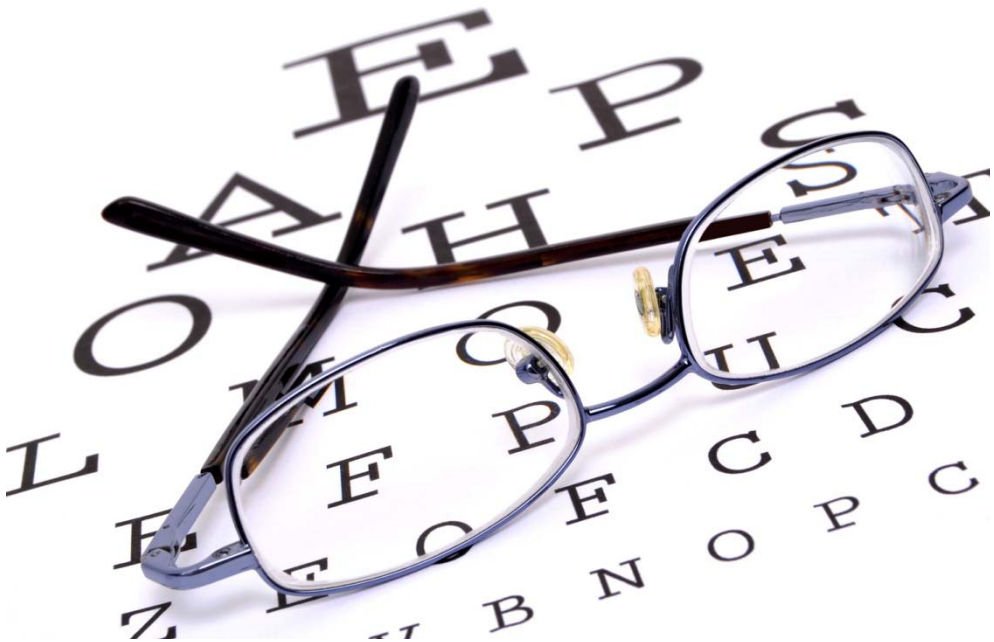
KCE REPORT 225

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

CORRECTION OF REFRACTIVE ERRORS OF THE EYE IN ADULTS – PART 3: ORGANISATION AND LEGAL FRAMEWORK OF EXTRAMURAL SURGERY CENTRES



KCE REPORT 225
HEALTH TECHNOLOGY ASSESSMENT

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CORRECTION OF REFRACTIVE ERRORS OF THE EYE IN ADULTS – PART 3: ORGANISATION AND LEGAL FRAMEWORK OF EXTRAMURAL SURGERY CENTRES

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COLOPHON

Title:	Correction of refractive errors of the eye in adults – part 3: organisation and legal framework of extramural surgery centres
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LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
ASA	American Society of Anesthesiologists
BBO UPBMO	Belgische Beroepsvereniging van Oogheelkundigen/Union Professionnelle Belge des Médecins Spécialistes en Ophtalmologie et Chirurgie Oculaire
BELAC	De Belgische Accreditatie Instelling
BFM	Budget of Financial means
BMI	Body Mass Index
B.S./M.B	Belgisch Staatsblad/Moniteur Belge (Belgian Official Journal)
ECJ	European Court of Justice
IGZ	Inspectie voor de Gezondheidzorg
LASEK	Laser-Assisted-SubEpithelial Keratectomie
LASIK	Laser In Situ Keratomileusis
NIHDI	National Institute for Health and Disability Insurance
NOG	Nederlands Oogheelkundig Gezelschap
OCMW/CPAS	Openbaar Centrum voor Maatschappelijk Welzijn/Centre Public d'Action Sociale
PRK	Photo refractive keratectomy
SGEI	Services of General Economic Interest
SOOS	Syndicat Ophtalmologique/Oftalmologisch Syndicaat
WTZi	Wet Toelating Zorginstellingen
ZKN	Zelfstandige Particuliere Klinieken Nederland

1. BACKGROUND AND OBJECTIVE

People suffering from myopia, hyperopia or astigmatism can choose between wearing glasses, contact lenses or undergoing “refractive surgery”. Refractive eye surgery primarily comprises laser techniques (PRK, LASEK and LASIK) and phakic intraocular lens implantation. Unlike the alternatives of wearing glasses or contact lenses, the operation has an invasive character whose possible consequences may be irreversible. The intervention is not reimbursed by the national compulsory health insurance. However, some patients may get a partial refund by their complementary insurance according to reimbursement schemes that vary greatly between and within the sickness funds. Since there is neither reimbursement by the national health insurance nor official registration, exact data on the number of performed refractive eye surgery interventions are missing. Yet, the growing popularity of this correction method gave rise to a number of questions from policy-makers, sickness funds and patients. This report is the last one of a trilogy that describes a health technology assessment of refractive eye surgery. The first report focused on the epidemiology of refractive error in the population.[a][1] The second report analysed the surgery techniques and their costs.[b][2] This third report is an analysis of the legislation and organisation of the expanding private clinics sector (“extramural eye surgery centers”), a setting where refractive surgery is increasingly performed. These centers do not fall within the definition of “hospital” in the sense of the hospital law. Therefore they do not have the legal obligation to comply with the recognition and norms applicable to recognized hospitals. Safeguarding safety and quality in extramural centers relies on voluntary initiatives of the professional body.

The case of refractive eye surgery will be an illustration for other interventions that may be performed in extramural surgery centers as well, such as plastic surgery, dermatology and orthopaedics.

a W. Christiaens, L. Kohn, C. Obyn, L. De Winter, S. Gussé, N. Defourny, C. De Laet, D. Paulus. Correction of refractive errors of the eye in adults – Part 1: Perceptions and experiences. Health Services Research (HSR). Brussel: Belgian Health Care Knowledge Center (KCE). 2013. KCE Reports 202.D/2013/10.273/26

b C. Obyn, Y. Smit, P. Post, L. Kohn, N. Defourny, W. Christiaens, D. Paulus. Correction of refractive errors of the eye in adults – Part 2: laser surgery and intraocular lenses –Synthesis. Health Technology Assessment (HTA) Brussels: Belgian Health Care Knowledge Center (KCE). 2013. KCE reports 215Cs. D/2013/10.273/104

2. DEFINITIONS

Health care institutions can be categorized into public hospitals, private not for profit hospitals and private for profit clinics (for this report called as "extramural centres") according to their ownership and the commercial nature of their interventions.[c] [3]

Public hospitals are managed by a public legal body, such as a province, a community, the federal State, an OCMW/CPAS, an association of public law etc. Private hospitals, in contrast, are managed by private legal bodies, such as for instance universities or associations without lucrative purpose.

