raise the level of reimbursement to 100 percent of the estimated DRG-cost from 2 October 2023. The new level of reimbursement (100 percent of the estimated DRG-costs) shall be applied on all applications for reimbursement which at the said date have not been finally decided by the Norwegian Health Economics Administration (Helfo) or National Office of Health Service Appeals. The Ministry would like to emphasize that this does not entail that the Ministry share the Authority's view on whether the current practice conflicts with the Directive.

The Ministry has instructed the Directorate of Health to ensure that Helfo raise the level of reimbursement to 100 percent of the estimated DRG-cost from 2 October 2023 and further ensure that the necessary changes in the relevant administrative circular are in place by the same date.

3 Claim deadline

3.1 Article 9 (1) of Directive 2011/24/EU and the principle of effectiveness

Article 9 of the Directive is entitled «administrative procedures regarding cross-border healthcare» and provides that:

1. *The Member State of affiliation shall ensure that administrative procedures regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are based on objective, nondiscriminatory criteria which are necessary and proportionate to the objective to be achieved.*

2. *Any administrative procedure of the kind referred to in paragraph 1 shall be easily accessible and information relating to such a procedure shall be made publicly available at the appropriate level. Such a procedure shall be capable of ensuring that requests are dealt with objectively and impartially.*

   […]

The principle of effectiveness entails that national procedural rules governing actions for safeguarding rights, which individuals and economic operators derive from EEA law, must not render practically impossible or excessively difficult the exercise of rights conferred by EEA law.

In order to further the principle of legal certainty, it is compatible with EEA law to lay down reasonable time-limits for bringing proceedings. Such periods are not liable by their nature to make it virtually impossible or excessively difficult to exercise the rights conferred by EEA law, even if the expiry of those periods necessarily entails the dismissal, in whole or in part, of the action brought.[2]

3.2 The national rules applied to claims relating to cross-border healthcare

Pursuant to Section 10(1) IR, claims for reimbursement relating to cross-border healthcare shall be submitted after the healthcare has been received and paid. The claim deadline is to be calculated in accordance with the generic provisions set out in Section 22-13 NIA.

The general rule set out in Section 22-13(2) NIA stipulates that claims for benefits disbursed as a one-time payment shall be submitted within six months from the earliest moment in time that a claim could have been submitted. The provision does not specify further what constitutes the "earliest moment in time", but in the preparatory work to the provision it is said[3] :

> *This provision must be understood so that the deadline runs from the time the person concerned had the right to claim the allowance in question. That is, from the time the right to the benefit arose. In the case of medical benefits which purpose is to cover certain expenses for health services, the right to such benefits begins from the time the person concerned has incurred expenses for health services.*

Furthermore, the legal comments to Section 22-13 (2) NIA say that the provision is to be interpreted strictly and in the administrative circular it is stated that the earliest moment in time that a claim could have been submitted shall be counted from the day of treatment.

The Parliamentary Ombud has on the 26 June 2023 made a written assessment of a complaint from a citizen regarding the claim deadline pursuant to Section 10(1) IR. The Parliamentary Ombud is of the opinion that the deadline for making a claim for benefits under Section 5-24 a NIA starts to run when the healthcare has been received and paid. The decisions from the Parliamentary Ombud are not legally binding, but the Storting has assumed that the administration comply with decisions in line with good administrative practice. Helfo and National Office of Health Service Appeals will therefore correct their previous practice in accordance with the decision.

3.3 The Authority's view

In the Authority's letter the Authority indicates that invoicing practices vary within the EEA entailing various degrees of efficiency. The Authority notes, that counting the deadline from the day of treatment becomes an issue where the invoice is only received at a later stage.

[2] Case E-10/17, Nye Kystlink, para 110-112
[3] NOU 1990:20 Forenklet folketrygdlov page 692

Moreover, the difficulties ensuing thereof are reinforced by applying the national legislation's general deadline of six months also to claims pertaining to cross-border healthcare.
The Authority is not aware that the generic provision set out in Section 22-13(2) NIA has been given a similarly strict application in other areas or whether this concerns singularly claims relating to cross-border healthcare. Moreover, the Authority has not been presented with any arguments as to why such a specific and strict application is considered necessary.

Furthermore, the Authority observes that the principle of equivalence requires that the protection of rights within a national system of EEA-law based rights must not be less favourable than in the case of individual rights based on national law.

The Authority further recalls that the principle of effectiveness entails that national procedural rules governing actions for safeguarding rights, which individuals and economic operators derive from EEA law, must not render practically impossible or excessively difficult the exercise of rights conferred by EEA law. Moreover, that principle precludes national provisions which deprive directives of their effectiveness.

