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Guidance note of the Commission services on the relationship between Regulations on the coordination of social security systems and Directive on the application of patients' rights in cross border healthcare
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ADMINISTRATIVE COMMISSION
FOR THE COORDINATION OF SOCIAL SECURITY SYSTEMS

Subject: **Guidance note of the Commission services on the relationship between Regulations (EC) Nos 883/2004 and 987/2009 on the coordination of social security systems and Directive 2011/24/EU on the application of patients' rights in cross border healthcare**

Note from the Commission of 21 May 2012

Delegations will find enclosed the guidance note of the Commission services on the relationship between Regulations on the coordination of social security systems and Directive on the application of patients' rights in cross border healthcare together with a graphical presentation of the scenarios described in the note.

The Administrative Commission has already had a first discussion on the subject in question. The Secretariat, together with DG SANCO, presented a joint note AC 422/11, identifying the main points of inter-relation between Regulations (EC) Nos 883/2004 and 987/2009 and Directive 2011/24/UE. The note was discussed at the Working Party of the Administrative Commission on Patients Mobility on 4 October 2011 (see minutes note AC 332/11) and the delegations subsequently submitted their written observations.

The present document aims at ensuring the coherent application of the Regulations and the Directive by the Member States with regard to social security aspects which are covered by both instruments, and at guiding Member States when transposing Directive 2011/24/EU. The document is intended for lawmakers and experts and will have to be supplemented by further guiding documents for institutions and citizens. The guidance note has been elaborated jointly by DG EMPL and DG SANCO and approved by the Legal Service of the European Commission.

The guidance note will be presented to the Members of the Committee on Cross-Border Healthcare at the meeting on 30 May 2012 and to the Members of the Administrative Commission for the Coordination of the Social Security Systems at the meeting on 12-13 June 2012.

Annexes:
1. Guidance note of the Commission services
2. Graphical presentation of the scenarios described in the guidance note

Annex 1

Guidance note of the Commission services on the relationship between Regulations (EC) Nos 883/2004 and 987/2009 on the coordination of social security systems and Directive 2011/24/EU on the application of patients' rights in cross border healthcare[1]

In the field of cross-border healthcare, Regulations (EC) Nos 883/2004 and 987/2009 on coordination of social security systems have put in place a system aimed at ensuring access to healthcare in various situations such as temporary stay abroad and residence outside the competent Member State. The Regulations also include provisions for planned healthcare.

On the other hand, Directive 2011/24/EU on the application of patients' rights in cross-border healthcare was adopted on 24 April 2011 with the aim to facilitate access to safe and high-quality cross-border healthcare. The Directive codifies the abundant jurisprudence of the Court of Justice on the application to healthcare of Article 56 of the Treaty FEU. The Directive has to be transposed by Member States by 25 October 2013.

Since both the Regulations and the Directive cover healthcare received in other Member States, the implementation of the Directive must take into account the obligations and requirements laid down by the Regulations. In order to support Member States when transposing Directive 2011/24/EU and to ensure the coherent application of the Regulations and the Directive by the Member States, the European Commission undertook to provide a specific legal analysis of the relationship between these two legal instruments and its practical consequences by way of this interpretative note.

[1] The interpretations and ideas set out in this Note do not constitute an authentic interpretation of EU law and do not engage the Commission as such. The contents of this document only represent the views of the Commission services. In any case, it does not prejudge the interpretation that the European Court of Justice, as the final instance responsible for interpreting the Treaty and secondary legislation, may develop on these matters

I. Horizontal rules

1. Relationship between the two instruments

When looking at the relationship between Regulations (EC) Nos 883/2004[2] and 987/2009[3] (hereinafter the Regulations) [4] and Directive 2011/24/EU[5] (hereinafter the Directive), it should be clear that both legal instruments are linked to the free movement of workers with respect to the EU fundamental freedoms. The Regulations fall within the framework of the free movement of persons, while the Directive falls within the framework of the freedom to provide services.

The **main purpose of the Regulations** is to ensure that insured persons – mainly workers - do not lose their social security protection when moving to another Member State.

The **main purpose of the Directive** is to facilitate access to safe and high-quality cross border healthcare, to ensure patients' mobility and to promote cooperation on healthcare between Member States, whilst respecting the competence of Member States' for organising their own healthcare systems. The Directive codifies a number of rulings of the Court of Justice of the European Union regarding the freedom of patients to seek medical services abroad and to be reimbursed for such services by their home Member State, and introduces a number of measures to facilitate the implementation of these rulings in practice.

The Regulations and the Directive are two independent instruments that apply within their own respective designated areas. In accordance with Article 1 of the Directive, the Directive clarifies the relationship of these two instruments. To this end, Article 2(m) specifies that the Directive shall apply without prejudice to the Regulations. Furthermore, Recital 30 of the Preamble to the Directive stresses the need for coherence between the two instruments, stating that rights under the two instruments cannot be used simultaneously.

Recital 31 moreover clarifies that patients should not be deprived of the more beneficial rights guaranteed by the Regulations (EC) No 883/2004 and No 987/2009 when the conditions of these Regulations are met. This Recital also provides that where the patient is entitled to cross-border healthcare under both the Directive and the Regulations, and the

[2] OJ L 166, 30.4.2004, p. 1

[3] OJ L 284, 30.10.2009, p. 1

[4] The EU legislation on the coordination of social security systems includes Regulation (EC) No 883/2004 on the coordination of social security systems, Regulation (EC) No 987/2009 implementing Regulation (EC) No 883/2004. These Regulations are also relevant for the EEA countries (Iceland, Lichtenstein, Norway) and Switzerland. The EEA countries and Switzerland are currently covered by Regulation (EC) No 1408/71 and Regulation (EC) No 574/72, but soon will be covered by Regulation (EC) No 883/2004 and Regulation (EC) No 987/2009.

[5] OJ L 88, 4.4.2011, p. 45

application of the Regulations is more advantageous to the patient, the patient's attention should be drawn to this by the Member State of affiliation.

The Directive furthermore clarifies the relationship between the Directive and the Regulations with regard to specific matters, such as granting of prior authorisation (Recital 46 and Article 8(3)), assumption of costs of necessary healthcare (recital 28) or reimbursement of costs of healthcare (Article 7(1) and (2)). The application of the two legal instruments with regard to these matters is examined in the relevant chapters of this note.

Conclusion: The Directive applies without prejudice to Regulations (EC) No 883/2004 and No 987/2009. The coherent application of the two instruments must be ensured by the Member States. As a general principle, when the terms of the Regulations are met, treatment should be delivered under the Regulations, unless a patient, fully informed about his/her rights, requests otherwise.

2. Material scope of application

The Regulations apply to the social security branches referred to in Article 3 of Regulation (EC) No 883/2004, which include, *inter alia,* sickness benefits (Article 3(1)(a)) and benefits in respect of accidents at work and occupational diseases (Article 3(1)(f)). These two branches are relevant for the purpose of this note, in so far as they refer to benefits in kind. When the text of this note refers to sickness benefits, it shall be understood as relevant also to benefits in respect of accidents at work and occupational diseases, for ease of reading. However, in accordance with Article 3(5) thereof, social and medical assistance are excluded from the material scope of the Regulations.

Article 1(va) of Regulation (EC) No 883/2004 provides for a definition of the benefits in kind for the purpose of the two above branches. These cover those benefits in kind which are intended to supply, make available, pay directly or reimburse the cost of medical care and products and services ancillary to that care, including long-term care benefits in kind, and are provided for under the national legislation or under the accidents at work and occupational diseases schemes of the Member States.

The Regulations cover both planned and unplanned treatment.

The material scope of the Directive is defined by the combined provisions of Article 1 and Article 3(a) and (e) thereof. In accordance with Article 1, the Directive applies to the provision of cross-border healthcare to patients, regardless of how it is organized, delivered and financed. Article 3(a) provides for a definition of healthcare which means health services provided by health professionals to patients to assess, maintain or restore

their health, including the prescription, dispensation and provision of medicinal products and medical devices. Article 3(e) defines the term "cross-border healthcare" as healthcare provided or prescribed in a Member State other than the Member State of affiliation.

Article 1(3) of the Directive lists the types of care excluded from the application of the Directive. These are long-term care services to support people in carrying out routine, everyday tasks; allocation of and access to organs for transplantation; as well as public vaccination programmes against infectious diseases which aim at protecting the health of the population of a Member State and are subject to specific planning and implementation measures.

Furthermore, it is clear from the above provisions that the Directive, as regards its scope, does not distinguish between planned and unplanned healthcare but applies in principle to all care received by patients in a Member State other than their Member State of affiliation, regardless of the circumstances[6]. This includes therefore both planned and unplanned healthcare.

Finally, under the Directive all providers, including non-contracted or private providers, are covered.

In the light of the provisions set out above, the material scope of the two instruments is very similar. Sickness benefits in kind and benefits in kind for accidents at work and occupational diseases covered by Article 3(1) (a) and (f) of Regulation (EC) No 883/2004 fall under the definition of healthcare provided in Article 3(a) of the Directive and therefore, within the material scope of application of the Directive defined in Article 1(1) and (2).

Conclusion: The material scope of Regulation (EC) No 883/2004 and the Directive overlap, except in the field of long-term care benefits, which are not covered by the Directive. Both the Regulations and the Directive apply to planned and unplanned healthcare. The Directive covers all providers, including non-contracted or private providers, while Regulation (EC) 883/2004 does not impose any obligation on the Member States with regards to treatment given by providers who are not subject to the national legislation of the Member State of treatment, such as certain non-contracted or private providers.

[6] Except for situations described in Chapter IV of this note.

3. Personal scope of application

The personal scope of the Regulations is defined in Article 2 of Regulation (EC) No 883/2004. In accordance with this provision, the Regulations apply to nationals of a Member State, stateless persons and refugees residing in a Member State who are or have been subject to the legislation of one or more Member States, as well as to the members of their families and to their survivors[7]. They also apply to the survivors of persons who have been subject to the legislation of one or more Member States, irrespective of the nationality of such persons, where their survivors are nationals of a Member State or stateless persons or refugees residing in one of the Member States.

Regulation (EU) No 859/2003, for United Kingdom, and Regulation (EU) No 1231/2010, for all the Member States except United Kingdom and Denmark, extend the application of the Regulations to nationals of third countries who are not already covered by these Regulations solely on the ground of their nationality as well as to members of their families and to their survivors, provided that they are legally resident in the territory of a Member State and are in a situation which is not confined in all respects within a single Member State[8].

