Brussels, 5 July 2023
Case No: 85598
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Decision No: 080/23/COL

REASONED OPINION

delivered in accordance with Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice concerning Norway's breach of Articles 7 and 9 of Directive 2011/24.

1 Introduction and correspondence

1. By a letter dated 30 September 2020 (Doc No 1152080), the EFTA Surveillance Authority ("the Authority") informed the Norwegian Government that it had received a complaint on the Norwegian legislation and administrative practices relating to the reimbursement of costs for cross-border healthcare.

2. Directive 2011/24 on patients' rights ("the Directive")[1] provides an extensive 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. It aims at promoting patient mobility throughout the EEA, whereby patients may receive medical care in another EEA State than the one in which they are socially insured.

3. Section 5-24a of the National Insurance Act[2] ("NIA") forms, together with the relevant implementing regulation ("IR")[3], 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.[4] Claims for reimbursement are handled by the Norwegian Health Economics Administration ("Helfo").[5]

4. In its letter of 30 September 2020, the Authority invited the Norwegian Government to answer a series of questions for the purposes of examining the issues raised by the complainant. The reply was received on 30 October 2020 (Doc No 1160689). A further set of questions was sent to the Norwegian Government by way of a letter dated 23 September 2021 (Doc No 1227746). The answer was received on 21 October 2021 (Doc No 1237151). The issues at hand were subsequently discussed at the package meetings in 2021 and 2022.

5. On 15 December 2022, the Authority issued a letter of formal notice to Norway (Doc No 1255341), identifying the following breaches of EEA law:

    - According to the national administrative practice, the reimbursement of costs related to cross-border healthcare is limited to 80 % of the relevant national "diagnosis-related-group" ("DRG"), in breach of Article 7(4) of the Directive, c.f. Article 7(1) thereof.

    - The national legislation's generic deadline is applied strictly to claims relating to cross-border healthcare, in breach of the principle of proportionality as

[1] Directive 2011/24 on the application of patients' rights in cross-border healthcare, which entered into force in the EEA on 01.08.2015.
[2] LOV-1997-02-28-Lov om folketrygd (*folketrygdloven*).
[3] FOR-2010-11-22-1466 Forskrift om stønad til helsetjenester mottatt i et annet EØS-land.
[4] Rundskriv til forskrift om stønad til helsetjenester mottatt i et annet EØS-land (F22.11.2010 nr 1466).
[5] See however the Authority's reasoned opinion to Norway of 20 October 2022 in Case 72376 concerning the general rules and the system in place in Norway for access to hospital treatment in other EEA States (Doc No 1311515), where the Authority, in Section 3.2.2.3, took note that, according to Section 7-2(1) of the Patients' Rights Act (LOV-1999-07-02-63-Lov om pasient- og brukerrettigheter (*pasient- og brukerrettighetsloven*), complaints regarding Chapter 2 of the Patients' Rights Act, including Section 2-4a(1)a regarding *inter alia* the Patients' Rights Directive, shall be made to the County Governor, and not to Helfo. By letter dated 20 December 2022 (Doc No 1338999), the Norwegian Government informed the Authority that this was due to a drafting error, and by letter dated 14 April 2023 (Doc No 1366950), the Norwegian Government informed the Authority that it had submitted a proposal to the Parliament to remedy the drafting error and clarify that such complaints shall be made to Helfo.

expressed by Article 9(1) of the Directive and the principles of equivalence and effectiveness.

- The translation requirements applicable to claims relating to cross-border healthcare amount to a breach of Article 9(1), Article 9(2) and/or the freedom to provide services c.f. Article 36 EEA and create a state of ambiguity and legal uncertainty contrary to Article 3 EEA.

6. In its reply to the letter of formal notice, the Norwegian Government provided for satisfactory solutions to the third and final issue set out above (Doc No 1364226). That issue, pertaining to national translation requirements, will therefore not be pursued further in the present reasoned opinion.

7. Having examined the Norwegian Government's response, the Authority maintains its conclusion that the Norwegian administrative practice consisting of limiting the reimbursement of costs related to cross-border healthcare to 80% of the relevant national DRG is in breach of Article 7(4) of the Directive, c.f. also Article 7(1) thereof.