The Authority has taken duly note of the Norwegian Government's measures to rectify the breach, but is concerned with regard to the effectiveness of the right to have the costs of healthcare in other EEA States reimbursed in Norway. The Authority refers to that the circular, which stipulates that the claim deadline is counted from the day of treatment, remains in force with its current wording.

The Authority recalls that it is essential that the legal situation resulting from national implementing measures is sufficiently precise and clear so that individuals are made fully aware of their rights. In particular, the Authority observes that the circular remains publicly available and serves as the explanatory text to Section 10(1) IR. The Authority is concerned that the circular is more accessible to the public than the letter, potentially discouraging patients that are eligible for reimbursement from applying. In the Authority's view, this deprives the right provided for by Article 9(1) of the Directive of its effectiveness and creates a state of ambiguity and legal uncertainty.

3.4 The Ministry's view

The application of the provision set out in Section 22-13(2) NIA regarding when the deadline starts to run, is the same for cross-border healthcare as for claims regarding benefits for healthcare within Norway in accordance with Section 5-4 to Section 5-12 NIA and for healthcare received abroad in accordance with Section 5-24 NIA (which is not restricted to the EEA area). Reference is made to the preparatory work and the legal comments to Section 22-13 NIA.

The application is the same in other areas and does not concern singularly claims relating to cross-border healthcare. In our opinion the application is therefore not less favorable than in the case of individual rights based on national law.

The Ministry understands that invoicing practices may vary within the EEA and finds it inexpedient if claims are not reimbursed because the claimant has not received an invoice from the healthcare provider within the deadline. The Ministry is therefore of the opinion that the deadline (in accordance with Section 22-13 (2) NIA) should start to run from the date of the invoice in cases where the claimant receives the invoice after the day of treatment.

The Ministry has launched a public hearing on 26 May to 29 September 2023, proposing to amend Section 10(1) IR to reflect that the claim deadline runs from the date of invoicing. The Ministry has regarded the consultation responses and have made some adjustments to take account of suggestions put forward during the hearing.

In most cases, also abroad, patients pay and receive the invoice at the same day they receive the healthcare. In the opinion of the Ministry the general rule should therefore be that the deadline runs from the date the patient receives the healthcare. To take account of those cases where the patient receives the invoice after the date of treatment, it is made an exception to the general rule. In such cases the deadline runs from the date of the invoice. In the opinion of the Ministry the provision should also clarify that when purchasing medicines, medical consumables or foodstuffs the deadline runs from the date of purchase.

Section 10(1) IR is, in accordance with the above, amended and reads from 2 October 2023:

> *Kravet om stønad må settes frem innen seks måneder etter at helsehjelpen er mottatt. Dersom tjenesteyter har utstedt faktura etter at helsehjelpen er mottatt, løper fristen fra fakturadato. Ved kjøp av legemidler, medisinsk forbruksmateriell eller næringsmidler løper fristen fra kjøpsdato. Frist for å fremsette krav beregnes for øvrig etter reglene i folketrygdloven § 22-13.*[4]

There is also a transitional provision which entails that applications on reimbursement submitted after the amendment came into force, are processed in accordance with the deadline provisions in force at the time of payment, if the provisions in force before 2 October 2023 would be more favorable for the applicant. Furthermore, to ensure that all applicants are guaranteed a deadline of six months upon the transition to the new provision, the deadline shall in no case expire before six months after 2 October 2023, if the healthcare is received and paid for on or after 2 October 2023.[5]

[4] Unofficial translation: *The claim for benefit must be submitted within six months of receiving the healthcare. If the service provider has issued an invoice after the healthcare has been received, the deadline runs from the date of the invoice. When purchasing medicines, medical consumables or foodstuffs, the deadline runs from the date of purchase. The deadline for submitting a claim is otherwise calculated according to the rules in the National Insurance Act § 22-13.*

[5] The transitional provision in Norwegian: *Forskriften trer i kraft 2.oktober 2023. Krav som er fremmet etter ikrafttredelse av forskriftsendringen som gjelder stønad for helsehjelp som er mottatt og betalt før 2. oktober 2023, skal vurderes etter fristbestemmelsen som gjaldt på betalingstidpunktet, dersom det vil gi gunstigere fristregler for søker. Dersom helsehjelpen er mottatt og betalt 2. oktober 2023 eller senere, skal fristen ikke i noe tilfelle utløpe før seks måneder etter 2. oktober 2023.*

4 Concluding remarks

As set out above the Ministry is of the opinion that the legislation and practice applicable before 2 october 2023 are compatible with EEA law requirements under Directive 2011/24, c.f. Article 7(1) thereof, the principle of proportionality as expressed in Article 9(1) of Directive 2011/24 and the principles of equivalence and effectiveness.

Yours faithfully,

Cathrine M. Lofthus
Secretary General

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