In accordance with Article 3(b) of the Directive, the personal scope of the Directive covers persons, including members of their families and their survivors, who are covered by Article 2 of Regulation (EC) No 883/2004 and who are insured persons within the meaning of Article 1(c) of that Regulation. The Directive also covers nationals of a third country who are covered by Regulation (EU) No 1231/2010 (all Member States except for United Kingdom and Denmark) or Regulation (EC) No 859/2003 (United Kingdom), or who satisfy the conditions of the legislation of the Member State of affiliation for entitlement to benefits (e.g. Denmark). Therefore, nationals of a third country and their family members legally residing in any of the Member States or, in the case of Denmark, who satisfy the conditions of the legislation of the Member State of affiliation for entitlement to benefits are covered by the Directive, provided they are in

[7] In accordance with the case law of the Court of Justice of the European Union (see e.g. case C-95/99 *Khalil* [2001] ECR I-07413), the social security coordination legislation applies only in situations which are not confined in all respects within one Member State.

[8] Regulation (EU) No 1231/2010 was adopted on the basis of Article 79(2)(b) TFEU. In accordance with the relevant Protocols (No 21 and 22) to the Treaty, Ireland has opted to take part in the adoption and application of Regulation (EU) No 1231/2010, while the United Kingdom and Denmark did not take part in the adoption of this Regulation and are not bound by it or subject to its application. Regulation (EU) No 1231/2010 repealed Regulation (EC) No 859/2003 between the Member States that were bound by this Regulation. In accordance with the relevant protocols to the EU and EC Treaties, United Kingdom opted to take part in the adoption and application of Regulation (EC) No 859/2003 and only Denmark was not bound by it or subject to it. Consequently, Regulation (EC) No 859/2003 continues to apply to the United Kingdom as this Member State has opted out from the adoption and application of Regulation (EU) No 1231/2010.

a situation which is not confined in all respects within a single Member State.

Conclusion: The Directive applies to persons covered by Regulation (EC) No 883/2004 as well as to the third country nationals and their family members who are legally resident in the territory of a Member State or, in the case of Denmark, who satisfy the conditions of the legislation of the Member State of affiliation for entitlement to benefits and are in a situation which is not confined in all respects within a single Member State.

II. Planned healthcare

1. Request for prior authorisation

As a rule, under the Regulations prior authorisation is a necessary requirement for receiving planned treatment in another Member State. In accordance with Article 20(1) of Regulation (EC) No 883/2004, the **insured persons and members of their family** travelling to another Member State with the aim of receiving benefits in kind during the stay must seek an authorisation from the competent Member State[9].

Article 1(s) of Regulation (EC) No 883/2004 defines the competent Member State as the Member State in which the institution with which the person concerned is insured or from which the person is entitled to benefits is situated.

If an insured person does not reside in the competent Member State, a request for prior authorisation for the planned treatment in a third Member State is made in the Member State where the person resides. The prior authorisation is then issued by the competent Member State on the basis of an assessment made by the Member State of residence (Article 26(2) of Regulation (EC) No 987/2009). The procedure applicable to planned treatment in a third Member State is described in detail in Chapter IV of this note.

Under the Directive, a requirement of prior authorisation is not the rule. In accordance with Article 8(1) of the Directive, the Member State of affiliation may provide for a system of prior authorisation only for certain kinds of cross-border healthcares and only in so far as it is necessary and proportionate to the objective to be achieved, and not constitute a means of discrimination or an obstacle to the free movement of patients.

Article 3(c) of the Directive defines the Member State of affiliation as the Member State competent to grant a prior authorisation under the Regulations.

The cross-border healthcare that may be subject to prior authorisation is listed in Article 8(2) of the Directive and it is limited to healthcare which:

- involves overnight hospital accommodation for at least one night; or
- requires use of highly specialised and cost-intensive medical infrastructure or equipment; or

[9] Where the members of the family of an insured person reside in a different Member State from this person and this Member State has opted to claim reimbursement from the competent Member State on the basis of fixed amounts, it is the Member State of residence of the members of family that is considered to be competent for them (Article 20(4) of Regulation (EC) No 883/2004).

- involves treatment presenting a particular risk for the patient or population; or

- is provided by a provider that could give rise to concerns relating to the quality or safety of the care.

In such instances, a request for prior authorisation is made by an insured person to the Member State of affiliation which is responsible for its assessment and for issuing the authorisation, whether the person resides in this Member State or elsewhere (see Chapter IV for more information on persons residing outside their competent Member State). The Member State of affiliation ascertains whether the conditions of Regulation (EC) No 883/2004 are met. If they are met, the prior authorisation is granted pursuant to the Regulations, unless the patient requests otherwise (Article 8(3) of the Directive).

It is important to note that the Regulations does not affect the freedom of the Member States to grant prior authorisation in cases where they are not obliged to under the Regulations (e.g. with regard to treatment given by providers who are not subject to the national legislation of the Member State of treatment, such as certain non-contracted or private providers). Under the Directive all providers, including non-contracted or private providers, are covered.

Conclusion: If the conditions of the Regulations are met, prior authorisation must be granted by using the Regulations, unless the patient explicitly requests the application of the Directive.

Points to consider in implementation

Member States will need to decide:

- whether to have an authorisation system under the Directive;

- the scope of authorisation system they want to have (given limitations imposed by the Directive and the need for justification of any such system);

- whether they wish to create one unified system of prior authorisation, which deals with requests for authorisation under both the Regulations and the Directive, or whether they have two separate systems.

If a unified system is chosen, there are certain crucial points which will need to be borne in mind:

The authorisation system will need to be capable of dealing with the differences between the two pieces of legislation, whilst also being straightforward for patients to access and for administrators to run. It will be very important to ensure that such a system can distinguish between:

- situations where a patient could benefit from their rights either under the Regulations or under the Directive; and

- situations where a patient could benefit from only one EU instrument.

Authorisation systems will need to communicate this to patients so they are aware of their rights and the implications of any decisions they make with regard to which instrument they may use

To illustrate the need to inform patients, insured persons applying for prior authorisation for reimbursement for treatment from private or non-contracted providers covered by an authorisation system under the Directive will need to be aware of the consequences (e.g. the reimbursement rates which will apply, particularly where the competent Member State doesn't reimburse for treatment from non-contracted or private providers under the Regulations).

Given the need to ensure that patients do not lose out their rights under the Regulations, patients who are assessed as facing a medically unjustifiable wait for treatment ("undue delay"[10]) should be informed of the implications of this assessment with regard to both instruments (as per Recital 31 of the Preamble to the Directive):

- that they are entitled to receive an authorisation under the Regulation (EC) No 883/2004 and to proceed with treatment on the basis of an S2 form; however the patient's choice of healthcare provider may be more limited than under the Directive;

- or that they are alternatively entitled to choose to receive an authorisation under the terms of the Directive and to proceed with treatment on that basis, being thereafter entitled to receive reimbursement up to the cost of the treatment in the Member State of affiliation.

Member States will also need to ensure that patients can still apply for prior authorisation under the Regulations for treatment not subject to prior authorisation under the Directive (and are not systematically

[10] A time limit which is medically justifiable based on an objective medical assessment of the patient's medical condition, the history and probable course of the patient's illness, the degree of the patient's pain and/or the nature of the patient's disability at the time when the request for authorisation was made or renewed (see Article 8(5) of the Directive).

directed to use the Directive for such treatments). This is because treatment via the Regulations may be more beneficial for the patient: it may involve greater coverage of the costs of the treatment; it may also not require the patient to pay directly for the treatment. Patients must therefore still have the possibility to access treatment on the terms of the Regulation if they meet the criteria to do so.

In any case Member States will have to ensure that the principles laid down in Article 9 of the Directive are respected.

2. Refusal of prior authorisation

The two instruments in question take a different approach as regards the refusal of prior authorisation.

Under the Regulations, prior authorisation may not be refused if the treatment is among the benefits provided by the Member State where the person concerned resides and cannot be provided within a time limit that is medically justifiable[11], either in the country of residence or in the competent Member State (Article 20(2), second sentence, of Regulation (EC) No 883/2004[12]; also Article 26(2), third subparagraph, of Regulation (EC) No 987/2009). Otherwise, Member States may choose when to grant or refuse it.

Under the Directive, prior authorisation may not, in principle, be refused if the patient is entitled to the healthcare in the Member State of affiliation and when this healthcare cannot be provided on its territory within a time limit that is medically justifiable (Article 8(5) of the Directive). However, Article 8(6) points a) to c) of the Directive list the situations related to safety or quality concerns, where the Member State of affiliation is able to refuse to grant the prior authorisation even in the circumstances referred to in Article 8(5). The situations listed in Article 8(6) should be treated as exceptions and interpreted in a restrictive way.

It has to be ensured that the administrative procedures relating to the use of cross-border healthcare, including the system for the grant and refusal of prior authorisation, are based on objective and non discriminatory criteria which are necessary and proportionate to their objective, in accordance with Article 9(1) of the Directive. Article 9(4) states that each individual decision relating to the use of cross-border healthcare must be properly reasoned. This means that the case of each patient must be

[11] A time limit which is medically justifiable, taking into account the person's current state of health and the probable course of the person's illness. This corresponds to the notion of "undue delay" in terms of the Directive (see footnote 10).

[12] Article 36(2a) of Regulation (EC) No 883/2004 for accidents at work and occupational diseases.

individually assessed and, where the concept of "undue delay" is used, a determination of what would constitute a time limit which is medically justifiable in that individual case must be made. In particular, if a request is refused on the grounds that there is no "undue delay", the patient must be advised as to what is considered to be a medically justifiable waiting time in his or her particular case. 9(4) also requires such decisions to be capable of being challenged in judicial proceedings

It is important to note that the Regulations do not contain any specific requirements relating to the decisions on the refusal of prior authorisation. However, the higher standards laid down by Article 9(4) of the Directive, as far as they correspond to general principles of law, will have to be considered by Member States as also of relevance to the implementation of the Regulations.

