Commission Regulation (EU) 2015/359 of 4 March 2015 implementing Regulation (EC) No 1338/2008 of the European Parliament and of the Council as regards statistics on healthcare expenditure and financing (Text with EEA relevance)

COMMISSION REGULATION (EU) 2015/359

of 4 March 2015

implementing Regulation (EC) No 1338/2008 of the European Parliament and of the Council as regards statistics on healthcare expenditure and financing

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work[(1)], and in particular Article 9(1) and Annex II, point (d), thereof,

Whereas:

(1) Regulation (EC) No 1338/2008 establishes a common framework for the systematic production of European statistics on public health and health and safety at work.

(2) Implementing measures determine the data and metadata to be supplied on healthcare expenditure and financing and the reference periods, intervals and time limits for the data provision.

(3) In accordance with Article 6(2) of Regulation (EC) No 1338/2008, a cost-benefit analysis, taking into account the benefits of the availability of data on healthcare expenditure and financing in relation to the cost of the data collections, which Member States have been conducting on a voluntary basis since 2005 according to the principles set out by the System of Health Accounts, and the burden on Member States, has been carried out. Pursuant to Article 6(1) of Regulation (EC) No 1338/2008, in 2013 and 2014, the Commission instituted pilot studies that were completed on a voluntary basis by the Member States. The Commission has discussed user needs with Member States at various meetings. The availability of EU-wide data is likely to be of great benefit for decisions relating to health and social policy.

(4) In order to ensure relevance and comparability of data, the System of Health Accounts 2011 manual[(2)], which was produced jointly by the Commission (Eurostat), the Organisation for Economic Cooperation and Development (OECD) and the World Health Organisation (WHO) and sets out the concepts, the definitions and the methods for data processing relating to healthcare expenditure and financing, should form the basis for the detailed questionnaire and the accompanying guidelines used in the joint annual data collection exercise carried out by these three bodies.

Changes to legislation: *Commission Regulation (EU) 2015/359 is up to date with all changes known to be in force on or before 24 December 2020. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(5) The measures provided for in this Regulation are in accordance with the opinion of the European Statistical System Committee,

HAS ADOPTED THIS REGULATION:

Article 1

This Regulation lays down rules for the development and production of European statistics in the area of healthcare expenditure and financing, one of the subjects for statistics on healthcare listed in Annex II to Regulation (EC) No 1338/2008.

Article 2

The definitions to be used in applying this Regulation are set out in Annex I.

Article 3

Member States shall provide data on the areas specified in Annex II.

Article 4

1 Member States shall provide the required data and the associated standard reference metadata on an annual basis. The reference period shall be the calendar year.

2 Data and reference metadata for the reference year N shall be transmitted by 30 April N+2.

3 Data and reference metadata shall be provided to the Commission (Eurostat) using the single entry point services or should be made available for retrieval by the Commission (Eurostat) by electronic means on an annual basis.

4 The first reference year shall be 2014.

5 The last reference year shall be 2020.

6 By way of derogation from paragraph 2, Member States shall provide the data and reference metadata for the reference year 2014 by 31 May 2016.

Article 5

1 Member States shall provide data at the level of aggregation specified in Annex II.

2 Member States shall provide the necessary reference metadata, in particular concerning the data sources, their coverage and the compilation methods used, information on features of national healthcare expenditure and financing specific to the Member States that deviate from definitions provided in Annex I, references to national legislation where this forms the basis for healthcare expenditure and financing, as well as information on any changes to the statistical concepts mentioned hereto.

Article 6

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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Done at Brussels, 4 March 2015.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX I

Definitions

1. ‘Healthcare’ means all activities with the primary purpose of improving, maintaining and preventing the deterioration of the health status of persons and mitigating the consequences of ill-health through the application of qualified health knowledge;

2. ‘Current expenditure on healthcare’ means the final consumption expenditure of resident units on healthcare goods and services, including the healthcare goods and services provided directly to individual persons as well as collective healthcare services;

3. ‘Healthcare functions’ relate to the type of need that current expenditure on healthcare aims to satisfy or the kind of objective pursued;

4. ‘Curative care’ means the healthcare services during which the principal intent is to relieve symptoms or to reduce the severity of an illness or injury, or to protect against its exacerbation or complication that could threaten life or normal function;