Hospitals are defined in the Belgian hospital law as establishments of health care, where appropriate medical-specialist examinations and/or treatments in the domain of medicine, surgery and possibly obstetrics can be provided in a pluridisciplinary environment, at any time, in the necessary and adapted medical, medical-technical, nursing, paramedical and logistic environment to patients able to be admitted and enabled to stay, because their health status necessitates care in order to cure of alleviate the disease, recover or improve the health status or to stabilize injuries (art. 2 Hospital Lawd). As such, several primary conditions are needed for a health care establishment to be labelled as a hospital:

- Continuity of care ("at any time");
- Basic coverage in medicine and surgery;
- Multidisciplinary setting;
- Appropriate organization and infrastructure;
- Possibility of overnight stay(s);
- Function as quickly as possible in relation to requirements of care.

Furthermore other legislation states that hospitals need to provide care accessible for all citizens, regardless of their age or sex, ideological philosophy or religion, race or sexual orientation and without any discrimination of the individual's financial status.[e]

Extramural centres are not considered as hospitals because they often do not guarantee continuity of care themselves, are often not accessible for all patients except for reimbursed interventions, they do not always provide curative or reconstructive care, and patients are not able to stay overnight.

Today there is no legal definition of "extramural centres". Yet Belgian legislation refers to the notion extramural environment to indicate the setting outside and not linked to a hospital.[f]

For this report, the following working definition has been drafted: health care centres, other than hospitals as defined in the Belgian hospital law or a health care setting linked to a hospital, where any eye surgical or other invasive procedure requiring general or locoregional anesthesia, or sedation, including cryosurgery and laser surgery, but without the patients staying overnight, is performed by a physician. This definition excludes ambulatory practices, where only minor interventions are performed belonging to the nomenclature for general practitioners, dermatologists and dentists. This definition needs to be scrutinised and refined for its generic use.

Internationally, the notion "private clinic" is more commonly used. Deber refined the classification of private for profit clinics into small business/entrepreneurs and investor-owned corporations[g].[4]

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c for an overview of the classification of hospitals S. CALLENS en J. PEERS, *Organisatie van de Gezondheidszorg*, Antwerpen, Oxford, Intersentia, 2008, p. 41 ev

d Law of 10 July 2008 regarding hospitals and other care institutions, *B.S/M.B.*. 7 November 2008 (Hospital law)

e Art. 3 § 1 Decree of 17 October 2003 regarding quality in healthcare- and well being institutions, *B.S./M.B.*. 10 November 2003

f Royal Decree of 16 February 2009 modifying art. 15, § 2, of the annex of the Royal Decree of 14 September 1984 on the nomenclature of medical interventions regarding the obligatory healthcare Insurance B.S./M.B. 16 maart 2009

g Deber RB. Delivering Health Care: Public, Not-for-Profit, or Private? In: Marchildon GP, McIntosh T, Forest P-G, eds. The Fiscal Sustainability of Health Care in Canada.Toronto: University of Toronto Press, 2004:233-96. http://siteresources.worldbank.org/INTHSD/Resources/376278-1202320704235/GuidingPrivHospitalsDeberetal.pdf

3. OUTLINE AND METHODOLOGY

This report presents an exhaustive analysis of the main topics to be considered to guarantee the quality and safety of healthcare provided in extramural centers.

- Chapter 4 outlines the current legal framework applying to hospitals, extramural centers and physicians working there.
- Chapter 5 explains how the profession set up voluntary initiatives to guarantee quality of care in extramural centers. A complementary topic is the absence of registration in these settings.
- Chapter 6 highlights The Netherlands and Denmark as possible examples to inspire a Belgian model.
- Chapter 7 proposes options to regulate quality and guarantee safety in extramural centers in Belgium.
- Chapter 8 addresses the impact of the provision of health care in extramural centers on the public health care system.
- Chapter 9 analyses the options to regulate the practice in extramural centra, with an insight to the European legislation.

In an explorative phase, different stakeholders were interviewed on the topic. For the study of Belgian legislation and initiatives, classical legal databases such as Jura and Juridat were used. For European legislation, Eur-Lex was used and doctrine was consulted. Furthermore grey literature on the topic was searched. Information was also obtained by personal communication with key persons. In the text this information source is referenced in footnote.

4. CURRENT LEGAL FRAMEWORK TO GUARANTEE QUALITY AND SAFETY

4.1. Strict regulation of hospitals

In contrast with extramural centers, public and private not for profit hospitals are strictly regulated. In the following section a brief and illustrative summary of the hospital legal framework is drafted. Interested readers can find more extensive details on the legislation and the organization of hospitals in literature.[h][3]

A hospital has to meet two general conditions in order to be allowed to operate. First, it has to fit into the national planning determined at the federal level. If a hospital complies with the programming criteria, it respects the national planning. Second, a hospital has to fulfil all recognition criteria.

4.1.1. Programming and planning

Programming reflects an estimation of the needed capacity, reflected in a maximum offer.[i] The federal government, responsible for determining the global hospital capacity[j] defines the programming standards and criteria. The communities can add norms as far as they respect the minimal federal norms and the federal competences. The communities are competent for decisions regarding the programming (e.g. licensing).

While in the 1960s and 1970s programming criteria mainly targeted the number of hospital beds, during the last decades programming regulation was extended to heavy medical equipment (e.g. PET-scans), medical and medico-technical services or care programs. Programming criteria are usually based on the size, age structure, and morbidity of the population and on the geographical dispersion.

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h For an extensive overview of legislation and the organization of hospitals see S. CALLENS en J. PEERS, *Organisatie van de gezondheidszorg*, Antwerpen-Oxford, Intersentia, 2008, 677 p.

i Decision of 18 Februari 1997 of the Flemish government regarding the defintion of the procedure to obtain a planning license and an exploitation license for intramural and transmural health care settings, *B.S./M.B.* 17 May 1997

j Art. 36 e.v. Hospital Law

Not every activity in a hospital is programmed (e.g. neurosurgery is not programmed), though. Another option to rationalize the activity in hospitals is inserted in the hospital law. According to art. 81, it can be defined which interventions need to be practiced in recognised hospitals and conversely what can be practiced extra muros. In the past, several attempts to draw up a list of medical interventions that can only be performed in a hospital have been made by the working group within the National Council of Hospital Services.[k] They concluded, however, that it was impossible to do so because of the fast evolution of medical techniques and the continuous stream of new techniques. Actually, there is a risk that new interventions could be done outside hospitals if this list is not continuously updated.

If a proposal for starting, changing capacity or altering the destination of a hospital or a hospital service respects the national planning, a planning license can be granted[l]. Furthermore a license to run the hospital services is needed to operate.