Conclusion: Both under the Regulations and the Directive, prior authorisation may not be refused if the patient is entitled to healthcare and that healthcare can not be provided within a time-limit which is medically justifiable. Exceptions listed in Article 8(6) of the Directive should be interpreted restrictively. Member States will also have to apply under the Regulations higher standards laid down in Article 9 of the Directive, in accordance with general principles of law, for all decisions concerning prior authorisation.

Points to consider in implementation

The requirement in Article 9(4) that decisions about cross-border healthcare should be "properly reasoned" should be understood as meaning that, where a request for authorisation is turned down on the basis of "no undue delay", then there should be a statement of what constitute a time limit which is medically justifiable in the case of that individual patient. Member States will therefore need to ensure that each decision meets these criteria.

3. Reimbursement of costs for planned treatment

The Regulations and the Directive set up different principles for reimbursement of costs of treatment received in another Member State.

Under the Regulations, to be reimbursed costs of planned treatment, the **insured persons and their family members** have to obtain prior authorisation. The person in question receives benefits in kind in a Member State of treatment on behalf of the **competent Member State**

(Article 20(2) of Regulation (EC) No 883/2004)[13]. Costs of the benefits in kind are reimbursed under the **conditions and reimbursement rates in the Member State of treatment** (Article 26(6) of Regulation (EC) No 987/2009).

The reimbursement procedure shall take place between the institutions of the Member States involved (Article 35 of Regulation (EC) No 883/2004). However, if the insured person has borne the costs of the provided benefits in kind, he/she may be reimbursed either directly in the Member State of treatment or in the competent Member State (Article 26(6) of Regulation (EC) No 987/2009).

If the costs of planned treatment were borne by the insured person and the costs that have to be reimbursed by the competent Member State under the legislation of the Member State of treatment (actual costs) are lower than the costs which the competent Member State would have to assume for the same treatment on its own territory (notional costs), the cost incurred by the person may be reimbursed up to the amount by which the notional cost exceeds the actual cost (the so called "*Vanbraekel* supplement"[14] as incorporated in Article 26(7) of Regulation (EC) No 987/2009).

The reimbursement must also cover costs of travel and stay that are inseparable from the planned treatment for which the prior authorisation was granted, if the national legislation of the competent Member State provides for the reimbursement of such costs in that Member State (Article 26(8) of Regulation (EC) No 987/2009).

The Regulations do not affect the freedom of the Member States to cover in their national legislation reimbursement of costs in cases where they are not obliged to under the Regulations (e.g. with regard to treatment given by providers who are not subject to the national legislation of the Member State of treatment, such as certain non-contracted or private providers).

Under the Directive, general principles for reimbursement of costs are laid down in Article 7, which should apply without prejudice to the Regulations.

[13] Where the members of the family of an insured person reside in a different Member State from this person and this Member State has opted to claim reimbursement from the competent Member State on the basis of fixed amounts, or where a pensioner and his/her family members reside in such a Member State, it is the Member State of residence that is considered to be competent for them (Article 26(1) of Regulation (EC) No 987/2009).

[14] Court of Justice ruling in case C-368/98 [2001] ECR I-05363 *Vanbraekel*: if the reimbursement of costs incurred in another Member State, calculated under the rules of that State, is less than the amount under the legislation in the competent Member State, additional reimbursement covering that difference must be granted to the insured person by the competent Member State.

In terms of the Directive, patients always have to pay the full cost of cross-border healthcare directly to the healthcare provider. The costs incurred are reimbursed to patients by the **Member State of affiliation**, if the provided healthcare is among the benefits in this Member State (Article 7(1)). The reimbursement is made according to the **conditions and reimbursement rates that would have been assumed for that healthcare on the territory of the Member State of affiliation**, without exceeding the actual cost of the received healthcare (Article 7(3) and (4) of the Directive). The Member State of affiliation may nevertheless decide to reimburse the full cost of healthcare (Article 7(4) of the Directive, second sentence).

The Member State of affiliation may also decide to reimburse other related costs, such as accommodation and travel costs, or extra costs incurred by persons with disabilities, in accordance with its national legislation and if there is sufficient documentation setting out these costs (Article 7(4) of the Directive, third sentence).

As a rule, reimbursement of costs of cross-border healthcare should not be subject to prior authorisation[15] (Article 7(8) of the Directive). However, if a prior authorisation was granted, the reimbursement should take place in accordance with this authorisation (Article 7(10) of the Directive).

In addition, a reimbursement rule has been laid down under Article 7(2)(b) of the Directive, according to which the competent Member State determined under the Regulations is obliged to cover the costs of healthcare received on its territory, if this healthcare is not provided in accordance with the Regulations, and is not subject to prior authorisation in the Member State of residence (see section 3 of Chapter IV of this note for more on the circumstances in which this rule might apply).

All healthcare providers, including non-contracted or private providers without contracts with the national health system, are covered by the Directive.

Conclusion: The procedures and level of reimbursement of planned treatment under the Regulations and the Directive are different. Under the Regulations, reimbursement of healthcare received in the Member State of treatment takes place in accordance with the legislation and tariffs of this Member State. Under the Directive reimbursement takes place in accordance with the legislation and tariffs of the Member State of affiliation.

[15] Except in cases set out in Article 8 of the Directive (see Chapter II of this note).

Points to consider in implementation

Each Member State will need to consider the extent to which they may be affected by the rule on assumption of costs set out in Article 7(2)(b) of the Directive (see Chapter IV of this note).

Member States will need to communicate clearly with patients to ensure that they understand the different levels of reimbursement which apply and the different commitments the patient may undertake (e.g. with regard to payment made directly to the healthcare provider or otherwise).

III. Unplanned healthcare

1. Rules applicable to unplanned healthcare

Under Article 19(1) of Regulation (EC) No 883/2004, **insured persons and their family members** staying in a Member State other than the competent Member State are entitled to the benefits in kind which become necessary on medical grounds during their stay. These benefits are provided on behalf of the competent Member State by the Member State of stay in accordance with the legislation it applies, as if the persons concerned were insured under this legislation.

In order to access the said benefits in kind, the competent Member State where the person is insured issues a European Health Insurance Card (in application of Article 25(1) of Regulation (EC) No 987/2009). Depending on the structure of the system in the Member State of stay, Member States may provide healthcare free of charge, apply a patient's fee[16] or charge full costs of healthcare.

In the Member States where healthcare is free of charge or only a patient's fee is charged, the patient requests the reimbursement directly from the Member State of stay. The competent Member State assumes the costs of benefits received and reimburses them to the Member State of stay (Article 35 of Regulation (EC) No 883/2004). Such reimbursement is administered between the two Member States involved, in accordance with the financial provisions laid down in Title IV of Regulation (EC) No 987/2009.

In the Member States which charge for the full cost of healthcare, the insured person covers the cost and is then reimbursed directly in the Member State of stay (Article 25(4) of Regulation (EC) No 987/2009). The Member State of stay later claims reimbursement from the competent Member State in accordance with the financial provisions laid down in Title IV of Regulation (EC) No 987/2009.

If the insured person did not request the reimbursement directly from the institution of the place of stay or did not possess the European Health Insurance Card[17], he/she covers the cost of the benefit received and is reimbursed by the competent Member State after returning there (Article 25(5) Regulation (EC) No 987/2009).

[16] Costs which under the legislation of the Member State patients always have to bear (this can be either a lump-sum or a percentage of the total cost of a treatment).

[17] Alternatively, a provisional replacement certificate (PRC) may be requested from the competent Member State. The PRC confirms the same rights as the European Health Insurance Card (in application of Article 25(1) of Regulation (EC) No 987/2009).

As a rule, reimbursement is claimed and made within the limits and under the conditions laid down in the legislation of the Member State of stay (Article 25(4) and (5) of Regulation (EC) No 987/2009)[18].

As set out in section 2 of Chapter 1 of this note, the Directive applies to unplanned healthcare. However, as it is stipulated in its Article 2 point m) and 7(1), the Directive should be applied without prejudice to the Regulations. That means, as it is stated in Recital 28 of the Preamble, that the Directive should not affect an insured person's rights in respect of the assumption of costs of healthcare which becomes necessary on medical grounds during a temporary stay in another Member State according to Regulation (EC) No 883/2004. It stems from these provisions, therefore, that, where the terms of the Regulations are met and the terms and conditions of the Regulations are more favorable to the patient, the Regulations must be used, unless the patient explicitly requests otherwise. The existence of the Directive can therefore under no circumstances be used to deny access to healthcare for insured persons who possess the European Health Insurance Card.

If the patient requests reimbursement under the terms of the Directive, his/her entitlement to the reimbursement of costs of cross-border healthcare is based on the legislation of the Member State of affiliation. In accordance with Article 7(1) of the Directive, the obligation of the Member State of affiliation to reimburse the costs of cross border-healthcare concerns only benefits which the insured person is entitled to in the Member State of affiliation.

For cross-border healthcare received under the Directive, the patient always has to pay the full cost of healthcare directly to the healthcare provider and claim reimbursement from the Member State of affiliation. The Member State of affiliation is only obliged to reimburse cross-border healthcare according to the conditions and tariffs that would have been assumed for that healthcare on its own territory, without exceeding the actual cost of the healthcare received (Article 7(3) and (4) of the Directive). Thus, if the cost of healthcare is higher, patients must pay the difference themselves. The Member State of affiliation may nevertheless decide to reimburse the full cost of healthcare (Article 7(4) of the Directive, second sentence).

It is important to recall that the Regulations do not affect the freedom of the Member States to cover in their national legislation costs of unplanned treatment in cases where they are not obliged to under the Regulations (e.g. with regard to treatment given by providers who are not subject to

[18] Except for cases which fall under Article 25(6) and (7) of Regulation (EC) No 987/2009 where the competent Member State may reimburse the cost within the limits and condition of its own legislation, if a patient agrees or without the patient's agreement - if the Member State of stay does not provide for reimbursement in accordance with Article 25(4) and (5) of Regulation (EC) No 987/2009.

the national legislation of the Member State of treatment, such as certain non-contracted or private providers). The Directive covers all providers.

Conclusion: Both the Regulations and the Directive apply to unplanned healthcare. However, the rights of patients under the Regulations to unplanned healthcare should not be affected by the Directive. The rules and procedures set out by the Regulations should be used to deal with unplanned care wherever the terms of the Regulations are met and the terms and conditions of the Regulations are more favorable to the patient, unless the patient explicitly requests otherwise.