5. ‘Rehabilitative care’ means the services to stabilise, improve or restore impaired body functions and structures, compensate for the absence or loss of body functions and structures, improve activities and participation and prevent impairments, medical complications and risks;

6. ‘Inpatient care’ means the treatment and/or care provided in a healthcare facility to patients formally admitted and requiring an overnight stay;

7. ‘Outpatient care’ means the medical and ancillary services delivered in a healthcare facility to a patient who is not formally admitted and does not stay overnight;

8. ‘Day care’ means the planned medical and paramedical services delivered in a healthcare facility to patients who have been formally admitted for diagnosis, treatment or other types of healthcare and are discharged on the same day;

9. ‘Long-term care (health)’ means a range of medical and personal care services that are consumed with the primary goal of alleviating pain and suffering and reducing or managing the deterioration in health status in patients with a degree of long-term dependency;

10. ‘Home-based care’ means the medical, ancillary and nursing services that are consumed by patients at their home and involve the providers' physical presence;

11. ‘Ancillary services’ (non-specified by function) means the healthcare or long-term care related services non-specified by function and non-specified by mode of provision, which the patient consumes directly, in particular during an independent contact with the health system and that are not integral part of a care service package, such as laboratory or imaging services or patient transportation and emergency rescue;

12. ‘Pharmaceuticals and other medical non-durable goods’ (non-specified by function) means pharmaceutical products and non-durable medical goods intended for use in the diagnosis, cure, mitigation or treatment of disease, including prescribed medicines and over-the-counter drugs, where the function and mode of provision are not specified;

13. ‘Therapeutic appliances and other medical goods’ (non-specified by function) means medical durable goods including orthotic devices that support or correct deformities and/or abnormalities of the human body, orthopaedic appliances, prostheses or

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artificial extensions that replace a missing body part, and other prosthetic devices including implants which replace or supplement the functionality of a missing biological structure and medico-technical devices, where the function and the mode of provision are not specified;

14. ‘Preventive care’ means any measure that aims to avoid or reduce the number or the severity of injuries and diseases, their sequelae and complications;

15. ‘Governance, and health system and financing administration’ means services that focus on the health system rather than direct healthcare, direct and support health system functioning, and are considered to be collective, as they are not allocated to specific individuals but benefit all health system users;

16. ‘Healthcare financing schemes’ means types of financing arrangements through which people obtain health services, including both direct payments by households for services and goods and third-party financing arrangements;

17. ‘Government schemes’ means healthcare financing schemes whose characteristics are determined by law or by the government and where a separate budget is set for the programme and a government unit that has an overall responsibility for it;

18. ‘Compulsory contributory health insurance scheme’ means a financing arrangement to ensure access to healthcare for specific population groups through mandatory participation determined by law or by the government and eligibility based on the payment of health insurance contributions by or on behalf of the individuals concerned;

19. ‘Compulsory medical savings accounts (MSA)’ means savings accounts that are legally compulsory, whereby the basic method for fund-raising and some issues concerning the use of the account to pay for health services are regulated by government, and where there is no pooling across individuals, except for family members;

20. ‘Voluntary health insurance schemes’ means schemes based upon the purchase of a health insurance policy, which is not made compulsory by government and where insurance premiums may be directly or indirectly subsidised by the government;

21. ‘Non-profit institutions financing schemes’ means non-compulsory financing arrangements and programmes with non-contributory benefit entitlement that are based on donations from the general public, the government or corporations;

22. ‘Enterprise financing schemes’ means primarily arrangements where enterprises directly provide or finance health services for their employees without the involvement of an insurance-type scheme;

23. ‘Household out-of-pocket payment’ means a direct payment for healthcare goods and services from the household primary income or savings, where the payment is made by the user at the time of the purchase of goods or the use of the services;

24. ‘Rest of the world financing schemes’ means financial arrangements involving or managed by institutional units that are resident abroad, but who collect, pool resources and purchase healthcare goods and services on behalf of residents, without transiting their funds through a resident scheme;

25. ‘Healthcare providers’ means the organisations and actors that deliver healthcare goods and services as their primary activity, as well as those for which healthcare provision is only one among a number of activities;