4.1.2. Recognition

The federal government disposes of a second instrument to regulate the hospital sector[m]. A hospital not only has to fit into the national planning, it also needs recognition before it can operate. Recognition needs to be distinguished from accreditation. Accreditation can be labelled as "*Initiatives to externally assess hospitals against pre-defined explicit published standards in order to encourage continuous improvement of the health care quality*". Whereas currently, accreditation is voluntary for hospitals, recognition allows hospitals to legally operate, grants the hospital the right to be subsidized and to be reimbursed by the sickness funds. Recognition is also needed for a hospital service (e.g. maternity service to operate a certain number of beds for each service category. Furthermore, hospital functions (e.g. the hospital pharmacy) and care programs (e.g. cardiac pathology)[n] also need to comply with recognition norms. The recognition of a care program, however, is not necessary to operate the respective service.

Recognition standards and criteria are set at the federal level. The communities can formulate additional norms, e.g. as a result of a visitation, as far as they respect the minimal norms of the federal government and do not override the federal government's competences.[o]

The standards and criteria for recognition are considered as a guarantee for hygiene, safety and quality of care. There are several recognition standards such as:

- Organizational standards: staff requirements and responsibilities, hygiene, ethical requirements;
- Architectural criteria concerning the number, size, comfort and hygiene of hospital rooms;
- Functional standards such as convenience and accessibility;
- Additional standards related to minimum activity.

These general norms and criteria are included in article 66 of the Hospital Act and further elaborated in executory Royal Decrees.[p] Apart from general standards, there are also specific standards and criteria (art. 67 Hospital Act) for example for university hospitals. Furthermore, additional specific recognition norms and criteria for several groups have been defined in the Hospital Act:

- Hospital departments (maternity department, rehabilitation department, etc.);

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k Nationale Raad voor Ziekenhuisvoorzieningen, Jaarverslag 2007, p. 13 http://www.health.belgium.be/eportal/Healthcare/Consultativebodies/NationalcouncilforhospitalfaciI/708701

l Art. 39 Hospital Law

m Art. 66 Hospital Law

n Royal Decree of 15 July 2004 regarding the definition of the norms care programs "cardiac pathology" have to comply with to be recognised, *B.S./M.B.*13 September 2004

o E.g. Decree of 17 October 2003 regarding quality of health care and wellbeing institutions, *B.S./M.B.* 10 November 2003

p Royal Decree of 23 October 1964 setting the norms hospitals and their services need to comply with, *B.S./M.B*. 7 November 1964; Royal Decree of 30 January 1989 setting the additional norms for the recognition of hospitals and hospital services and the description of hospital groups en the particular norms these have to comply with, *B.S./M.B*. 21 February 1989

- Divisions and functions (hospital blood bank; hospital pharmacy; palliative care, intensive care, ombudsman, etc.);
- Medical and medico-technical services (center for human genetics, computed tomography (CT) medical imaging, magnetic resonance imaging (MRI), center for chronic kidney failure treatment, radiotherapy, service for nuclear medicine with PET scanner, transplantation center, etc.);
- Care programs (cardiac pathology, children, geriatrics, etc.)

Compliance with the recognition norms in hospitals is checked by the respective community- or regional governments[q]. Recognition follows a rigorously regulated procedure and has to be renewed every couple of years. Hospitals governed by the Flemish Community, however, get recognition for an unlimited period and a yearly thematic inspection is performed. Additionally, system inspection (leadership, strategy and policy, the safety management and the quality system) is carried out for hospitals that are not accredited by internationally recognized hospital accreditation institute (such as het the Joint Commission International and Nederlands Instituut voor Accreditatie in de Zorg).[r] An existing recognition can be withdrawn, which leads to closure of the hospital or of the respective service.

From 1 July 2014 on, the Communities will be – on top of the existing powers – competent to define the norms hospitals and the services (including the psychiatric hospitals and the psychiatric divisions in a general hospital), the care programs, the hospital services, etc. will have to comply with to be recognised. It concerns the recognition as defined in art. 66 and following of the Hospital law. Hereto the exception f) article 5, § 1, I, 1°, of the special law of 8 August 1980 was abrogated. Consequently the Communities are competent for the matters included the texts enumerated in the explanation of article 6 of the bill of law of the special law regarding the sixth state reform.[s] The Communities need to respect the organic federal legislation and the federally defined programming criteria. Furthermore the financing of the hospitals, except A1 (budget for the construction and renovation of the hospitals) and A3 (investment costs for heavy medical equipment (MRI, PET-scan, radiotherapy) of the budget financial means, as well as the rules related to the definition and the calculation of the budget financial means of the hospitals remains the competence of the federal government. Yet, a procedure to evaluate the impact of draft legislation related to the definition of recognition norms or hospitals and the services, the care programs and hospital functions on the budget of the federal government and social security is foreseen and if necessary a veto can be imposed by the competent federal minister or by the council of ministers.[t]

4.1.3. Other quality and safety norms

Besides the quality and safety requirements included in the recognition norms, the Hospital Act contains several requirements which can promote quality of care, such as the description of the tasks of the medical manager, the obligation to maintain a medical file, the tasks of the Medical Council, the establishment of an ethical committee, a committee for hospital hygiene, a medical pharmaceutical committee, a committee for medical material, a committee for blood transfusions, as well as other specialized committees.

Furthermore, hospitals needs to comply with other national, regional and European rules related to the organization and promotion of quality of care in hospitals.

With regard to the organization of hospital hygiene for instance, the integration of the hygienist physician and nurse team has been emphasized. Additional measures are in place to improve staff compliance and to generalize registration with an obligation to register methicillin-resistant

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q In principle the Communities are competent for the hospital recognition. The French Community however transferred its competences to the Walloon region and to the French Community Commission (Brussels).

r Toezicht op de algemene ziekenhuizen. Naar een nieuw inspectiemodel: zorgtrajecten en eisenkaders http://www.zorg-en-gezondheid.be/Beleid/Procedures/Ziekenhuizen/Toezicht-op-algemene-ziekenhuizen/

s Bill of law of the special law regarding the sixth state reform, *Parl. St.* Senaat, 2012-2013, 5 - 2232/1, p. 28

t Special law of 6 January 2014 regarding the sixth state reform, *B.S./M.B.* 31 January 2014

Staphylococcus aureus (MRSA) and Clostridium difficile[u]. Special attention has been given to hand hygiene through national campaigns. In addition, a committee for antibiotherapy was set up in the hospitals in order to promote a better use of antibiotics and to reduce resistance[v]. Patient safety in general in hospitals is a topic for which the government has elaborated a national policy.[w]

Hospitals also have to comply with environmental norms (e.g. Vlarem legislation), food hygiene norms in the hospital kitchen (e.g. Hazard Analysis and Critical Control Points) and safety norms such as for instance fire safety[x].