Points to consider in implementation

Under the Directive Member States cannot refuse reimbursement in cases of treatment by certain non-contracted or private providers which are not covered by the Regulations.

Given the need to ensure that patients do not lose out on their rights under the Regulations Member States will need to ensure:

- that healthcare providers do not refuse to treat patients seeking unplanned care under the terms of the Regulations, insisting instead that patients pay directly at the healthcare provider and claim reimbursement under the Directive;

- that local health systems do not refuse to treat such patients in the public health system, instead passing them on to non-contracted or private providers for treatment under the terms of the Directive;

- that patients are not deprived of their rights. To that aim, the National Contact Points (hereinafter NCPs) established by Article 6(1) of the Directive[19] (see also Chapter V of this note) should provide full information to patients about their rights of access to healthcare in another Member State under both instruments, and the terms of access they can expect (including any payments they may be required to make). It should also be clear to whom patients may complain if they are deprived of those rights.

[19] In accordance with Article 6 of the Directive each Member State shall designate one or more national contact points for cross-border healthcare. Member States shall ensure that the national contact points consult with patient organisations, healthcare providers and healthcare insurers.

IV. Residence outside the competent Member State

It is important to note that the term 'competent Member State' is relevant for the purposes of the Regulations, while the term 'Member State of affiliation' is relevant for the purposes of the Directive.

As already stated in Chapter II of this note, under Article 1(s) of Regulation (EC) No 883/2004 the competent Member State means the Member State in which the institution with which the person concerned is insured or from which the person is entitled to benefits is situated.

Article 3(c) of the Directive 2011/24/EU defines the 'Member State of affiliation' as the 'Member State competent to grant a prior authorisation under the Regulations'. This definition means that the rules on cross-border healthcare are generally consistent with the Regulations regarding where patients should apply for prior authorisation and reimbursement of costs of this healthcare. The scope of the entitlements to healthcare and the reimbursement tariffs might however differ under the two instruments.

However, when it comes to persons who do not reside in their 'competent Member State' within the meaning of the Regulations, attention should be paid to distinguish between the 'competent Member State' and the 'Member State competent to grant a prior authorisation under the Regulations', as these terms do not necessarily refer to the same Member State.

The situation of these persons requires a more in-depth analysis in order to clarify which Member State is responsible for costs and which procedures apply under the two instruments.

1. Access to benefits in kind in the Member State of residence

Under Article 17 of Regulation (EC) No 883/2004, **insured persons and their family members who reside outside their competent Member State** are entitled to benefits in kind in their Member State of residence, as if they were insured there. Also **pensioners receiving pensions from one or more Member States** and **their family members**[20] are entitled to benefits in kind under the legislation of the Member State of residence, as if they were insured in that Member State.[21]

[20] If the family members reside in other Member State than the pensioner, Article 26 of Regulation (EC) No 883/2004 applies.

[21] The costs of benefits in kind provided in the Member State of residence are borne by the Member State determined in accordance with Articles 23-25 of Regulation (EC) No 883/2004.

The entitlements to the benefits in kind in the Member State of residence are therefore determined by referring to the entitlements of persons insured in that Member State. The costs of these benefits are reimbursed to the Member State of residence by the competent Member State, either on the basis of actual cost payments, or fixed amounts.

As far as the Directive is concerned, when insured persons and members of their family who reside outside their competent Member State receive healthcare in the Member State of residence, such a scenario is considered as lacking a cross-border element within the terms of the Directive. This is in accordance with the notion of Member State of affiliation which is defined by Article 3, point c) of the Directive, as the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment **outside the Member State of residence** according to Regulations (EC) No 883/2004 and (EC) No 987/2009. Therefore, healthcare received in the Member State of residence is not considered as a cross-border situation falling in the scope of the Directive.

Conclusion: When an insured person resides outside the competent Member State, access to benefits in kind in the Member State of residence must be regulated by applying only the Regulations in order to allow the person to enjoy those benefits, as though the person was insured in the Member State of residence. The Directive does not apply in these situations.

2. Procedure applicable to planned treatment in a third Member State[22]

For patients residing outside the competent Member State, the Directive and the Regulations set out two different procedures applicable to planned treatment received in a third Member State.

Under the Regulations, the procedure applicable to scheduled treatment is laid down in Article 26 of Regulation (EC) No 987/2009. According to paragraph 2 of this provision, **insured persons and members of their family who reside outside their competent Member State** submit in the Member State of residence a request for prior authorisation in order to receive planned treatment in another Member State. The prior authorisation is issued by the competent Member State on the basis of an assessment made by the Member State of residence. The competent Member State may refuse to grant the prior authorisation only if, in accordance with the assessment by the Member State of residence, the

[22] The section does not cover specific categories of persons residing in a Member State which claim reimbursement based on fixed amounts. Please refer to section 4 of this Chapter.

treatment is not among the benefits provided by the Member State of residence or, if the same treatment can be provided in the competent Member State or in the Member State of residence within a medically justifiable time limit.

The Member State of residence may itself grant a prior authorisation on behalf of the competent Member State where there is a need for urgent vitally necessary treatment, in accordance with Article 26(3) of Regulation (EC) No 987/2009, or if the Member State of residence claims reimbursement based on fixed amounts (see section 4 of this Chapter).

If the prior authorisation is issued, the treatment is provided to the patient under the same conditions and at the same cost (in some countries free of charge) as to persons insured in the Member State of treatment (Article 26(6) of Regulation (EC) No 987/2009). In other words, if the persons insured in the Member State of treatment receive treatment free of charge, so should the patient. If they pay directly to the healthcare provider and claim reimbursement, so should the patient.

The costs are borne by the competent Member State. As a rule, these costs are dealt with between the institutions of the concerned Member States so the patients do not have to pay directly to the healthcare provider. If a patient has paid directly at the healthcare provider, he/she must be reimbursed by the competent Member State up to the amount by which the notional cost exceeds the actual cost (the so called "*Vanbraekel* supplement"[23] as incorporated in Article 26(7) of Regulation (EC) No 987/2009).

Under Chapter III of the Directive, it is the Member State of affiliation (which is the 'Member State competent to grant a prior authorisation under the Regulations') which is responsible for issuing a prior authorisation, if applicable, and for the reimbursement to the patient of costs of the cross-border healthcare. Therefore, with regard to healthcare received in a third Member State by an insured person residing outside the Member State of affiliation, the Member State where this person resides is not involved in the procedure of application for prior authorisation under the Directive[24].

In terms of the Directive, patients always pay the full cost of healthcare directly to the healthcare provider. Patients make a claim for reimbursement directly from their Member State of affiliation. The costs are borne by this Member State under the conditions and within the tariffs of the Member State of affiliation (Article 7(1) of the Directive).

[23] Court of Justice ruling in case C-368/98 [2001] ECR I-05363 *Vanbraekel* (see section 3 of Chapter II of this note).
[24] With certain exceptions described in section 4 of this Chapter.

It is important to note that the Directive does not create additional rights for persons residing outside the competent Member State with regard to access to healthcare in a third Member State; it establishes a different procedure to obtain a prior authorisation, if applicable, or claim reimbursement for this healthcare by the persons concerned, which could result in different entitlements and reimbursement amounts than those existing under the Regulations. For example, under the Regulations it is the "basket of benefits" of the Member State of residence (benefits provided under its legislation) which is used in determining entitlements, but under the Directive it will be that of the Member State of affiliation. To take another example, it should be borne in mind that the Directive also applies to healthcare received from private or non-contracted healthcare providers.

Conclusion: When an insured person resides outside the Member State of affiliation, the Directive can be used to request prior authorisation, if applicable, or claim reimbursement for healthcare received in a third Member State directly from the Member State of affiliation, subject to the specific conditions of the Directive. The patient may choose to do this as an alternative to the procedure set out in Article 26 of Regulation (EC) No 987/2009. The entitlements and the reimbursed amount may be different depending on whether the Regulations or the Directive is used. In principle, the Regulations ensure that the planned treatment is provided as if the person was insured in the Member State of treatment, while under the Directive it is provided according to the legislation and tariffs of the Member State of affiliation.

Points to consider in implementation

To ensure the minimum of problems for insured persons in accessing their rights, Member States should ensure the following:

a) for persons resident on their territory for whom they are not the competent Member State

- that these persons have access to information about all their rights under the Regulations and the Directive: entitlements, terms and conditions, whose concept of "undue delay" applies etc. The Member State of residence should clearly explain to these persons who they should contact to exercise their various rights (e.g. the National Contact Point of the Member State of affiliation for rights under the Directive).

- that this category of people has full access to their reimbursement and authorisation mechanisms (e.g. patients should not be denied

their right to apply for a prior authorisation under the Regulations in order to push them towards using the Directive).

b) for persons for whom they are the competent Member State who are resident on the territory of another Member State

- that these persons are aware of all their rights under the Regulations and the Directive: whether those directly from the competent Member State or those via the Member State of residence (e.g. via a particular section on the NCP website).

- that this category of people have access to reimbursement and authorisation mechanisms under the Regulations which deal with their requests in a timely and efficient manner. If Member States choose to use the system of prior authorisation under the Directive, then there must be a fair and efficient way of working out the offer of treatment in the Member State of affiliation and the delay it involves.

- that people are not deprived of their rights under the Regulations. The general principle that Member States have to draw the attention of patients to their rights under the Regulations, even if the conditions for prior authorisation for planned care are fulfilled under the Directive, has also to be respected under this Chapter.

3. Coverage of healthcare in the competent Member State which is not subject to prior authorisation

Under Article 18(1) of Regulation (EC) No 883/2004, **insured persons and their family members** who reside in another EU Member State are entitled to benefits in kind while staying in their competent Member State, as if in fact they resided there.

However, certain Member States have restricted the access of **families of frontier workers** for whom they are the competent Member State in accordance with Article 18(2) of Regulation (EC) No 883/2004 and who are resident outside their territory (that is, living in the same Member State as the frontier worker). These are the Member States listed in Annex III to Regulation (EC) No 883/2004. In those Member States, the persons in question are entitled only to necessary care, based on the rights given by Article 18(2) of Regulation (EC) No 883/2004.

Pensioners and their family members who reside outside their competent Member State also have limited rights to benefits in kind in their competent Member State, unless this Member State is listed in Annex IV to Regulation 883/2004. In a competent Member State listed in Annex IV, pensioners and their families have the same entitlement to

benefits in kind as residents of that Member State, in accordance with Article 27(2) of Regulation No 883/2004[25]. In competent Member States, which are not listed in Annex IV, on the contrary, the pensioners in question and their families are entitled only to necessary care on the basis of Article 27(1) of Regulation (EC) No 883/2004.