8. With regard to the issue of the national legislation's generic deadline for reimbursement of costs being applied strictly to claims relating to cross-border healthcare, the Authority acknowledges the Norwegian Government's efforts to ensure that the processing body, Helfo, does not apply the deadline in the strict manner set out in the circular whilst corresponding amendments to the IR are pending (Doc No 1376076). The Authority's concerns with regard to the effectiveness of the right to claim costs of healthcare in other EEA States reimbursed in Norway however remain as long as the circular is in force with its current wording, c.f. paragraph 43 below. To the Authority's understanding, no amendments have currently been proposed to the circular. The Authority therefore maintains that the problem arising from a strict application of the national legislation's generic deadline to claims relating to cross-border healthcare, in breach of the principle of proportionality as expressed by Article 9(1) of the Directive and the principles of equivalence and effectiveness has not been resolved.

2 Relevant national law

2.1 Reimbursement level

9. Section 5-24a of the NIA provides that:

> *"§ 5-24a. Financial assistance for healthcare received in another EEA State*
>
> *Financial assistance is provided to cover expenses incurred by the member for healthcare services received in another EEA State pursuant to provisions determined by the ministry by means of an implementing regulation.*
>
> *The implementing regulation may set out provisions concerning:*
>
> *[…]"*

10. Section 7 of the IR concerns the calculation of the financial assistance for healthcare received in another EEA State and appears to, prima facie, accurately transpose the relevant provisions of the Directive.

11. Referring to the "diagnosis-related-group" ("DRG") classification system, the administrative circular clarifies how the above provisions are to be interpreted and applied in practice.

"The DRG is an average cost which does not only encompass treatment costs, but also the hospital's other costs (such as service, administration, emergency preparedness, education etc). In order for the amount to be reimbursed in accordance with Section 5-24a of the National Insurance Act to reflect, to the greatest extent possible, only the actual treatment costs, a percentage reflecting other costs shall be deducted from the DRG. This deduction is set to 20%, but is subject to later amendment (any such amendment will appear in this circular).

This entails that a patient seeking treatment in another EEA State shall be able to receive a reimbursement of up to 80% of the DRG-cost which would have been applied had the treatment taken place at a public, Norwegian hospital.

If the treatment abroad is more expensive than the estimated DRG-cost for a similar treatment in Norway, the patient must cover the exceeding amount himself.

When patients affiliated with other EEA States invoke the patient rights' Directive to received planned treatment in Norway, the hospital shall invoice the patient 80 % of the DRG-cost.

2.2 Claim deadline

12. Section 10(1) of the IR provides that:

"§ 10. Procedural provisions, claim submission and complaint

Reimbursement claims shall be submitted after the healthcare has been received and paid. The claim deadline is calculated in accordance with the provisions in Section 22-13 of the National Insurance Act."

13. Section 22-13 (2) of the National Insurance Act provides that:

"Claims for benefits which are disbursed as a one-time payment, c.f. Section 22-10 first paragraph and fourth paragraph letters a,b and c, must be submitted within six months from the moment the claim could have been submitted at the earliest."

14. The administrative circular clarifies what point in time is considered as the earliest for which a claim could have been submitted:

"The claim deadline corresponds to that applicable to other situations covered by chapter 5; six months from the moment the claim could have been submitted at the earliest, c.f. Section 22-13(2) of the National Insurance Act. Six months will be counted from the day of the treatment."

3 Relevant EEA law

15. 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.

[…]

9. The Member State of affiliation may limit the application of the rules on reimbursement for cross-border healthcare based on overriding reasons of general interest, such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.

[…]

11. The decision to limit the application of this Article pursuant to paragraph 9 shall be restricted to what is necessary and proportionate, and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of goods, persons or services. Member States shall notify (…) of any decisions to limit reimbursement on the grounds stated in paragraph 9."

16. 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, non-discriminatory 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.

[…]"

4 The Authority's Assessment

4.1 Reimbursement level – 80 % of national DRG

4.1.1 Financing of the Norwegian health care system, activity-based funding linked with national DRGs and "guest settlement" between regions[6]

17. Norway has a universal, nationalised health care system. The system is semi-decentralised: the central government is responsible for specialist care, which is delivered through four regional health authorities (RHAs), which own twenty hospital trusts. The municipalities are principally responsible for primary care.[7]

18. The four RHAs fund public hospitals and contracted, private hospitals. The latter are regulated by contracts concluded following competitive tenders.