Qualitative care was also translated as a patient right (art. 5 Patients' Rights act[y]). It implies amongst others that physicians need to comply with the standards according to the current scientific 'state of the art'. Clinical practice guidelines can be a source for the interpretation of this notion. [z]

4.2. Weaker legal framework for extramural centers to guarantee quality

4.2.1. No overview of who does what and where

The number of extramural centers in Belgium is unknown. Some data of extramural centers have been registered in Flanders under the Decree for the notification of risky medical interventions.[aa] This Decree has been annulled, however. The Constitutional Court judged that the Decree violates the federal competence related to the practise of medicine (cfr. Infra 7.1).[bb] Moreover, there is no registration for interventions that are not reimbursed by the compulsory health insurance. Hence, data on the nature and the number of these interventions are lacking[cc], which renders quantification of refractive surgical interventions in Belgium impossible and hampers quality evaluation. Furthermore, there is no publicly available overview of the physicians working in extramural centers.

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u Royal Decree of 19 June 2007 modifying the Royal Decree of 25 April 2002 on the determination and the compensation of the hospital budget financial means, *B.S./M.B.* 28 June 2007

v Royal Decree of 12 February 2008 modifying the Royal Decree of 4 March 1991 regarding the definition of norms hospital pharmacies have to comply with to be recognised, *B.S./M.B.* 28 March 2008

w http://www.health.belgium.be/eportal/Healthcare/Healthcarefacilities/Patientsafety/index.htm

x Royal Decree of 7 July 1994 setting the basic norms for fire and explosion prevention of new buildings *B.S./M.B.* 26 April 1995; Royal Decree 6 November 1979 setting the norms regarding fire security and panic, which hospitals need to comply with, *B.S./M.B.* 11 January 1980; for a more extensive overview of quality and patient safety issues see report J. Pauwels et. Al. Naar een geneeskunde met kantooruren? Voorstellen voor het waarborgen van de continuïteit van acute zorg. Zorgnet Vlaanderen 2012

y Act of 22 August 2002 on patients' rights, *B.S./M.B.* 26 September 2002.

z I. Vinck, D. Paulus, H. Van Brabandt, D. Ramaekers. Medico–legale aspecten van klinische praktijkrichtlijnen. Brussel: Federaal Kenniscentrum voor de Gezondheidszorg (KCE); mei 2006. Reports vol. 26A. Ref. D/2006/10.273/05.

aa Decree of 22 June 2012 regarding the obligatory notification of risky medical practices of 22 June 2012, *B.S./M.B.* 20 July 2012

bb Constitutional Court 19 December 2013, nr. 170/2013, http://www.const-court.be/public/n/2013/2013-170n.pdf

cc Data on the reimbursement of cataract operations in extramural eye surgery centers are available at RIZIV/INAMI. As the day care lump sum is not paid to extramural centers, the data on the number of cataract interventions in extramural eye surgery centers could be identified.

4.2.2. No recognition and no legal quality control

Since extramural centers do not fall within the scope of the definition of "hospital" in the sense of the hospital law, they do not have to comply with the recognition norms and the quality norms embedded in the hospital law and many other rules and initiatives.[dd][6] There is no recognition, physicians do not need a permission to start an extramural centre and can operate without inspection regarding safety and quality.

Yet, rules related to basic requirements such as for instance hygiene in the operation room seem to be necessary regardless of the setting. Some studies show that there is less risk for MRSA in extramural centres.[ee][7] Today, it is not obvious, however, whether this is inherent to the setting or due to other elements such as the – in general - less weakened population and the shorter stay in extramural settings.[ff][8]

4.2.3. Legislation for distribution and use of medical devices or pharmaceuticals in extramural centers exists but did not enter into force yet

In hospitals pharmaceuticals and medical devices are available in the hospital pharmacy. The question rises how medical devices and pharmaceuticals that are intended for hospital use but may be needed when invasive interventions are practiced or when complications take place are distributed to the extramural centres. According to the law regarding medical devices, physicians or dentists using implantable medical devices for their patients are allowed to hold a storage of medical devices and the appropriate pharmaceuticals (art. 54 Law of 15 December 2013 regarding medical devices[gg]). The pharmaceuticals and medical devices need to be purchased at a public officina or a hospital pharmacy and they can solely be delivered in the scope of a medical act (art. 4, §4, van het Royal Decree n° 78[hh]). Therefore the physician needs to contract an agreement with the titular of the officina or the hospital pharmacy. The question can be raised, however, if hospitals will be ready to sign such agreements and whether they have the obligation to contract. It also has to be noted that the respective legislation did not enter into force yet. At the time of the writing of this report the existing regulation is not very sound. Several medical devices such as for instance implantable medical devices can solely be distributed to other distributors and public- or hospital pharmacies (see for the list art. 10bis §3, Royal Decree of 18 March 1999 on medical devices). Exceptions are listed in law: intra ocular implants (solely to ophthalmologists), scalpels, needles, hypodermic syringes, bandages, material for examinations and interventions in surgery (cabinet), except for implantable devices etc. can be directly delivered to health care professionals as far as they use the devices in the scope of their medical practice and as far as they do not offer or sell them to patients for ulterior use (art. Ministerial Decree implementing art. 10bis § 7 Royal Decree of 18 May 2005 on medical devices). Hospital pharmaceuticals may only be used for in hospital patients, apart from some specific exceptions mentioned in law or to a limited extent after dismissal of the patient for the continuity of treatment (art. 4 Royal Decree of 19 October 1978 related to regulations on public pharmacies and storage of pharmaceuticals in care institutions).