Under Article 7(2)(b) of the Directive, a reimbursement rule has been laid down regarding healthcare received in the competent Member State which in particular affects two of the groups referred to above: namely pensioners and their family members from Member States not currently in Annex IV of Regulation (EC) No 883/2004; and families of frontier workers who reside in the same Member State as the worker, and whose competent Member State is listed in Annex III to Regulation (EC) No 883/2004.

This rule affects those two groups in particular since, under the Regulations, they have fewer rights regarding healthcare in the competent Member State than other groups. However, in principle, the reimbursement rule covers all insured persons.

On the basis of the above provision in the Directive, the competent Member State is obliged to cover the costs of any healthcare received on its territory by these categories of people which is not provided in accordance with the Regulations and is not subject to prior authorisation in the Member State of residence. Member States may make the assumption of such costs subject to the same terms, conditions, criteria and procedures, as if the person was a resident there (e.g. the same basket of benefits may be applied; the same co-payment may be required), provided that this is compatible with the Treaty. This may include, for example, a requirement that the patient go through a specific procedure (e.g. a 'gatekeeping' procedure) to access specialised care, or restrictions on the type of providers which a patient can access (provided that such restrictions are in themselves compatible with the Treaty).

It is also important to note that Article 7(2)(b) of the Directive creates reimbursement rules only by establishing which Member State is liable to bear the cost of the treatment once it has been received; it does not create any new rights for the persons concerned with regard to access to healthcare.

Conclusion: Under the Directive, the costs of healthcare not subject to the prior authorisation procedure and provided by the competent Member State determined under the Regulations, must be paid for by this Member State. As a consequence, in such situations, for members of the family of frontier workers and

[25] In that case, according to Article 64 (3) of Regulation 987/2009, the competent Member State is entitled to a reduction in the lump-sum payment that it owes to the Member State of residence.

pensioners and their family members, those costs are borne by the competent Member State, irrespective of an entry into Annex III or a non-entry into Annex IV of Regulation (EC) No 883/2004. It is important to note, however, that this reimbursement rule does not create any right of access to healthcare in the competent Member State.

Points to consider in implementation

In principle the reimbursement rule in Article 7(2)(b) covers all insured persons, and Member States will need to take this into account in implementation. In practice, however, Article 7(2)(b) of the Directive is likely to be mainly of relevance for Member States listed in Annex III and/or not listed in Annex IV to Regulation (EC) No 883/2004. Those Member States in particular will have to consider what procedures they need for identifying those items of healthcare for which they will be obliged to bear the costs under Article 7(2)(b).

4. Procedure applicable to pensioners and family members residing in a Member State claiming reimbursement on the basis of fixed amounts

Some Member States have opted to claim reimbursement from the competent Member State on the basis of fixed amounts[26] and are listed, to this end, in Annex 3 to Regulation (EC) No 987/2009.

Fixed amounts can be claimed with regard to specific categories of persons residing in those Member States, namely:

- **family members of an insured person residing in a different Member State than this person, if that Member State is a Member State listed in Annex 3;**

- pensioners and their family members residing in such Member State.

The fixed amounts are claimed by the Member State of residence from the competent Member State. They cover costs of healthcare provided to these persons in the Member State of residence and costs of planned treatment provided in a third Member State on behalf of the Member State of residence.

[26] Fixed amounts = annual lump-sum payments established by the Audit Board made for these categories of persons by the competent Member State to the Member State of residence (Articles 63-65 of Regulation (EC) No 987/2009)

With regard to **planned treatment** provided in a third Member State to the categories of persons in question, the Regulations stipulate that the Member State responsible for issuing a prior authorisation for such treatment and for bearing its costs is the Member State of residence (see Articles 20(4) and 27(5) of Regulation (EC) No 883/2004 and Article 26 (1) of Regulation (EC) No 987/2009, last sentence).

Accordingly, the Member State of residence, being responsible to grant a prior authorisation under the Regulations, becomes the 'Member State of affiliation' for the purposes of the Directive. The request for prior authorisation for planned treatment provided to persons in a third Member State is therefore introduced in the same Member State (Member State of residence) under the two instruments. However, the level of reimbursement may differ depending on whether the Directive or the Regulations are applied (see above section 2).

Nevertheless, for the purposes of **unplanned necessary treatment** received in a third Member State, it is still the competent Member State where the person is insured which issues the European Health Insurance Card, and which assumes the costs of this treatment, in accordance with Article 25 of Regulation (EC) No 987/2009. The reimbursement is made by the competent Member State (for the general modalities concerning the reimbursement of unplanned healthcare please refer to Chapter III of this note). In any case, the Member State of residence is not involved in this process.

As was concluded in Chapter III of this note, the Directive applies also to unplanned healthcare. However, in accordance with Recital 28 of the Preamble to the Directive, the rights of patients in respect of the assumption of costs of such healthcare under the Regulations should not be affected by the Directive. The Directive may therefore apply if the terms of Regulation are not met[27] or, if the patient chooses instead to seek reimbursement under the terms of the Directive.

Under Article 7 of the Directive it is always the Member State of affiliation which ensures the reimbursement of costs of the cross-border healthcare. The Directive offers therefore the categories of persons referred to above a possibility to claim in their country of residence the reimbursement of costs of unplanned treatment received in a third country. The reimbursement is made by the Member State of affiliation.

Conclusion: With regard to planned healthcare received in another Member State, when an insured pensioner and his family members or a family member of a frontier worker do not reside in the

[27] For instance, in case of claims for the reimbursement of the costs related to treatment administered by certain non-contracted or private healthcare providers not covered by the legislation of the Member State of treatment.

competent Member State and the Member State of residence opted for reimbursements on the basis of fixed amounts, it is always the Member State of residence which is responsible for reimbursement of costs of such healthcare. With regard to unplanned healthcare, it is still the competent Member State that handles the procedure for reimbursement of costs of such unplanned healthcare where it is delivered under the Regulations. Where such healthcare does not fall within the scope of the Regulations – or where the patient wishes to do so – the patient may claim reimbursement of costs of this healthcare from the Member State of residence, which is in this case also the Member State of affiliation for the purposes of the Directive.

Points to consider in implementation

Member States which have opted to claim reimbursement from the competent Member State on the basis of fixed amounts should be aware of their obligations towards such patients. With regard to unplanned treatment those Member States may not refuse to reimburse the patients on the grounds that the treatment could have been carried out using the European Health Insurance Card under the Regulations as the rights to reimbursement under the Directive exist independently of rights under European Health Insurance Card. The corollary of this is that Member States of treatment must ensure that providers meet their obligations under the Regulations and that patients are not systematically directed towards treatment under the terms of the Directive, as noted in the Chapter III of this note.

The Directive offers patients in this category an option with regard to unplanned healthcare received in a third country. They may be treated under the terms of the Regulations, or may claim reimbursement in their competent Member State of residence under the terms of the Directive. Member States should put in place appropriate measures to avoid the situation where one claim for reimbursement is dealt with under both systems.

In this context, it is important that Member States monitor claims, in particular by collecting relevant statistics and data.

In the information provided to the persons concerned by this chapter, competent Member States will need to be clear about the different rules which apply depending on the Member State in which people reside.

V. Information and procedural guarantees

1. Information guarantees

The Regulations contains a general obligation to provide information to insured persons on their rights under the Regulations, their entitlements, and the procedures which apply when they wish to claim benefits. Member States designate liaison bodies under the Regulations (Article 1(b) of Regulation (EC) No 987/2009), which have an obligation to respond to queries about the exercise of rights (see Article 76(4) of Regulation (EC) No 883/2004, second sentence and Article 3 of Regulation (EC) No 987/2009).

Article 76(2) of Regulation (EC) No 883/2004 lays down an obligation of mutual assistance between the authorities and institutions of the Member States as if they were implementing their own legislation. Article 76(4) thereof also provides for a general obligation for mutual information and cooperation between the institutions and the persons covered by the Regulations to ensure their correct implementation. This article lays down an obligation for the persons concerned to inform the relevant institutions of any changes affecting their right to benefits under the Regulations[28].

Article 6 of the Directive requires Member States to set up National Contact Points (NCPs). These NCPs must provide patients seeking treatment in another Member State with information about their rights and entitlements, and the procedures which apply (Articles 5(b) and 6(4) of the Directive). Applicable national procedures must include appeals and redress procedures for patients who feel their rights have not been respected.

NCPs must also provide patients from other Member States with information on healthcare providers (including information on a specific provider's right to practice) (Article 6(3) of the Directive). They must also provide general information on patients' rights, complaints procedures, mechanisms for seeking remedies, and dispute resolution options. Moreover, Article 4(2)(a) of the Directive requires NCPs to provide information about the quality and safety systems of that Member State (which should include information about the supervision and assessment of providers).

In addition to these tasks, NCPs have a general duty of exchanging information on quality and safety standards and supervision, and of mutual assistance regarding understanding invoices.

As well as the information to be provided by NCPs, Article 4(2)(b) of the Directive requires Member States to ensure that individual providers

[28] To this end, see also Article 3(2) of Regulation (EC) No 987/2009.

provide a number of information to patients: treatment options, prices, invoices, registration status and insurance cover.

It can be generally observed, then, that the Directive will result in greater information being available to both incoming and outgoing patients. This increase in information will be of relevance to the operation of both instruments.

2. Procedural guarantees

Article 9 of the Directive makes explicit certain general principles of law with regard to administrative procedures related to cross-border healthcare (some of which are discussed in Chapter II of this note). Member States will have to ensure that the principles laid down in Article 9 of the Directive are respected.

Conclusion: With regard to patients seeking treatment in another Member State, the requirements of the Directive and the Regulations regarding the provision of information are broadly similar. The provision of greater information to patients as a result of the Directive should be considered of relevance to the implementation of both instruments. Member States will also have to apply under the Regulations the general procedural and administrative guarantees made explicit in Article 9 of the Directive to the benefit of the patient.

Points to consider in implementation

- Member States will need to decide which modalities and tools are needed to adequately inform patients of their rights under both instruments.

