CPME/AD/consultation/090408/004/EN

CPME comment on the Draft Report of the Committee "Environment, Public Health and Food Safety" of the European Parliament on the proposal for a directive on the application of patients' rights in cross-border healthcare 2008/0142(COD)

CPME welcomes and supports the general remarks of the explanatory statement which emphasises the reasons for this much needed directive. Certainty and clarity for the European citizen and patient, who has clearly mandated the European lawmaker on patient mobility, should be the drive behind this initiative.
CPME would have preferred to see more commitment towards patient safety issues. The statement to remain patient-centred does not exclude this but, rather on the contrary, actually reinforces the need to include this important aspect of European healthcare.
CPME understands the subsidiary issues addressed by Members States on the subject of Social Security. Nevertheless quality and safety standards across the Union should be encouraged to strive towards the same levels.
CPME would like to draw attention to the fact that the successful implementation of this proposed directive depends to a large degree on the "information" chapter. Providing European citizens with access to information about standards ("no more, no less") sounds easy but will prove to be tremendously difficult to implement and will require a considerable collaborative effort of everyone involved.
In general CPME does not support the amendments which narrow the scope down to the patient's perspective only. It is equally important to provide clarity about the cross border movement of healthcare providers, including temporary situations.

SPECIFIC ISSUES

Amendment 11, recital 35

CPME recommends to coordinate this text with proposals on e-health. If the regulations of the "receiving" state (telemedicine) are applied we consider this as a barrier towards the development of telemedicine and a legal and regulatory uncertainty. It is sort of paradoxical on one hand to declare not to apply this directive towards cross border activity of healthcare providers and then, on the other hand, to introduce a virtual cross border activity through the back door through this interpretation of telemedicine. What about licensing, insurance, responsibility et al?
The location of the initiating physical encounter which is at the base of the telemedicine request should determine which legislation is applied.

Amendment 14, article 5 paragraph 1

(i) How will you provide this information and based and what? How will you update this information and how will this information be standardised (content and language)?

(ii) Same as above

(iii) Based on which standards? There are no medical record templates. Languages?

Comment on justification on article 5:

CPME notes that quality and safety standards should be dealt with as a matter of applicable law and without setting new or common European standards. Without wishing to infringe on the subsidiary principle a commonly defined framework would facilitate the evolution towards high quality healthcare throughout the EU.
On the subject of compensation for patients who have been harmed during the healthcare process, CPME insists once more on the need for a European "no-fault" compensation scheme as this is a vital requirement in the context of patient safety (for instance reporting systems)

Amendment 16, article 6 – paragraph 1

"all methods of treatment that are sufficiently tried and tested by international medical science"
CPME understands the argument against experimental and non verified treatments but considers that the above mentioned definition will be difficult to implement. Which authority will define this and on the basis of what?
In consequence C PME does not support this amendment.

Amendment 18, article 8 – paragraph 1

By taking out the "specific list" on hospital definition, which was not immune to critical input, this present definition becomes even more subject to interpretation and inequalities between member states. There has to be some kind of common definition or a common defining body. Who is going to define the current (a) and (b) criteria as every country has a different interpretation, depending on existing standards or levels of equipment and infrastructure?
CPME considers that this amendment does not improve the situation on the difficult definition of hospital care and does not support this amendment.

Amendment 23, article 9 – paragraph 3a (new)

A system of prior authorisation exists in the form of regulation 1408/71 and this could easily be made available on a voluntary basis to those patients wishing to benefit from third party billing. But in order to satisfy equal access criteria in all member states this regulation should be equally applied and not left to individual member states interpretation. So *Member States **shall** offer patients a voluntary system of prior authorisation.*

Amendment 24, article 9 – paragraph 5a (new)

CPME can understand and support equality of access for European patients (based on need and not on means), but wants to stress that this should be achieved without creating a supplementary bureaucratic layer on top of the existing ones. Access should be easy and swift. (also see above)

Amendment 27, article 10 – paragraph 2a (new)

CPME has intervened repeatedly on this subject. As everyone is innocent until proven guilty the text should address "final convictions" instead of "disciplinary proceedings". Only

convictions which affect the health professional's ability to practice should be delivered to the competent authority (i.e. suspensions or withdrawals of the license to practice and not warnings or reprimands)

Amendment 33, article 15 – paragraph 3 – point a

CPME fully supports the link between European Reference Networks and rare diseases

Amendment 35, article 16

Conform to the applicable data protection laws in each Member State
If we have to make sure that interoperability of information and communication technology systems satisfies every single data protection act in the EU we will be confronted with the impossible. Introducing interoperability will prove difficult enough by itself. We desperately need a common framework and CPME would like to recommend collaboration with the working party on article 29 on this issue. Instead of adopting the lowest common denominator this common framework should strive for the highest available level of data protection.

Amendment 36, article 17

CPME has claimed before that the medical profession should be included in such a network, amongst other stakeholders. This network should work on both existing and new health technology taking advantage of the critical mass factor of the size of the European Union. We have seen this principle applied towards rare diseases as well.
Analysis and recommendations should be part of the work plan of such a network. CPME would like to have more information about the intended shape and organisation of such a network.