Regulatory impact analysis pertaining to the preliminary draft of the Federal Law on the Electronic Health Record

Report

compiled on behalf of the Federal Office of Public Health FOPH and the State Secretariat for Economic Affairs SECO

ECOPLAN
Economic research and policy consultancy
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Gesellschaft für Kommunikations- und Technologieforschung mbH
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Nota bene

This report replaces the version dated November 2010 compiled based on the first phase of this comprehensive regulatory impact analysis.

Sources

www.bag.admin.ch

www.seco.admin.ch/rfa

Synopsis

Purpose and content

In October 2009, the Federal Council commissioned the Federal Department of Home Affairs (FDHA) to submit a report illustrating the legal regulatory requirements for the implementation of the "eHealth Strategy Switzerland" by the end of 2010. This report was compiled by the "eHealth panel of experts" appointed by the FDHA.[1] A draft of this report was used as the basis for the preliminary version of a regulatory impact analysis (RFA) presented by the external contractors empirica and Ecoplan on 17 November 2010. It contained a rough assessment of the implications associated with the networking of clinical information systems.

The Federal Council heeded the recommendations of the "eHealth panel of experts" as well as the RFA and commissioned the FDHA on 3 December 2010 to submit a preliminary draft and an illustrative report concerning a federal statutory regulation for the introduction of a cross-community electronic health record by September 2011 as a basis for the commencement of the consultation process. In this context, the FOPH also ordered the refinement of the RFA associated with the "eHealth Strategy Switzerland" in a second phase. Consequently, the report at hand replaces the version dated November 2010 which was compiled on the basis of the first phase of the comprehensive RFA.

The work is based on the preliminary draft of the Federal Law on the Electronic Health Record (EPDG)[2] and the new knowledge gained from the definitive version of the "eHealth panel of experts" report as well as feedback from stakeholder groups. The purpose is to integrate the outcomes of the refined RFA into the preparation of the chapter "Economic implications" in the illustrative report pertaining to the preliminary draft of the Federal Law on the Electronic Health Record.

Below is a short description of the research method, followed by a presentation of the main results of the analysis based on the five test points of the RFA. It illustrates that the implementation of the "eHealth Strategy Switzerland" promoted by the regulation is expected to have a positive impact as early as in the medium term. With the exception of medical practices, the individual stakeholder groups also are expected to see positive results over the long term. However, losses are expected in the short and medium terms. The summary ends with an outlook of possible additional RFA phases.

Method

In terms of the method, the analysis at hand is based on a model of the implications associated with the implementation and networking of clinical information systems previously used in other countries in a similar format. It is an estimate of costs and benefits as well as incentives and risks associated with the further implementation of the "eHealth Strategy Switzerland", particularly in consideration of the implementation of an electronic health record.

[1] eHealth panel of experts (2010), implementation of the "eHealth Strategy Switzerland": recommendations for the legal regulation. Report compiled by the "eHealth panel of experts" to the attention of the Fed. Dept. of Home Affairs.

[2] "Vorentwurf des Bundesgesetzes über das elektronische Patientendossier (EPDG)", version dated 26 August 2011.

Three scenarios are analysed: the regulation scenario is based on the presumed implementation of the measures set forth in the proposed regulation according to the preliminary draft of the law as well as additional proposals by the "eHealth panel of experts". The reference scenario without regulation foregoes governmental action altogether, while the alternative scenario expands the partial compulsory regulation to medical practices while providing for the absorption of part of their investment costs by the government in return.

First and foremost, the analysis is limited to the collaboration and networking of private medical practices[3], hospitals and pharmacies. Only the clinical use of patient data is analysed rather than possible secondary uses, such as e.g. uses for research and prevention purposes.

The analysed cumulative socio-economic net benefit for society takes into account financial implications, staff-related and other tangible implications as well as intangible implications. It covers all included stakeholder groups and all the years during the analysed period between 2011 and 2031. 2015 was assumed to be the year the law as well as the required implementation legislation will enter into effect. All costs and benefits accumulated in the future are discounted at an interest rate of 2.0% of their present value.

Necessity and possibility of governmental action

Without governmental intervention, the standardised, comprehensive networking of the information systems in medical practices, pharmacies and hospitals will be possible only with major delays, and the networking of these local IT systems would at most be implemented on a regional level. While hospitals – based on the implementation of uniform and performance-related flat rates to compensate hospital-provided services (DRG system) until January 1, 2012 – and pharmacies (in their own interest, at an advanced level already now) will be investing in local IT systems independent of the EPDG, without governmental regulation an investment delay is expected for medical practices, for which incompatible data formats (due to missing technical and semantic standards) may cause a long-term dependability on the respective provider of an information system. The resulting investment uncertainty impairs the amalgamation into group practices and inhibits the voluntary participation in the electronic health record.