- Member States should consider the potential future development of the role and function of NCPs. Member States may decide to broaden the role of the NCPs further: for example into advocacy services for their own patients. Member States may also wish, in the future, to have closer co-operation between NCPs to resolve day-to-day issues.

- There is some possibility of institutional synergy by using liaison bodies to carry out the role of NCP. However, it is important to note that the duties and obligations of the NCP are broader in scope and depth than the current duties of the liaison bodies e.g. with regard to information on individual providers, quality and safety systems, and enforcement.

- NCPs are also required to give patients impartial and independent information about their rights and entitlements. There is therefore a potential risk of a conflict of interest if the NCP is a payer organisation (as some liaison bodies currently are). Member States must ensure that NCPs provide all information in an independent and impartial manner.

- It will therefore be important for NCPs to operate in a transparent manner so that there is no question of such a conflict of interest. In this context it is also worth noting the general duty of consultation between NCPs and patient organisations, healthcare providers, and healthcare insurers, which is provided by Article 6(1) of the Directive.

- As well as institutional synergies, there are clear possibilities for Member States to align the appeals and complaints procedures under the two instruments

- In all cases, these synergies or alignments should always be to the higher standard, to ensure that patients are not deprived of their rights.

- The increase in information available on patients' rights, alongside more accessible information on, for example, healthcare providers, may increase people's willingness to use cross-border healthcare in the future.

- Explaining rights to patients in a straightforward manner may be challenging. The Commission is open to working with Member States to develop material and resources for patients and institutions in order to assist Member States in meeting their obligations to provide information.

Annex 2

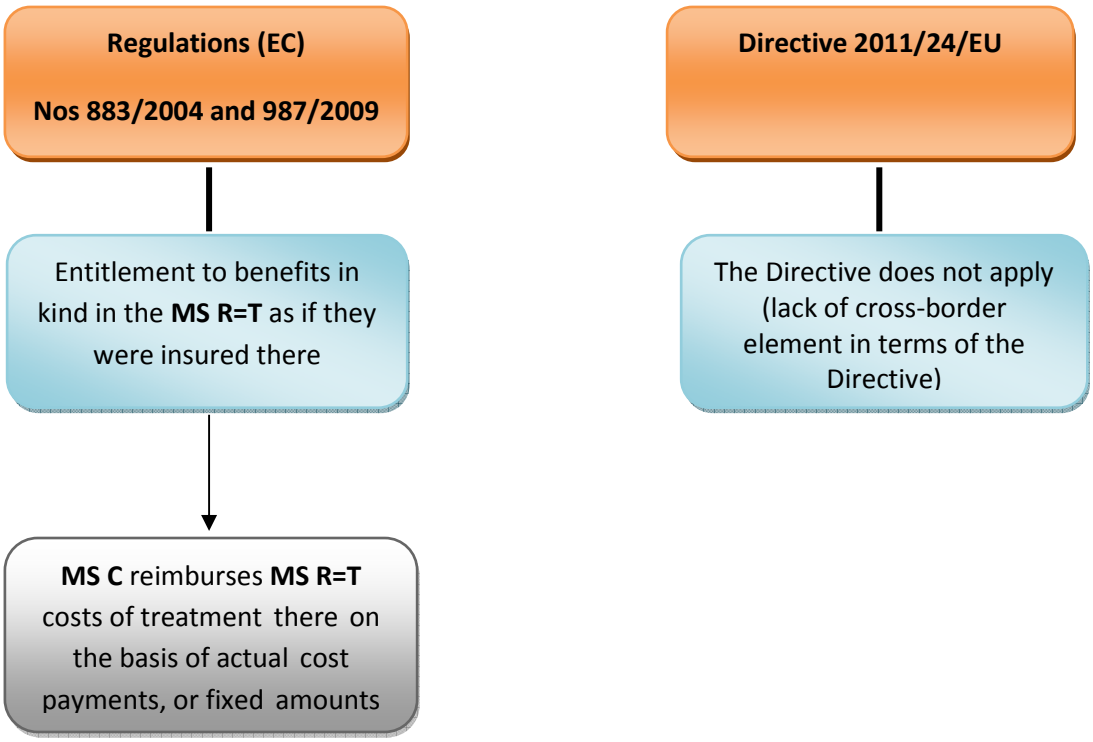
Presentation of possible scenarios when residence is outside the competent Member State

(see also Chapter IV of the guidance note)

I. Healthcare received in a Member State of residence when residence is outside the competent Member State

Scenario 1:

Planned and unplanned healthcare for insured persons and their family members, pensioners and their family members



MS C – competent Member State in terms of Regulation (EC) No 883/2004

MS R – Member State of residence

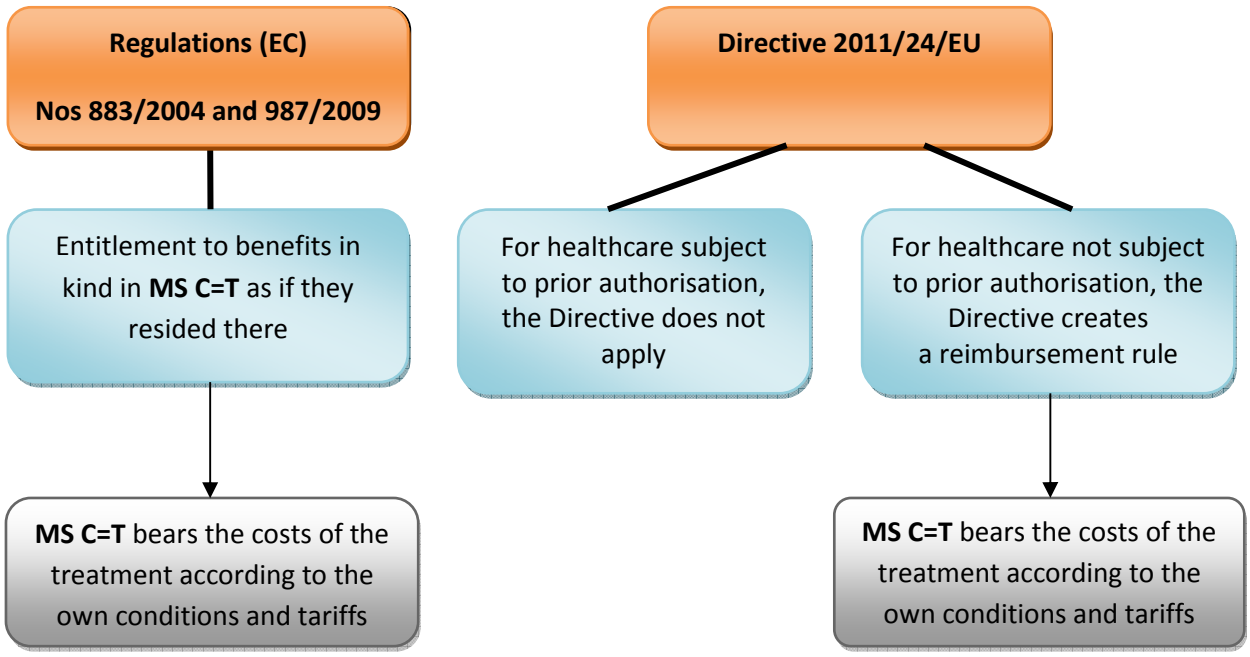
MS T – Member State of treatment

II. Healthcare received in a <u>competent Member State</u> when residence is outside the competent Member State

(see also Articles 3(e) and 7(2)(b) of the Directive 2011/24/EU)

Scenario 1:

<u>Planned</u> healthcare for insured persons and family members



MS C – competent Member State in terms of Regulation (EC) No 883/2004

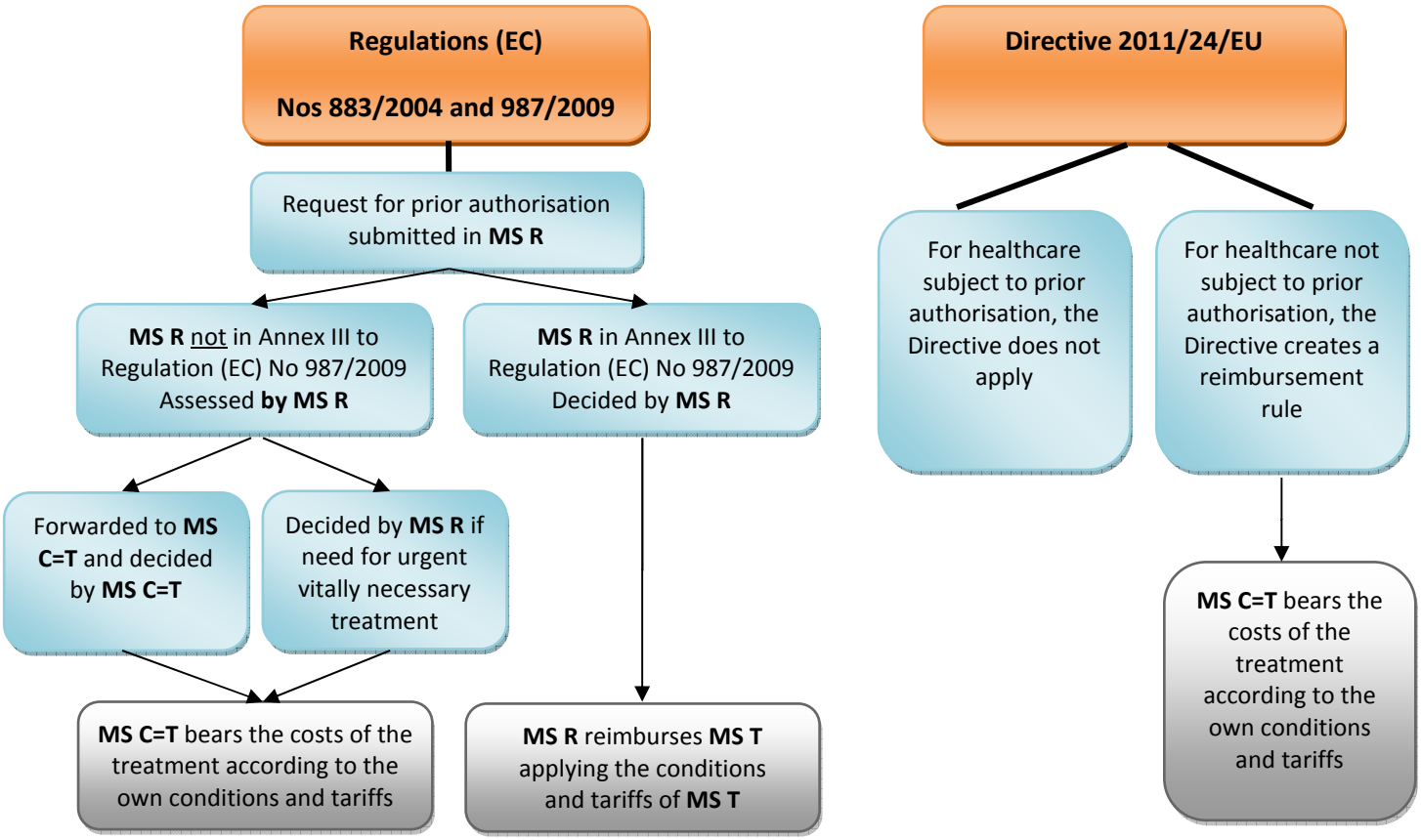
MS R – Member State of residence

MS T – Member State of treatment

II. Healthcare received in a competent Member State when residence is outside the competent Member State

Scenario 2:

