

6.12.2023

Amendment 2

Patrick Breyer

Report

A9-XXXX/2023

Tomislav Sokol, Annalisa Tardino

European Health Data Space

(COM(2022)0197 – C9-11202 – 2022/0140(COD))

Proposal for a regulation

Article 7 – paragraph 1a (new)

Text proposed by the Commission

Amendment

1a. ***Member States may provide for natural persons to have the right to object to the registration of their personal health data in an EHR system. If a Member State provides for such a right, it shall establish the rules and specific safeguards regarding such objection mechanisms.***

Or. en

Justification

Following the principle of data minimisation there is no need for mandatory registration of health data which cannot be used because of patient opt-outs. Due to the risk of unauthorised access to or unauthorised disclosure of health data that is imminent in the collection and registration of health data in interconnected Electronic Health Records, patients may refrain from seeking treatment if they cannot keep sensitive conditions and therapies off interconnected Electronic Health Records. Member States should therefore be able to give patients a right to opt-out of the registration of their health data in interconnected Electronic Health Records by all or specific healthcare providers.