Standards for the provision and retrieval of treatment-relevant patient data as well as for the identification of patients and healthcare professionals would accelerate the implementation and dissemination of the electronic health record. Certification procedures aimed at ensuring these standards would create investment certainties while at the same time promoting the voluntary amalgamation of health service provider organisations into communities and the exchange of treatment-relevant patient data.

A lack of user trust in data privacy can fundamentally call into question the dissemination of electronic health records and, consequently, the realisation of the corresponding economic potential. Governmental action to enforce data privacy therefore represents a legitimate public interest.

[3] This is based on the current situation. Political developments resulting in structural changes, such as e.g. widespread amalgamation of physicians into large communities or a reform of the accounting system for general practitioners, would significantly alter the outcomes. However, these considerations are not concrete at this time and were, therefore, not taken into account.

Implications for the individual stakeholder groups

In recent years, the majority of **pharmacies** have invested in local electronic information systems, and the networking amongst them is in part fairly advanced. Pharmacies incur costs mainly due to the fact that no law is in place that would govern e.g. patient identification or the consent to view data exceeding individual cases within the meaning of the preliminary draft of the EPDG. Indeed, regulation would necessitate further investments, which initially exceed the benefit. In the medium term, however, pharmacies are expected to achieve a rapid increase in benefit over time. The cumulative net benefit for pharmacies is estimated to reach CHF 89 million by the year 2031.

In **hospitals,** local electronic information systems are expected to establish themselves area-wide promptly and independently of the e-health record due to the implementation of the DRG system until January 1, 2012. Consequently, the costs and benefits of these clinical information systems are not attributed to the bill at hand. The proposed obligation to create the conditions for participation in the electronic health record can be implemented quickly thanks to the local clinical information systems. Amongst other benefits, information accessible via the electronic health record (e.g. laboratory test and X-ray data) can prevent duplicate or unnecessary diagnostic and treatment activities. As a result, the annual total benefit will exceed the annual total costs as early as 3 or 4 years after the beginning of the required investments. The net benefit will accumulate to CHF 150 million by 2031.

Only a trend toward a positive net benefit is expected for **medical practices**, given that the majority of medical practices are not yet equipped with a treatment-supporting electronic practice information system. While the existing fears concerning the reliance on the respective IT provider would be all but removed with the binding definition of technical and semantic standards, the willingness of medical practices to pursue the voluntary amalgamation into communities remains low because of high investment and certification as well as ongoing operating costs. This is problematic insofar as the overall economic benefit of a Switzerland-wide uniform electronic health record is dependent upon the number of health service provider organisations amalgamated intocommunities. Although a positive trend can be identified, at CHF -439 million the cumulative net benefit through the end of the observation time frame of this RFA remains negative.

The **population** will be the main beneficiary of the electronic health record[4]. People with long-term disorders (chronically ill patients), a population group which includes about 1.7 million persons in Switzerland, will benefit directly, given the fact that they normally receive treatment from different institutions, whose networking will result in a significant improvement of treatment quality. The net benefit for this segment of the population increases to up to CHF 145 million per year. Even though patients without chronic disorders may require medical care less often, the availability of information through the e-health record still has a positive effect once they do require treatment. Consequently, they too are benefitting. The cumulative net benefit by 2031 will amount to CHF 3.569 billion for both population groups.

The **public sector** is incurring costs to safeguard an identification infrastructure for patients and healthcare professionals as well as for coordination and accreditation duties. These

[4] This is one of the key differences compared to the outcomes of the model calculation in the first phase of the RFA. The reasons are the newly planned active efforts undertaken by the government aimed at achieving better acceptance and trust, a higher participation rate and, thus, a greater benefit.

costs are offset by system-related savings. From a system point of view, a net benefit of CHF 131 million is expected by 2031.

The table below provides an overview of the estimated amount of discounted costs and benefits for the various stakeholder groups by category of implication. Please note the distinction between implications for the individual affected organisations (e.g. hospitals) and for the associated staff (e.g. hospital staff).

Estimated cumulative costs and benefits for individual stakeholder groups during the period between 2011 and 2031, in millions of CHF

	Costs			Benefit			Total		
	Financial costs	Staff-related and other tangible costs	Intangible costs	Financial benefit	Staff-related and other tangible savings	Intangible benefit	Total costs	Total benefit	Net benefit
Medical practices, incl. general practitioners	968	243	73	-	505	340	1,284	845	-439
Hospitals	128	23	486	714	67	6	637	787	150
Pharmacies	90	46	13	-	130	108	149	238	89
Federation and cantons	373	63	-	567	-	-	436	567	131
Medical practice staff	-	-	16	-	-	18	16	18	2
Hospital staff	-	-	18	-	-	22	18	22	4
Pharmacy staff	-	-	5	-	-	21	5	21	16
Population	-	-	1,602	8	-	5,163	1,602	5,171	3,569
- chronically ill patients	-	-	410	2	-	2,282	410	2,284	1,874
- remaining population	-	-	1,192	6	-	2,881	1,192	2,887	1,695
Grand total:	1,559	375	2,213	1,289	702	5,678	4,147	7,669	3,522

