

Executive Order no. 160 of 12 February 2013 on Standards for IT application in the Health Sector¹

The following shall be laid down in pursuance of section 193A of the Danish Health Act, cf. Executive Order no. 913 of 13 July 2010, as amended by Act no. 605 of 14 June 2011:

- 1.-**(1) The Danish Health Data Authority (DHDA)², shall approve standards, including data standards, classifications and interface standards, for IT applications in the health sector upon consultation with the national board of health IT.
- (2) The DHDA lays down the requirements, including requirements to documentation that standards must satisfy to be approved under subsection (1).
- (3) The DHDA may withdraw the approval of a standard if the prerequisites for approval are changed, cf. section 3(1).
- 2.-**(1) The government, regions, municipalities, private hospitals and clinics, etc., including practising health professionals, are obliged to ensure that their IT systems use the standards for IT application in the health sector approved by the DHDA pursuant to the provisions of this executive order.
- (2) If the DHDA so requests, the regions, municipalities, private hospitals and clinics, etc., cf. subsection (1), shall provide the information necessary for the DHDA to assess if their existing and planned IT systems use the standards approved by the DHDA.
- 3.-**(1) When approving a standard, the DHDA shall establish:
- the recommendation grade of the standard, cf. section 5.
 - what the standard is to be used for.
 - who is to use the standard.
 - how to adhere to the standard.
 - the time when the standard is to be applied.
- (2) An approved standard must include information about the name and version of the standard as well as a detailed description of its content.
- 4.** The DHDA can make the approval of a standard subject to the requirement that the party responsible for the standard must document and publish the standard, offer guidance on the standard and maintain the standard, etc.
- 5.-**(1) When approving a standard, cf. section 3(1)(i), the DHDA assigns either of the following recommendation grades to the standard:
- Standard which is mandatory and to be applied to both existing and new IT solutions, cf. catalogue of standards in the health IT area.
 - Standard which is recommended and to be applied, unless special circumstances may justify departing from it.
 - Standard which is maintained and can still be applied to existing IT solutions, but has been replaced by a new standard and therefore should not be applied to new IT solutions.
 - Standard which is advised against because it is no longer used in general, and there is no guarantee of support or maintenance, which ought not to be applied to existing or new IT solutions, unless special circumstances may justify departing from it.
- (2) The DHDA may lay down other recommendation grades for standards.
- (3) Any government authority, region, municipality, private hospital or clinic, etc. not wanting to apply a recommended standard, cf. subsection (1)(ii), or wanting to apply a standard that is advised against, cf. subsection (1)(iv), must submit its reasons thereof to the DHDA in advance.
- 6.** The DHDA may upon application from a region, municipality, private hospital or clinic, etc. grant a time-limited derogation from the requirement to apply a mandatory standard, cf. section 5(1)(i) if warranted by special circumstances.
- 7.** The DHDA shall publish a catalogue of approved standards and candidate standards. The catalogue is updated regularly.

Entry into force

- 8.** This executive order shall enter into force on 1 March 2013.

Ministry of Health, 12 February 2013

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¹ This is a translation of the Danish executive order of 12 February 2013 (Danish title: *Bekendtgørelse om standarder for it-anvendelsen i sundhedsvæsenet*). Only the Danish version has legal validity.

² The Danish Health Data Authority (DHDA) was not established until 2015, but is used for ease of reference in this translation.