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dd D. FORNACIARI, *De wisselwerking tussen het mededingingsrecht en het recht op kwaliteitsvolle zorg van de patient*, Brugge , Die Keure, 2011, p. 45 ev.

ee I. Uçkay, S. Harbarth, R. Peter, D. Lew, P. Hoffmeyer, D. Pittet. Preventing Surgical Site Infections. Expert Rev Anti Infect Ther. 2010;8(6):657-670.

ff S. Dudareva, Cases of community-acquired meticillin-resistant Staphylococcus aureus in an asylum seekers center in Germany, November 2010. Euro Surveill. 2011 Jan 27;16(4). pii: 19777; I. Matouskova. Current knowledge of methicillin-resistant Staphylococcus aureus and community-associated methicillin-resistant Staphylococcus aureus. Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub. 2008 Dec;152(2):191-202. www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Jun7(2)/Pages/61.aspx

gg Law of 15 December 2013 regarding medical devices, *B.S./M.B*. 20 December 2013

hh Royal Decree n° 78 of 10 November 1967 concerning the exercise of health care professions, *B.S./M.B.* 14 November 1967

4.2.4. General norms applicable to extramural centers

4.2.4.1. General norms regarding quality and safety related to the systems or medical devices

Although hospital-specific[ii] regulations do not apply to extramural centers, general legislation related to quality and safety of the setting, such as for instance fire prevention or environmental regulations with regard to sewage applies to extramural centers. Furthermore medical devices, including medical systems used in extramural centers need to be CE marked. The CE marking indicates that the device performs as labelled and that issues were identified. Furthermore, ISO norms are available for medical devices or systems such as for instance airflow systems in operation rooms. ISO norms, although not legally binding, are considered to be in conformity with the essential requirements for devices or systems. The value of ISO is to be compared with the value of clinical practice guidelines. In the assessment of possible liability of the extramural centers for the non-application of ISO norms by an extramural center, a fault could be withheld if another extramural center would have applied the norms in the same circumstances.

In contrast to hospitals, however, legal pro-active control of the existing quality and safety in extramural centers is lacking. Control of these items may, however, be organized by the field such as for instance the certification and registration by the Belgian Working Group for Extramural Eye Surgery (cfr. infra). The controlled items are listed in appendix 1. Yet, in general, extramural centers are not obliged to participate to certification processes to operate.

4.2.4.2. Patients rights

The Belgian Patients' Rights act regulates the right to qualitative care, the right to information about his or her health status and its probable evolution, the right to free and informed consent, the rights to be assisted by a reliable person and to be represented by a representative, rights regarding the direct access to the patient file, the right to privacy, the right to pain relief, the right to freely choose a health care professional and the right to complain.[jj] [9]

The respect of patients' rights has been integrated in the Hospital law (art. 30 Hospital Law). Hospitals need to respect the relevant patients' rights and need to make sure that self-employed health care professionals working in the hospital respect the patients' rights. Furthermore the hospital is liable for the breaches of the patients' rights committed by the health care professionals working at the hospital (self-employed, employee or statutory), except if the hospital explicitly and priorly informed the patient that it will not be liable.[kk][10] The hospital can solely appeal to the exception for self-employed physicians since according to the civil liability rules hospitals can be held liable for the wrongful acts (or omissions) of their personnel working under subordination (art. 1384, al. 3 Civil Code). The advantage of such a so called centralized liability is that patients know who to direct their claim at in case of presumed violation of patients' rights.

As extramural centers do not fall into the definition of hospitals, the obligation to respect the relevant patients' rights and the central liability formulated in the hospital law does not apply to these centers. Although extramural centers do not fall within the scope of the Patients' Rights act, all physicians do.[ll] Consequently, patients treated in extramural centers do "benefit" from patients' rights. Although there is no legal centralised liability regulation for extramural centers, there are voluntary initiatives by health care

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[ii] The notion "hospital" must be understood as in the definition of the hospital law

[jj] Act of 22 August 2002 on patients' rights, *B.S./M.B.* 26 September 2002; X., "De Wet Patiëntenrechten", *T.Gez.* 2003-04, afl. 2, 65-159; T. VANSWEEVELT, "Definitie en toepassingsgebied van de wet patiëntenrechten", *T. Gez*. 2003-04, 66-73

[kk] S. CALLENS, "Aansprakelijkheid van het ziekenhuis en de naleving van de Patiëntenrechtwet", *T.Gez*. 2003-04, afl. 2, 125-130.

[ll] S. CALLENS, "Aansprakelijkheid van het ziekenhuis en de naleving van de Patiëntenrechtwet", *T.Gez*. 2003-04, afl. 2, p. 127; T. VANSWEEVELT, "Definitie en toepassingsgebied van de wet patiëntenrechten", *T. Gez*. 2003-04, p. 68

professionals to include the central liability in the insurance contracts of the respective extramural centers.[mm]

4.2.4.3. General civil and criminal liability rules

Furthermore the general (contractual or non-contractual) civil and criminal liability rules apply also to extramural centers as legal persons.[nn][11] Extramural centers could be held liable for violation of the 'general duty of care', if fault, damage and a causal link can be proven (art. 1382 Civil Code). The content of this general concept is interpreted by judges and could also contain elements of patients' rights. Furthermore extramural centers can be held liable for the damage resulting from acts of the personnel working under subordination (art 1384, al. 3 Civil Code). Medical injuries can also be caused by the use of defective or faulty material or products, such as for instance medical devices. Different options exist for the injured patient to claim compensation from different parties. A producer of a defective material or product shall be automatically liable for damage caused by a defect in his product if the plaintiff can prove the defect in the product, the reality and importance of the damage suffered, as well as the causal link between the defect and the damage.[oo] The affected person does not have to prove the producer's fault. Pursuant to articles 1382 and 1383 of the Civil Code, any act which causes damage to another obliges him by whose fault it occurred to make reparation and each one is liable for the damage which he causes not only by his own act, but also by his negligence or imprudence. The liability is extended by the article 1384, al. 1 of the Civil Code to things that one has in his keeping. The injured party must therefore prove the fault, the damage and the causal link between the fault and the damage. Extramural centers are also contractually held to use safe material or products, based on article 1135 Civil Code.[pp][12] Furthermore, pursuant to articles 1641 to 1649 of the Civil Code, the seller guarantees the buyer for the hidden defects in the product sold. This article can also be applied to extramural centers in their use of defective products or devices for patient.[qq][13] The injured party does not need to prove the fault, but has to prove the defect, the existence of the defect at the moment of the use, that the defect rendered the product/device inappropriate for its intended use and the severity of the defect.

4.2.4.4. Personal data protection

The data in the patient file fall within the scope of the law on processing of personal data (hereinafter called as the data protection act) and its implementing decree[rr]. A set of rights that are partly overlapping with those of the patients' rights related to the patient file are granted to data subjects, such as patients. Patients have the right to information on the processing of the data, to directly access the personal data, to request correction, erasure or objection. Extramural centers (legal person) or the physicians working there can be considered to be controllers as defined in law since they determine the purposes and the means for the data processing of the patient's medical data. The data controller must ensure that all obligations and all stipulations stated in the law on the processing of personal data are respected (art. 4 §2; art. 9 §1-2, art. 10 §1 art. 15bis data protection act). He can be held liable if the data subject suffers any damage by infringement of stipulations imposed by the data protection act unless he proves that he has not caused the damage (art. 15bis data protection act).The data controller has the general obligation to take adapted technical and organizational security measures regarding the data processing to protect personal data against accidental or unlawful destruction, accidental loss, the modification of or the unauthorized access and any other non-authorized processing of

