

Standardisation of Health and Social Services

Position of the *European Social Insurance Platform (ESIP)*

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About the *European Social Insurance Platform* (ESIP)

The *European Social Insurance Platform* (ESIP) represents over 40 national statutory social insurance organisations (covering approximately 240 million citizens) in 15 EU Member States and Switzerland, active in the field of health insurance, pensions, occupational disease and accident insurance, disability and rehabilitation, family benefits and unemployment insurance. The aims of ESIP and its members are to preserve high profile social security for Europe, to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European debate and is a consultation forum for the European institutions and other multinational bodies active in the field of social security.

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General remarks

ESIP considers standards to be useful in areas where they assist the safety of products that are used in health or nursing care and serve patient safety as well as the safety of the personnel. This relates in particular to medical devices, the ergonomic design of hospital beds or the safe setting for the use of laboratory equipment.

However, in the context of health and social issues the standardisation of products is not comparable to the standardisation of services. ESIP does not support recent proposals and activities related to standardisation of services in this context and in particular with regards to services that are provided by social insurance systems.

Health and social services have unique characteristics. Unlike purely commercial services, at the centre of health and social services is a person and his/her individual situation. The market driven approach of EU standardisation is not appropriate to the services provided by social security systems. In addition, relevant guidelines covering the quality of these services have already been developed and applied by social security systems. Introducing European standards in the same field could jeopardise patient safety rather than improve it and lead to legal uncertainty.

ESIP therefore calls upon:

- The EU Commission, CEN and ISO not to pursue recent proposals and activities related to the standardisation of health and social services, in particular those services provided by statutory social insurance systems.
- The EU Commission to clearly state in its work programme or in a commitment – similar to CEN guide No. 15 – not to support standards that conflict with Member States' competences in the field of social security.
- The EU not to adopt ISO standards through CEN, in the sense of the Vienna agreement, that concern health and social services.

Key issues:

The European Commission and standardisation organisations are currently interested in exploring a possible role of standards in healthcare and social services.

Regulation (EU) No 1025/2012 on European standardisation enables the EU Commission since 2013 to mandate standardisation institutes, namely CEN, with the creation of standards in the field of services. Subsequently, the EU Commission has mentioned healthcare services as one of the areas for consideration under the annual work programmes 2013-2016. In addition, in its Digital Single Market Strategy¹, it has declared its intention to establish an integrated standardisation plan with standardisation priorities which include standards for healthcare (telemedicine, mHealth).

At the same time, there are an increasing number of requests at European and international level for standardisation initiatives in the field of health and social services. These include requests for standardisation covering quality of care for elderly people (CEN) and patient involvement in person-centred care (CEN), as well as healthcare administration (ISO). Furthermore, there is a current proposal to establish a focus group on “Health services” at CEN level. In this context, ESIP points to the CEN guide No. 15 which clearly states that there shall be no standards in fields that are the responsibility of the Member States.

The EU Commission sees standards as a tool to support the quality of services in the health sector. However, ESIP considers that Member States themselves are best placed to develop appropriate mechanisms within their national health and social systems. The procedures adopted and the services provided by social insurances depend on the characteristics and traditions of each health and social insurance system. These national differences are recognised in the European Treaties. Article 153, 168 of the TFEU make it clear that in the activities of the European Union, Member States’ responsibility for their own health and social policy and the organisation of their health sectors, medical care and rehabilitation is to be preserved.

ESIP sees no need for European standards to further support the quality of services in the health sector. Diverse yet coordinated instruments in the Member States ensure quality, based on reliable evidence and taking into account advances in medicine e.g. through own guidelines. Medical guidelines are developed by experts in the specific medical fields in a transparent and open process and then assessed in the national health systems. The evaluation of European standards is not guaranteed. Standards, elaborated by external interested parties have no added value. Privately-organised standardisation institutes such as CEN/CENELEC are therefore neither legitimate nor qualified for the development of standards in healthcare.

Moreover, European standards could contradict already existing national instruments, for example national guidelines, and thus jeopardise patient safety rather than improve it. This in

¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the regions: A Digital Single Market Strategy for Europe – COM (2015) 192 final.

particular, since the aim of national guidelines in the field of social security is to ensure high quality services that fulfil the goals of social security systems and the needs of the insured person and the payers. In contrast, the core aim of European standardisation is to promote the competitiveness of companies and to simplify the trade in services in the single market. Unlike the trade in products, health and social services provided as part of a social and health insurance systems and often provided as benefits in kind are only partially subject to free market conditions. The trade in such services can be limited by national provisions within the Member States. For this reason they were excluded from the scope of the EU Services Directive (2006/123/EC).

Social insurance institutions also provide social services such as long-term care, social and occupational reintegration services as well as participation services, which are adapted to the needs of the individual person. This individualised approach is not compatible with the aims of standardisation; European wide standards could unnecessarily restrict and endanger the individual adaptation of services. Wherever services are directed by statutory provisions and are provided according to specific procedural principles there is a danger that the development of parallel structures will ultimately lead to legal uncertainty or the danger that legal requirements will be circumvented. Even though standardisation efforts are currently focused on health and care services it is, in our view, only a question of time before CEN mandates are further extended to other social services provided by social insurance institutions such as social and occupational reintegration measures.

If privately-organised standardisation organisations and their members start to influence national social insurance systems and encroach on their competencies the question arises if this type of action falls within the scope of the European Treaties and whether it is in accordance with the EU Acquis, which all Member States have agreed to and which is the basis for European cooperation and the principle of democracy. European and international initiatives must not interfere with the core areas of the national social insurance systems and their statutory responsibilities.

ESIP therefore calls upon the EU decision-makers and the standardisation organisations involved in these processes to take our arguments into consideration and put the discussions on standardisation of health and social services provided by social security institutions to bed.