When interpreting the costs, please note that these are an estimate of the possible development of a further implementation of the "eHealth Strategy Switzerland", not costs imposed on the stakeholders as a result of the proposed regulation. For example, the administrative expenses for the patient are based on an estimate of the voluntary access permission consent granted by the population and are not deemed mandatory expenses imposed by the regulation.

Implications for the economy as a whole

From an economic point of view, the implementation of the proposed measures is expected to improve the quality of healthcare and to achieve greater efficiency in public healthcare over the long term. These mainly intangible benefits are offset by investment, certification and maintenance costs for the eHealth technologies as well as administrative and process change-related costs. All in all, the currently proposed regulation is expected to achieve a positive socio-economic result of the implications on society as a whole over the long term.

According to the model calculations for the analysed period between 2011 and 2031, a cumulative net benefit of approximately CHF 3.522 billion is expected. This cumulative net benefit amounts to an average of nearly CHF 176 million per year during the observed time frame. This average value does not take into account that the annual net benefit will increase over time because the investment costs are disproportionately high during the first few years. Compared to the public health costs for 2009 in the amount of almost CHF 61 billion, the average annual net benefit is 0.3%.

At CHF -270 million, the financial cost-benefit ratio is negative, while the economic one (financial and other tangible implications) is slightly positive (CHF 57 million[5]).

Alternative regulations

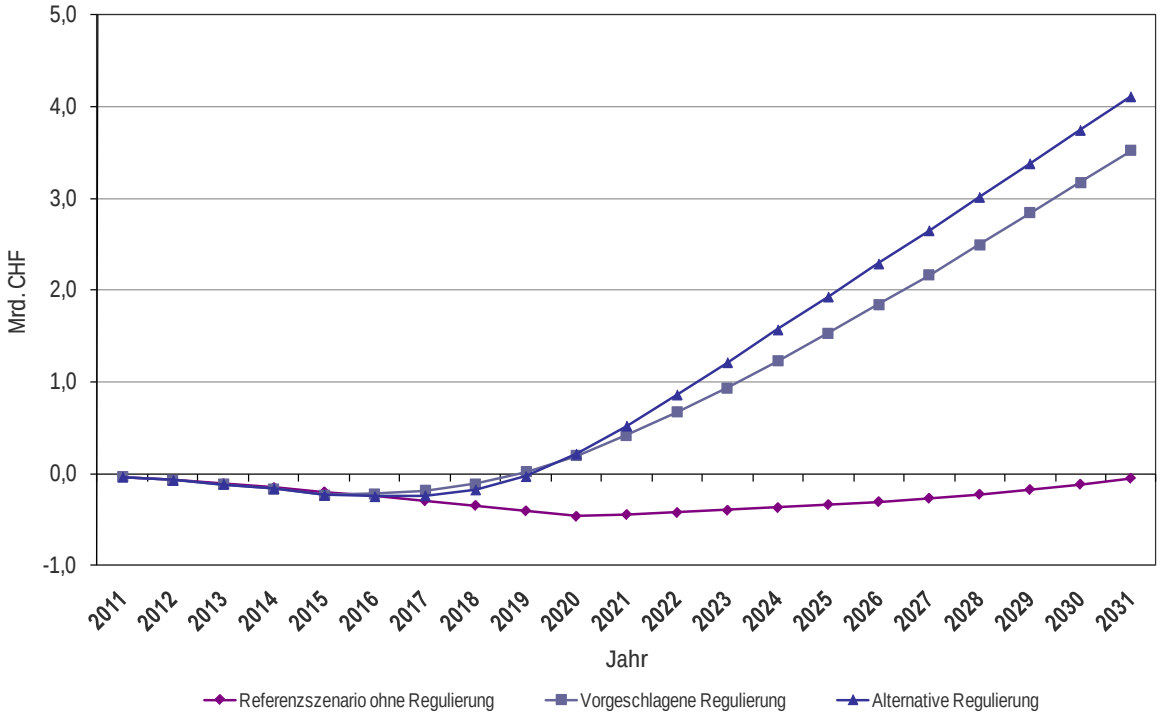
A multitude of alternative and supplementary regulations are conceivable, whose analysis was impossible within the scope of this phase of the comprehensive RFA. Aside from the proposed regulation and the reference case (no regulation), one alternative regulation was selected. It contains start-up funding and a compulsory regulation for medical practices (cf. section 5.1) in addition to the elements already governed by the draft law. The modelling of costs and benefits of this alternative was based on the assumption that the government will absorb the investment costs for medical practices during the first seven years after the law goes into force. However, we would like to emphasise that the option selected here has no political origin and is in no respect considered part of the consultation. Rather it is an extreme form of regulation selected for purely scientific interests – the purpose is to investigate to what extent such a regulation is capable of changing the outcome of the cost-benefit model calculation.