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mm Personal communication Marnix Claeys

nn Act 4 May 1999 regarding the introduction of penal liability of legal persons, *B.S./M.B.* 22 June 1999; M.G. Faure, C.A. Schwarz, *De strafrechtelijke en civielrechtelijke aansprakelijkheid van de rechtspersoon en zijn bestuurders* Antwerpen, Intersentia, 1998, 283 p.

oo Act of 25 February 1991 on Liability for defective products, *B.S./M.B.* 22 March 1991

pp W. DIJKHOFFZ, "Organisatiefouten in ziekenhuisverband", *T. Gez.* 2006-2007, p. 252

qq A. VIJVERMAN, "Hergebruik van voor eenmalig gebruik bestemde medische hulpmiddelen: nood aan een duidelijke regeling", *T. Gez.* 2008-2009, p.22

rr Act of 8 December 1992 regarding the protection of privacy for the processing of personal data, *B.S./M.B.* 18 March 1993 and Royal Decree of 13 February 2001 executing the act of 8 December 1992, *B.S./M.B.* 13 March 2001

personal data. Additionally the law adds some specific organizational security measures to be taken by the data controller. This implies that the extramural centers (and the physicians working there) need to take the necessary measures to safely store the patient file.

4.2.4.5. The EU Directive on Patients' Rights to Cross Border Healthcare

The Directive on Patients' Rights to Cross Border Healthcare[ss] (hereinafter called as the Patients' Rights Directive) intends to impose member states to have a minimal framework of quality and safety norms for healthcare delivered in a EU member state. The directive obliges member states to provide healthcare according to the quality and safety norms set by the member state where the medical intervention takes place (art. 4). The directive covers treatment in both state-run hospitals and by private service providers. Solely the qualification of the person providing the medical service and the character of the medical service are decisive to determine if an act can be conceived as healthcare or not. As health care providers are defined as any natural or legal person or any other entity legally providing healthcare on the territory of a Member State, extramural centers are also concerned.

The directive imposes several duties on the member states, amongst others with regard to quality and safety (art. 4, 2° b and recital 20), that may be of importance for the elaboration of national legislation that is also applicable to extramural centers.

According to art. 4, 2° Member States are obliged to ensure that:

a) *patients receive from the national contact point upon request, relevant information on the standards and guidelines on quality and safety laid down by the Member State of treatment, including provisions on supervision and assessment of healthcare providers, information on which healthcare providers are subject to these standards and guidelines and information on the accessibility of hospitals for persons with disabilities;*

b) *healthcare providers provide relevant information to help individual patients to make an informed choice, including on treatment options, on the availability, quality and safety of the healthcare they provide in the Member State of treatment and that they also provide clear invoices and clear information on prices, as well as on their authorisation or registration status, their insurance cover or other means of personal or collective protection with regard to professional liability.*

c) *there are transparent complaints procedures and mechanisms in place for patients, in order for them to seek remedies in accordance with the legislation of the Member State of treatment if they suffer harm arising from the healthcare they receive;*

d) *systems of professional liability insurance, or a guarantee or similar arrangement that is equivalent or essentially comparable as regards its purpose and which is appropriate to the nature and the extent of the risk, are in place for treatment provided on its territory;*

e) *the fundamental right to privacy with respect to the processing of personal data is protected in conformity with national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC;*

f) *in order to ensure continuity of care, patients who have received treatment are entitled to a written or electronic medical record of such treatment, and access to at least a copy of this record in conformity with and subject to national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.*

[ss] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, *O.J. L.* 88/45 4 April 2011

The directive needed to be transposed into national legislation by 25 October 2013 (art. 21).[tt][14] Several rules regarding the information on quality, safety and transparency of financial consequences of healthcare interventions already exist in Belgium. The Patients' Rights act for instance includes some dispositions on the duty of qualitative care (art. 5). The right to qualitative care implies that the applicable standards according to the actual scientific state of affairs have to be applied. According to art. 8 § 2 of the same law, health care professionals need to inform the patient on the financial consequences of the intervention. This comprises the total cost of the intervention, including the honoraria, the co-payments, the supplements that need to be paid by the patient and whether the health care professional works according to the conventioned tariff or not.[uu] This applies for reimbursed as well as for non-reimbursed interventions.[vv][15, 16] Article 8 of the patients' rights act also states that health care professionals need to complete the information listed in the law with other clarifying elements that are estimated as relevant by the patient or by the health care professional. Elements such as information on quality and safety, the health care professional's registration status or insurance cover may thus be implicitly included. According to the law on qualifications for aesthetic interventions a detailed budgeting of the costs needs to be provided to the patient if the estimated amount of the planned intervention exceeds 1000 euro (art. 18 § 1, 6°). For interventions in hospitals, patients are informed on the tariffs of the interventions and the used materials in the admission declaration.

On the other hand, the existing legal framework needs to be further elaborated to be in line with the directive. According to art. 4, 2° b) for instance health care providers (also including extramural centers) need to inform the patient on relevant information in order to allow them to make an informed choice. This article contains a non-limitative enumeration of such information. According to Nys, the right to receive information to make an informed choice is not the same as the right to informed consent, although there is overlap. The right to an informed choice could be interpreted as a right to select a healthcare provider on the basis of relevant information.[ww][17] It is questionable, however, whether health care providers themselves are best placed to provide this information themselves, because they have a conflict of interest and it might be a time consuming and costly procedure. A more collective approach could be an option. For hospitals the legislation attempted to centralise information and to be more transparent. From the 1st of July 2014 on, hospitals need to have a website mentioning information on the offered care in the hospital, the financial information related to the costs of stay and the convention status of the physicians working there.[xx] The latter obligation does not apply to extramural centers, however.