Planned healthcare for members of the family of the frontier workers whose competent Member State is listed in Annex III to Regulation (EC) No 883/2004[1] and pensioners and their family members whose competent Member State is not listed in Annex IV to Regulation (EC) No 883/2004[2]



MS C – competent Member State in terms of Regulation (EC) No 883/2004

MS R – Member State of residence

MS T – Member State of treatment

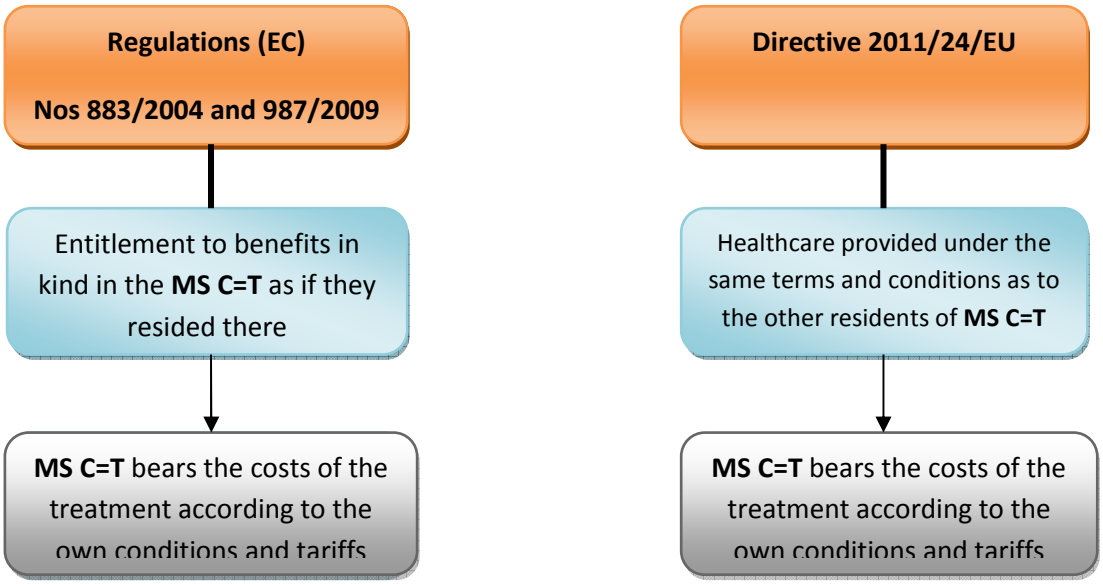
[1] Annex III to Regulation (EC) No 883/2004 lists Member States which apply restrictions on rights to benefits in kind for members of the family of a frontier worker

[2] Annex IV to Regulation (EC) No 883/2004 lists Member States which grant more rights for pensioners returning to the competent Member State

II. Healthcare received in a competent Member State when residence is outside the competent Member State

Scenario 3:

Unplanned healthcare for insured persons and their family members



MS C – competent Member State in terms of Regulation (EC) No 883/2004

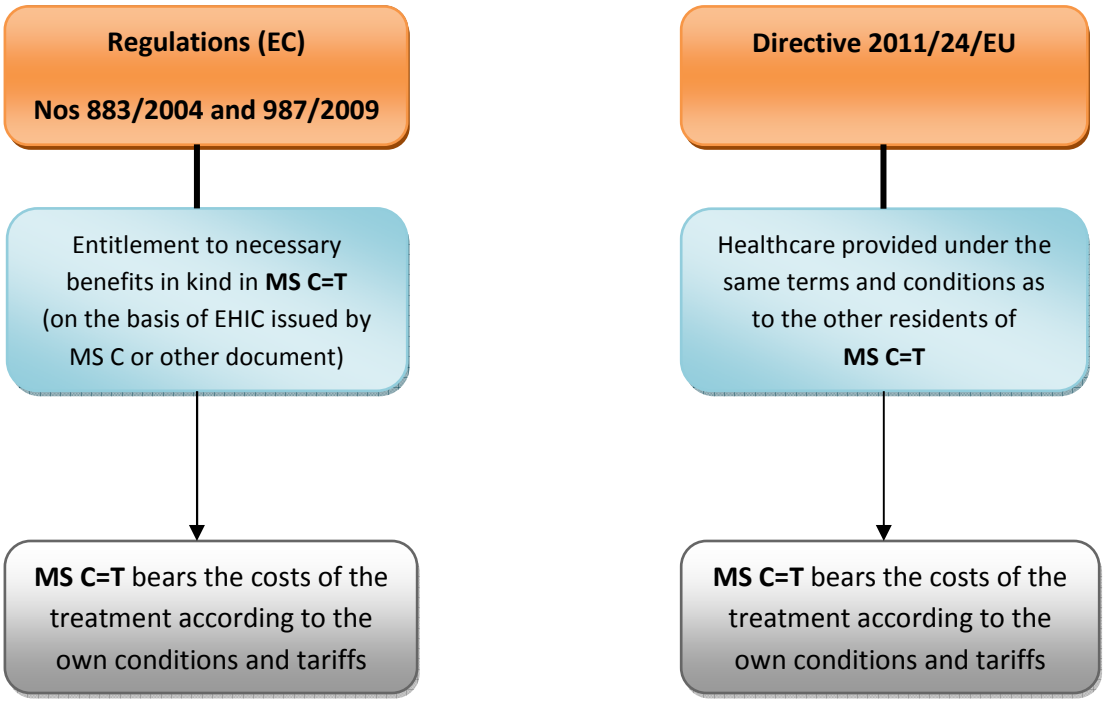
MS R – Member State of residence

MS T – Member State of treatment

II. Healthcare received in a competent Member State when residence is outside the competent Member State

Scenario 4:

Unplanned healthcare for members of the family of the frontier workers whose competent Member State is listed in Annex III to Regulation (EC) No 883/2004[3] and pensioners and their family members whose competent Member State is not listed in Annex IV to Regulation (EC) No 883/2004[4]



MS C – competent Member State in terms of Regulation (EC) No 883/2004

MS R – Member State of residence

MS T – Member State of treatment

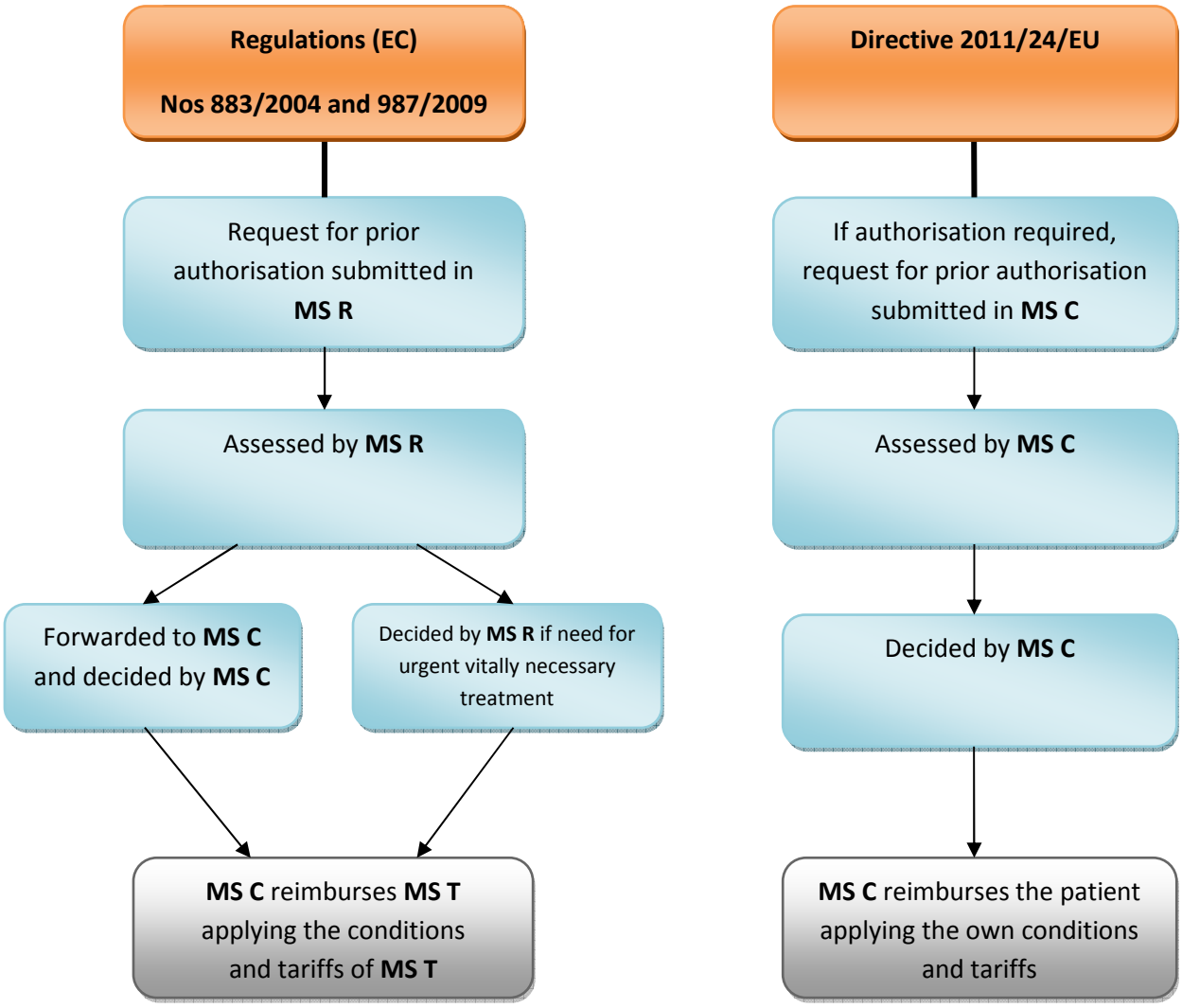
[3] Annex III to Regulation (EC) No 883/2004 lists Member States which apply restrictions on rights to benefits in kind for members of the family of a frontier worker