The dissemination of local information systems at practices, the amalgamation of medical practices into communities and the networking with other organisations are thereby accelerated in the alternative scenario. Accordingly, the information content and, as a result, the benefit of an electronic health record are growing faster. Through absorption of the investment costs, the cumulative net benefit for the public sector (including system savings in the healthcare system) will drop from CHF +131 million (regulation) to about CHF -61 million (alternative regulation), while the net benefit for medical practices will increase from CHF -439 million (regulation) to CHF +90 million (alternative regulation).

For the economy as a whole, a cumulative socio-economic net benefit of approximately CHF 4.116 billion can be forecast in the alternative scenario, exceeding the net benefit of the proposed regulation by CHF 594 million. The following graph illustrates the comparison between the proposed regulation and the alternative as well as the reference case without regulation.

[5] Based on the sum of tangible net benefits in the amount of CHF 327 million and financial net benefits of CHF -270 million.

Comparison of alternatives – cumulative socio-economic net benefit for society



Likewise, the purely tangible net benefits (CHF 458 million in the alternative scenario versus CHF 327 million in the regulation scenario) as well as the financial net benefits (CHF -176 million in the alternative scenario versus CHF -270 million in the regulation scenario) are also higher, in both cases, with the alternative. Furthermore, the break-even point is reached two years earlier (in about 2028).

Enforcement feasibility

Since the details regarding execution rights are unknown at this point in time, it is currently impossible to evaluate their enforcement feasibility. However, the outcomes of the analysis of incentives and risks can help optimise the further concretisation of measures and enforcement (cf. chapter 4). The incentives include primarily the expected benefit for the individual stakeholder groups (affected organisations and individuals), the health policy-related signal effect of a regulation per se and the greater investment certainty. Risks that should be considered in the further concretisation of measures and enforcement were identified in particular in connection with the following topics:

- The **benefit for the population is not a given**. Obviously, the existence of content in an electronic health record (i.e. clinical data) is the very first prerequisite. No benefit can be achieved without it.[6] Furthermore, the population is not yet actively involved in the design process, calling into question the voluntary participation in the electronic health record. A lack of interest on the part of the majority of the population might inhibit organisations' willingness to invest. As a result, the use of the electronic health record would remain lower than expected and even lower than the critical threshold required for its success. In this respect, the intended broad information campaign by the media, physicians and other

[6] Compare also the corresponding experiences made in England: Greenhalgh, T. (2010): Adoption, non-adoption, and abandonment of a personal electronic health record: case study of HealthSpace. British Medical Journal 2010; 341:c5814.

healthcare practitioners along with other measures aimed at a better involvement of the population are commendable. The information campaign should specifically address three topics: benefit, necessity and trust.

- **Focussing the regulation idea on technology rather than on the redesign of different processes.** The preliminary draft of the EPDG foregoes interference with treatment structures. Thus, important process-related changes could be disregarded and the eHealth potential might not be optimally exploited. Although the EPDG is unable to regulate the treatment processes, they should still be considered and reviewed, e.g. by means of accompanying measures.
- **Lack of medical practices' motivation to participate in the electronic health record**, amongst other reasons **because of the considerable financial burden**. In the event that a significant share of providers decide against participating in the exchange of patient data, this may result in the non-attainment of a critical quantity and consequently in failure. Given the principle of voluntary participation not only by patients but (especially) by medical practices, delays are to be expected, in particular due to investment uncertainty.
- The **lateness** at which the **benefit for individual stakeholder groups** can be **realised**. The future benefit cannot indiscriminately be assumed to be an incentive for current investments for all actors.
- The **misuse of the discussions,** in the course of which the implementation of the "eHealth Strategy Switzerland" has in some instances become a **battleground for other conflicts of interest**, such as e.g. the negotiations between health service provider organisations and health insurance companies.
- **Different starting conditions** may result in the delayed participation of individual stakeholder groups, which can lead to **information gaps** and, consequently, to a **reduced value of the electronic health record** for healthcare practitioners.

Outlook on additional phases of the RFA

At the present time and given the current level of information, the proposed regulation appears to make sense. However, some unanswered questions still require clarification and certain approaches need to be substantiated. The regulatory impact analysis can only be enhanced in a meaningful way upon additional concretisation of the measures based on healthcare policy targets.