Another issue that will need to be aligned with the requirement of the directive is the lack of regulation in Belgium for a complaint procedure for extramural centers. Hospitals are legally obliged to provide an ombudsservice dealing with complaints regarding the respect of the patients" rights related to the care provided.[yy] For complaints with regard to patients' rights against ambulatory health care providers, a Federal

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tt H. NYS, "The transpositions of the Directive on Patients' Rights in Cross-Care Healthcare in National Law by the Member States: still a lot of effort to be made and question to be answered", *European Journal of Health Law* 21 (2014), 1-14

uu Report Gilkinet en Brouns, *Parl.St.* Kamer 2001-2002, 1642/012, p. 79; Bill of law on patients' rights, M.v.T., *Parl. St.* Kamer 2001-2002, 1642/001, 26; for the obligation to inform on the convention status see also Art. 73, §1 Act of 14 July 1994 regarding the obligatory health care insurance, *B.S./M.B.* 27 August 1994

vv G. SCHAMPS, "Le droit à l'information et le droit au consentement libre et éclairé", in S. BRILLON, S. CALLENS, V. GAUCHE, N. NOEL, G. SCHAMPS en M.N. VERHAEGEN (eds.), *Mémento des droits du patient et de la responsabilité médicale*, Brussel, Kluwer, 2003, 41-67 ; S. TACK en T. BALTHAZAR," Patiëntenrechten. Informed consent in de zorgsector: recente evoluties", *CABG*, 2007/5-6, 9; W. DIJKHOFFZ, "Het recht op informatie en geïnformeerde toestemming", *T.Gez./Rev. dr. Santé* 2003-2004, 111

ww H. NYS, "The right to informed choice and the Patients' Rights Directive" *European Journal of Health Law* 19 (2012) 327-331

xx Art. 31 – 34 Act of 7 Februari 2014 regarding diverse dispositions on the accessibility of healthcare, *B.S./M.B.* 25 February 2014

yy Art. 71 Hospital Law

ombudsservice is foreseen.[zz] Patients with a complaint regarding the respect of patients' rights by a health care professional working in an extramural center can thus address their claim to the Federal ombudsservice. If the complaint concerned addresses the extramural center (rather that the health care professional working there), it is not clear where the patient can obtain advice as extramural centers do not fall within the scope of the patients' rights act.

At the time of the writing of this report, a bill of law setting a minimal framework for quality and safety of medical practice, regardless of the setting, has been approved by the Council of Ministers (dd. 25 April 2014) and is sent to the Council of State for advice (within 60 days), foreseen by the 7th of July 2014 (expiration date). This bill comes forward to several requirements of the directive (cfr. Infra).

4.2.4.6. Council recommendation on patient safety, including the prevention and control of healthcare associated infections

Other EU documents such as the Recommendation on patient safety[aaa] express their concern for patient safety at the member state level. According to the recommendation member states are in charge of the provision of a safe health care system. In that scope, member states are invited to take measures which are in place to reduce or prevent errors and harm resulting from healthcare. In particular, member states should

- support the establishment and development of national policies and programmes on patient safety
- empower and inform citizens and patients
- support the establishment or strengthen blame-free reporting and learning systems on adverse events,
- promote, at the appropriate level, education and training of healthcare workers on patient safety,
- classify and measure patient safety at Community level, by working with each other and with the Commission,
- share knowledge, experience and best practice on patient safety matters by working with each other and with the Commission and relevant European and international bodies and
- develop and promote research on patient safety.

Furthermore, additional recommendations on prevention and control of healthcare associated infections are set.

Although this recommendation has no legally binding force, it stressed the need for a legal framework ensuring patient safety, independent of the setting the patient is cared in.

4.2.5. Norms applicable to physicians

Independent from the setting they work in, general legal and deontological rules apply to all practicing physicians. Only those regulations relevant for this report will be mentioned.

4.2.5.1. Deontological code

Interventions practiced in extramural centers, such as refractive eye surgery, are acts of health care and people undergoing this intervention are considered as patients. Therefore, physicians who perform these acts are compelled to work in line with their traditional duties, such as for instance professional secrecy (art. 55 Deontological code[bbb]; also article 458 of the Belgian Penal Code[ccc]). The duties with regard to patient files may be of particular interest to guarantee seamless care between extramural centers and other health care establishments or health care professionals. The patients' rights act states in general that patients have the right to a carefully

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zz Royal Decree of 1 April 2003 on the composition and the functioning of the Federal Commission "Patients' rights " inserted by article 16 of the Act of 22 August 2002 on patients' rights, *B.S./M.B.* 13 May 2003

aaa Council Recommendation 2009/C 151/01 of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections, *O.J.* 3 July 2009, vol. 52 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:151:0001:0006:EN:PDF

bbb Nationale Raad van de Orde van Geneesheren, Code van Geneeskundige Plichtenleer. http://www.ordomedic.be/nl/code/inhoud/

ccc Penal Code 8 June 1867, *B.S./M.B.* 9 juni 1867

and safely stored patient file (art. 9 § 1) but there is no specification on the modalities of the careful and safe storage. The modalities of storage and details on the content of the patient file are elaborated in diverse legal texts, be it primarily in legislation applying to hospitals and not to extramural centers.[ddd] According to the hospital law, for instance, patient medical files need to be stored under the responsibility of the chief physician in hospitals (art. 25 § 1 Hospital Law). Furthermore patient files in hospitals need to be stored in the hospital for at least 30 years (art. 1 § 3 Royal Decree on the minimal criteria for medical files in hospitals[eee]) Patient files, independent of the setting where they are created, also fall within the scope of the data protection act, defining rights for the patient and duties for the healthcare professional and the hospital treating the medical patient data defined in the data protection act.[fff][18] For the interpretation of the general legislation applying to patient files, it may be useful to refer to the Deontological code. According to art. 46, medical files need to be stored for 30 years after the last patient contact. Furthermore, physicians need to transfer the medical files to another physician when the former's activity stops (art. 47 deontological Code). It has to noted that the modalities of the content and a storage period of 30 years are foreseen in the bill of law regarding practice in health care, setting a minimal framework for quality and safety of medical interventions, regardless of the setting (cfr. Infra).

Although the dispositions of the deontological code apply to all physicians and thus provide to some extent minimal guarantees for quality, there is no pro-active control of compliance with these norms. Furthermore the Deontological Code is not legally binding. Yet, disciplinary sanctions can be imposed if there was a violation of the Code.

4.2.5.2. Royal Decree n° 78 of November 10, 1967 concerning the exercise of health care professions

The practice of medicine, regulated in Royal Decree n° 78 has defined general duties that need to be complied with by all physicians.[ggg] The duty to guarantee the continuity of care is particularly important in the scope of care provided in extramural centers. In practice, patients will often need to appeal to the after-hours services of hospitals, as not all extramural centers organise after hours. Indirectly, the cost of the complications of non-reimbursed and often luxury care is then (partly) financed by public means. Since there is no registration of the setting where non reimbursed healthcare interventions are performed, the extent of this practice is unknown. According to article 8 and following of R.D. n° 78 health care professionals, including those working in extramural centers need to guarantee continuity of care. In case of an interruption of the continuity of a treatment because of the daily closing time, continuity of care can be guaranteed by the after-hours services as far as the health care professional participates to after-hours services regulated in art. 9 R.D. n° 78. This article foresees amongst others the possibility for the Crown to delegate the organisation of the after-hours service to the employer. Although the preparatory works of the law regarding various dispositions related to health care refer to the situation of a hospital where after hours is organised for all medical specialties, the notion employer can also apply to an extramural center.[hhh]