[4] Annex IV to Regulation (EC) No 883/2004 lists Member States which grant more rights for pensioners returning to the competent Member State

III. Healthcare received in a <u>third Member State</u> when residence is outside the competent Member State

Scenario 1:

<u>Planned</u> healthcare for insured persons and family members



MS C – competent Member State in terms of Regulation (EC) No 883/2004

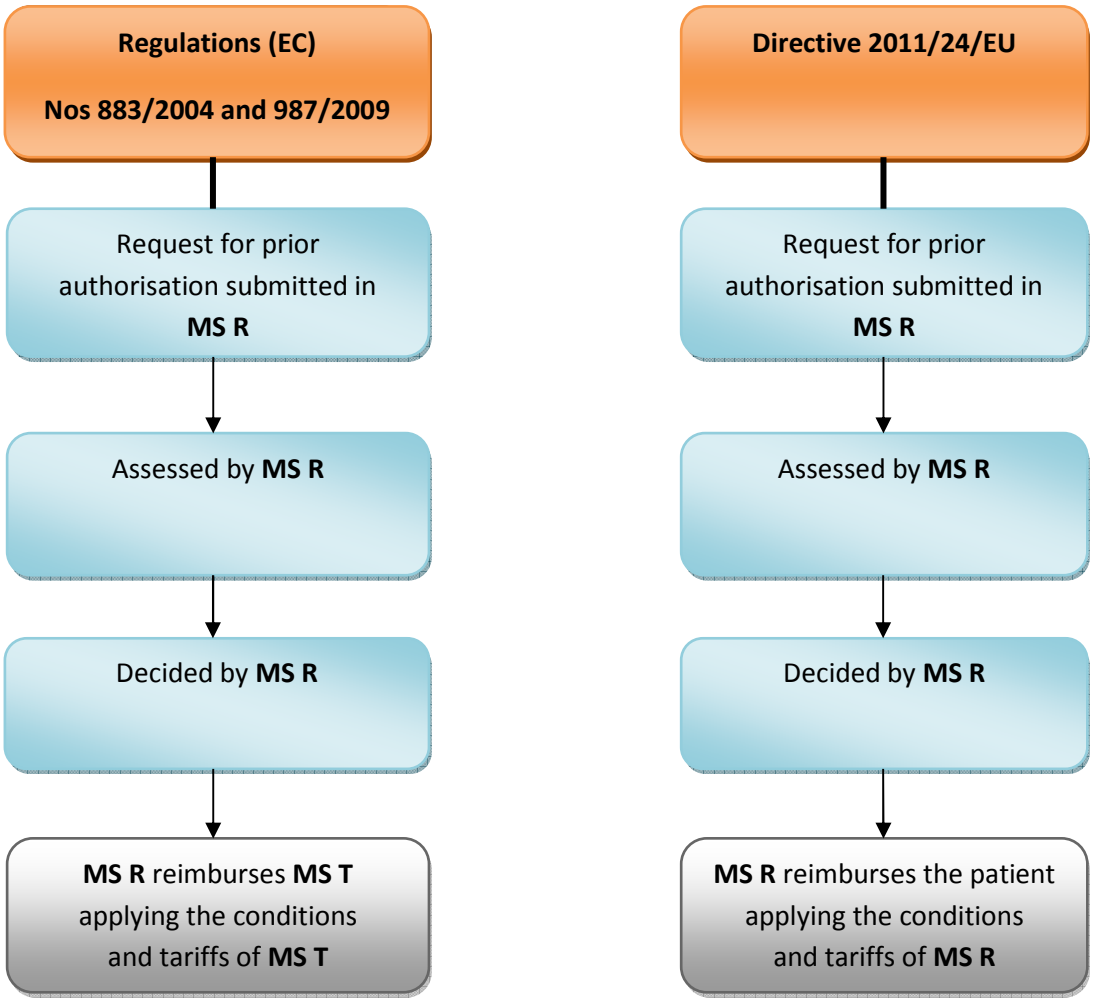
MS R – Member State of residence

MS T – Member State of treatment

III. Healthcare received in a third Member State when residence is outside the competent Member State

Scenario 2:

Planned healthcare for members of the family of the frontier workers and pensioners and their family members residing in Member State listed in Annex III to Regulation (EC) No 987/2009[5]



MS C – competent Member State in terms of Regulation (EC) No 883/2004

MS R – Member State of residence

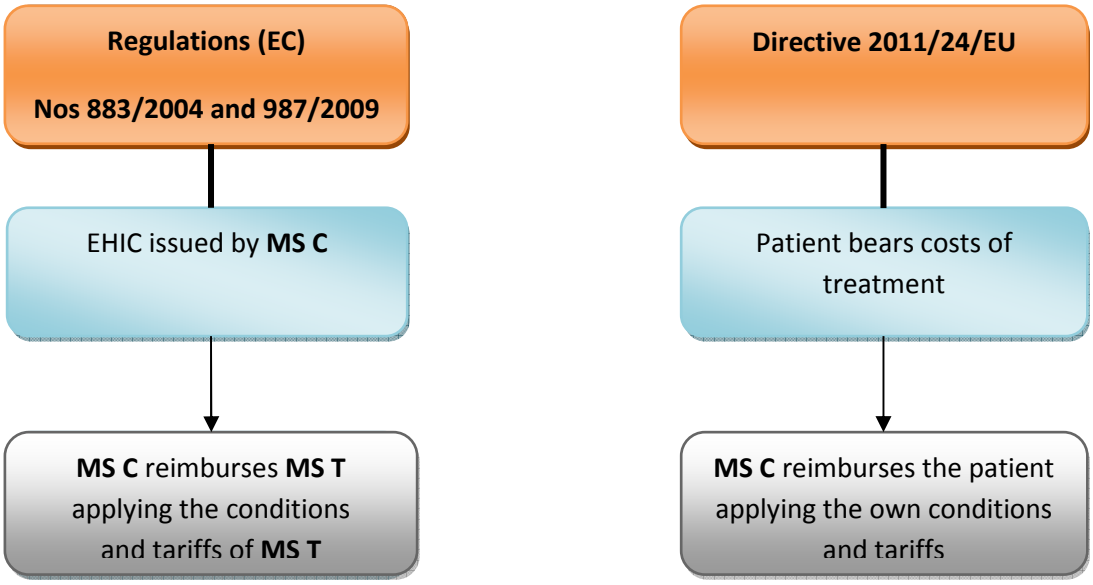
MS T – Member State of treatment

[5] Annex III to Regulation (EC) No 987/2009 lists Member States which for the concerned categories of persons claim the reimbursement of the costs of benefits in kind on the basis of fixed amounts (annual lump-sum payments)

III. Healthcare received in a third Member State when residence is outside the competent Member State

Scenario 3:

Unplanned healthcare for insured persons and their family members



MS C – competent Member State in terms of Regulation (EC) No 883/2004

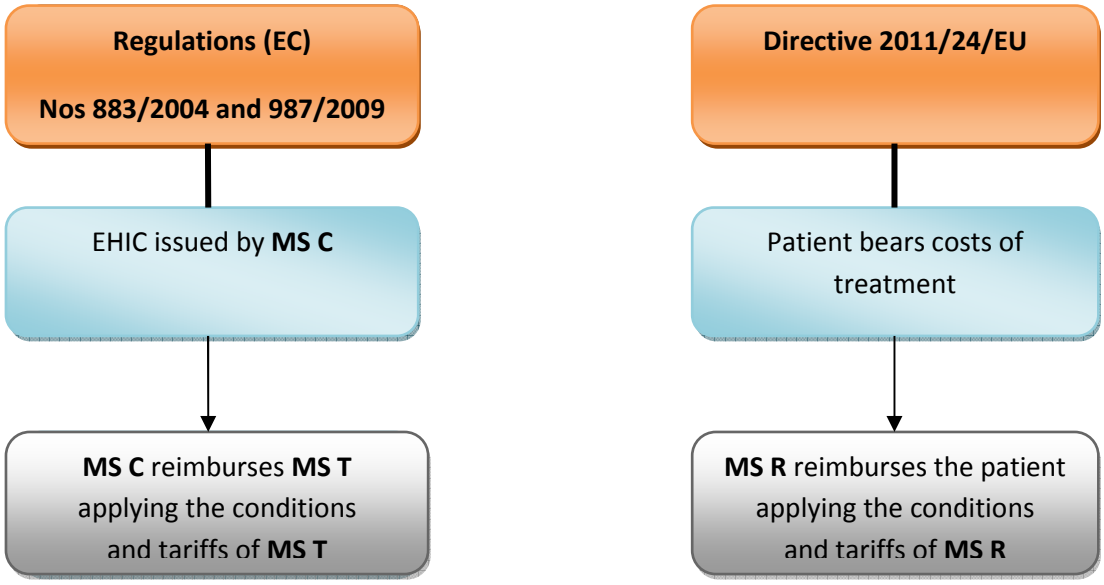
MS R – Member State of residence

MS T – Member State of treatment

III. Healthcare received in a third Member State when residence is outside the competent Member State

Scenario 4:

Unplanned healthcare for members of the family of the frontier workers and pensioners and their family members residing in a Member State listed in Annex III to Regulation (EC) No 987/2009[6]



MS C – competent Member State in terms of Regulation (EC) No 883/2004

MS R – Member State of residence

MS T – Member State of treatment

[6] Annex III to Regulation (EC) No 987/2009 lists Member States which for the concerned categories of persons claim the reimbursement of the costs of benefits in kind on the basis of fixed amounts (annual lump-sum payments)