19. Funds for public hospitals are allocated to the four RHAs, which are free to decide how the hospitals are paid. For somatic care, funding comprises block grants and activity-based funding (in roughly equal shares). The block grant for each RHA is based on the number and age of inhabitants in the regions, health indicators and cost level etc. The activity-based funding is based on the Nordic diagnosis-related groups (DRG) system to classify patients.[8]

20. There are approximately 980 DRGs for inpatients and outpatients in Norway. Each DRG has a calculated cost weight. These cost weights are used as a basis for the calculation of refunds to the RHAs within the activity-based financing mechanism. The cost weight attributed to each DRG expresses the average cost for all patients in that group. Defined cost groups in the system are operations, intensive care, radiology, laboratories, cytostatics, radiations, dialysis, direct care and basic costs (administration etc.). Length of stay is a key factor. Capital and research costs are not included in the cost weights.

21. The cost weights are updated annually to reflect changes in medical practice and other cost-related changes in hospitals. They are based on reported cost per patient data from all public hospitals in Norway.

22. For a patient treated in another region than that of residence, there is a "guest settlement" between the RHAs, which entails a payment amounting to 80% of the DRG-cost. This practice assumes that the marginal cost is lesser than the average cost when using available capacity. In other words, the payment for a guest-patient shall cover costs related to treat one more patient (the marginal cost), whereas the average cost expressed by the relevant DRG covers all types of costs as mentioned above.

4.1.2 Reimbursement of costs related to cross-border healthcare within the EEA – Norway's administrative practice

23. As reflected by the administrative guidelines, c.f. point 2 above, the current Norwegian practice consists of limiting the reimbursement of costs related to cross-border healthcare to 80 % of the relevant, national DRG. The rationale behind this practice is that the reimbursement should reflect only the treatment costs themselves, excluding other costs such as service, administration, education etc.

24. Indeed, referring to the *guest settlement* mechanism applicable between the domestic RHAs and described above, the Norwegian Government has confirmed that it "found it rational" to adopt the same approach to the reimbursement of costs related to healthcare received in another EEA State.[9]

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[6] This point is largely based on the overview provided by the Norwegian Government in its letter of 30 October 2020.
[7] Health Systems in Transition, WHO, Vol. 22 No. 1 2020, p. 64.
[8] Idem.
[9] Letter of 30 October 2020 (Doc No 1160689), p. 2.

25. Based on the above, the Authority observes that the application of the same rationale to two distinct situations, entails significantly different outcomes for the patient. Thus, while a patient resident in Norway but being treated in another region than his or her region of residence sustains no financial disadvantage – as he or she will in any event, not be obliged to pay for the treatment - a patient resident in Norway who seeks healthcare in another EEA State will potentially have to cover a part of the expenses him- or herself.

4.1.3 Assessment – Article 7(4) of the Directive

26. The question is whether the Norwegian administrative practice at issue complies with Article 7(4) first paragraph, which provides that the costs of 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".*

27. First, the Authority notes that the wording "without exceeding the actual costs of healthcare received" cannot serve as a basis for limiting the reimbursement to what might be conceived as the alternative, marginal cost on the part of the EEA State of affiliation. This leg of the provision merely makes clear that if the costs of the healthcare received were in fact lower than what would have been assumed by the EEA State of affiliation, the latter's responsibility is reduced accordingly.

28. Second, and of particular importance to the issue at hand, the provision requires reimbursement up to the level of costs "that would have been assumed *by the Member State* (…)". This entails, the Authority contends, that the relevant benchmark is what costs the EEA State of affiliation – as a whole – would have borne had the treatment taken place in its territory.

29. While the rationale underpinning the practice of applying a "guest settlement" between the national RHAs might certainly make sense due the Norwegian financing model, the Authority cannot see that the provision in Article 7(4) of the Directive allows for it to be transposed to the cross-border situations safeguarded therein. Rather, as argued above, the wording of Article 7(4) first paragraph refers to the costs carried by the EEA State of affiliation altogether, pointing to the total average costs as determined by the applicable DRG in any given reimbursement claim.

30. The Authority contends that its interpretation of Article 7 of the Directive, as set out above, finds support in the judgment by the European Court of Justice in *Veselības ministrija*, in which it held that[10]:

> (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."

31. The Authority notes that in its interpretation of Article 7 of the Directive, the CJEU focussed on "the healthcare system" (as such) of the "Member State of affiliation" (as a whole). Moreover, the Authority cannot see how the Norwegian administrative practice

[10] Case C-243/19, *A vs. Veselības ministrija*, paras. 74-75.

at issue purports to avoid a risk of additional costs linked to the assumption of the costs related to cross-border healthcare.

32. In its judgment, the CJEU clarified that the reimbursement provided for by Article 7 of the Directive shall be calculated *"on the basis of the fees for healthcare in the [EEA] State of affiliation."* Applied to the Norwegian healthcare system, 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.

33. In further support of its interpretation of Article 7(4) first paragraph and its application to the Norwegian practice at hand, the Authority observes that the provision contained in Article 7(1) of the Directive is centred 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.

34. 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).

4.2 Claim deadline

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

35. 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.

36. 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".

37. The Authority observes that, for the purposes of applying that generic provision of national law to claims for reimbursement relating to cross-border healthcare, the relevant administrative circular demands for a specific, strict application: the earliest moment in time that a claim could have been submitted shall, as regards claims relating to crossborder healthcare, be counted from the day of treatment.[11]

4.2.2 Assessment – Article 9(1) of the Directive / principle of effectiveness

38. The Authority recalls that Article 9(1) of the Directive requires that administrative procedures regarding the use of cross-border healthcare and reimbursement of costs incurred in another EEA State be *"based on objective, non-discriminatory criteria which are necessary and proportionate to the objective to be achieved*".

39. According to the complainant, invoicing practices vary within the EEA entailing various degrees of efficiency. Concretely, the Authority notes, counting the deadline from the day of treatment becomes an issue where the invoice is only received at a later stage.

[11] Rundskriv til forskrift om stønad til helsetjenester mottatt i et annet EØS-land , § 10 (R05-24A-FOR, as revised per 1 July 2022).

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.

40. 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.

41. 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.[12]

42. 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.[13] Moreover, that principle precludes national provisions which deprive directives of their effectiveness.[14]

43. The Authority has taken duly note of the Norwegian Government's measures to rectify the breach. In a letter from the Ministry of Health and Care Services to the Directorate of Health, the Directorate is asked to ensure that the processing body, Helfo, adopts a more lenient practice and does not deny any reimbursement claims before six months has passed since the *date of invoicing*. Furthermore, the Ministry launched a public hearing on 26 May 2023, proposing to amend Section 10(1) IR to reflect that the claim deadline runs from the date of invoicing.

44. The Authority's concerns with regard to the effectiveness of the right to have the costs of healthcare in other EEA States reimbursed in Norway however remain to the extent 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.[15] 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.

45. In light of the above considerations, the Authority concludes that the Norwegian practice at issue amounts to a breach of Article 9(1) of the Directive, the principle of equivalence and the principle of effectiveness.

46. For the sake of good order, the Authority has taken duly note of the Norwegian Government's further, intended measures to rectify the breach. Thus, in its reply to the letter of formal notice, Norway informed the Authority of its commitment to launch a public consultation with a view to amend the national regulation at issue. Equally important, Norway has thereafter confirmed its intention to amend the administrative circular at issue accordingly.

[12] Case E-7/13, *Creditinfo Lánstraust*, para 45.
[13] Case E-10/17, *Nye Kystlink*, para. 110
[14] Case E-08/07, *Celina Nguyen*, para 24.
[15] Case E-15/12, *Wahl*, para 52.

FOR THESE REASONS,

THE EFTA SURVEILLANCE AUTHORITY,

pursuant to the first paragraph of Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice, and after having given Norway the opportunity of submitting its observations,

HEREBY DELIVERS THE FOLLOWING REASONED OPINION

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.

Pursuant to the second paragraph of Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice, the EFTA Surveillance Authority requires Norway to take the measures necessary to comply with this reasoned opinion within *two months* of its receipt.

Done at Brussels

For the EFTA Surveillance Authority

Arne Røksund President	Stefan Barriga Responsible College Member	Árni Páll Árnason College Member

Melpo-Menie Joséphidès
Countersigning as Director,
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This document has been electronically authenticated by Arne Roeksund, Melpo-Menie Josephides.