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ddd E.g. Royal Decree of 3 May 1999 regarding the definition of general minimum criteria for medical files, as defined in art. 15 of the hospital law, coordinated on 7 August 1987, *B.S./M.B.* 30 July 1999; Royal Decree of 28 December 2006 regarding the definition of general minimum criteria for the nursing file, as defined in art. 17quater of the hospital law, coordinated on 7 August 1987, *B.S./M.B.* 30 January 2007

eee Royal Decree of 3 May 1999 regarding the definition of general minimum criteria for medical files, as defined in art. 15 of the hospital law, coordinated on 7 August 1987, *B.S./M.B.* 30 July 1999

fff R. HEYLEN, "Deel II bis. Het medisch dossier en de Wet Patiëntenrechten: vele verduidelijkingen, maar toch enkele nieuwe problemen", *T. Gez.* 2003-2004, 94-102

ggg Royal Decree n° 78 of 10 November 1967 concerning the exercise of health care professions, *B.S./M.B.* 14 November 1967

hhh Bill of law regarding various dispositions related to health care, *Par. St.* Kamer 2013-14, 3349/001, p. 97; Law regarding various dispositions related to health care, *B.S./M.B*. 10 May 2014

4.2.5.3. Patients' Rights

Health care professionals as defined in Royal Decree n° 78 as well as professionals exercising a non-conventional practice need to respect the patients' rights defined in the patients' rights act, independent of the setting they work in (see for the included patients' rights 4.2.4.2). Yet, the specification and interpretation of some patients' rights particularly focuses at the hospital environment. As mentioned above the patients' rights act states in general that patients have the right to a carefully and safely stored patient file (art. 9 § 1) but there is no further specification on the modalities of the careful and safe storage. Furthermore there is no definition of the minimal content of the medical file in the patients' rights act. For patients treated in a hospital setting more details on the modalities of the hospital medical file and the modalities of storage are defined.[iii] Yet, often patients are transferred between medical settings. The risks of transitions across settings of care such as for example drug interactions render transparency in the care process and a detailed description in the patient file necessary. As mentioned above the modalities of the content and a storage period of 30 years are foreseen in the bill of law regarding practice in health care, setting a minimal framework for quality and safety of medical interventions, regardless of the setting (cfr. Infra).

4.2.5.4. Law on qualifications for aesthetic interventions

Aesthetic medical interventions often take place in extramural settings. The law regarding the required qualifications to perform non-surgical aesthetic medicine and aesthetic surgery (hereinafter called as the law on qualifications for aesthetic interventions) explicitly inserts aesthetic medical interventions in the field of application of the patients' rights law.[jjj] Although such interventions were never explicitly excluded from the field of application, there was some discussion whether these interventions without curative character could be labeled as "healthcare" to which the patients' rights are applicable. The law on qualifications for aesthetic interventions extends particular patients' rights. It specifies the particular information that needs to be communicated before an aesthetic intervention takes place (art.18). Furthermore a reflection period between the provision of the information and the date of the intervention is foreseen (art. 20). Additionally, specific protective measures are foreseen for aesthetic interventions for minors (art.17). The notion "aesthetic" is perceived as changing the patients' appearances, primarily for aesthetic reasons and in absence of a reconstructive or therapeutic aim (art. 2, 2°). Refractive eye surgery cannot be considered as aesthetic surgery as defined in the law on the qualifications for aesthetic interventions because there is a therapeutic aim. Consequently the extended patients' rights do not apply to refractive eye surgery. Plastic surgeons and surgeons are competent to perform aesthetic surgical and non-surgical medical interventions in the orbito-palpebral region. For the other specialists, solely ophthalmologists are allowed to perform these interventions in the scope of guaranteeing quality and safety for the patient (art. 12, 1°). As refractive eye surgery is not considered to be an aesthetic intervention, this restriction does not apply. In principle, physicians have an overall competence to practice any medical act, but in practice mostly ophthalmologists will be involved. At the time of writing, several requests for annulment of this law are pending at the Constitutional Court.[kkk] The law may include several possible discriminations, for instance the more severe patients' rights only apply to those physicians who are legally competent to perform the respective aesthetic medical interventions. Those who perform non aesthetic interventions do not have to take the restrictions into account.[lll][19] Yet, the definition of what is considered to be aesthetic is not very clear either. In contrast with the law regarding the compensation of damage resulting from health care (cfr. Infra,), where non reimbursed aesthetic medical interventions are excluded, the law on qualifications for aesthetic interventions does not refer to the reimbursement status of the aesthetic interventions, but only focuses on the absence of a therapeutic or reconstructive aim. It is thus not clear, for instance whether for instance

[iii] Royal Decree of 3 May 1999 regarding the definition of general minimum criteria for medical files, as defined in art. 15 of the hospital law, coordinated on 7 August 1987, *B.S./M.B.* 30 July 1999

[jjj] Law of 23 May 2013 regarding the required qualifications to perform non-surgical aesthetic medicine and aesthetic surgery, *B.S./M.B.* 2 July 2013

[kkk] Cases 5777, 5779, 5783, 5784, 5785 and 5795 pending at the Constitutional Court: http://www.const-court.be/

[lll] A. DIERICKX, "Esthetische geneeskunde andermaal kop van Jut!", *T.Gez*. 2013-14, afl. 2, 74-76

reimbursed ear corrections are excluded from the scope of the law as it is not obvious whether these interventions are free from any therapeutic or reconstructive aim.

The law on qualifications for aesthetic interventions also reserved the surgical and non-surgical aesthetic interventions in the orbito-palpebrale region to ophthalmologists (art. 12, 1°) in the scope of guaranteeing quality and safety for the patient. As refractive eye surgery is not considered to be an aesthetic intervention, this restriction does not apply. In principle, physicians have an overall competence to practice any medical act, but in practice mostly ophthalmologists will be involved. At the time of writing, several requests for annulment of this law are pending at the Constitutional Court.

4.2.5.5. Personal data protection

As physicians working in extramural centers can be regarded as controllers of the patient file (and also patient related data that do not belong to the patient file), they have to work in line with the duties formulated in the law on processing of personal data and its implementing decree (see supra 4.2.2.4). As mentioned above, many of the duties included in the data protection act, are also covered in the patients' rights act, applying to all physicians.

4.2.5.6. General rules of civil and criminal law

General civil rules (e.g. exercising the care that a reasonably prudent physician would exercise in like circumstances) and criminal rules (e.g. intentional or unintentional assault, manslaughter…) apply to the acts of physicians performing refractive eye surgery.[mmm] Furthermore physicians can also be held liable for the use of defective products.[nnn][3, 20]

4.2.5.7. Liability

Violation of criminal rules may lead to criminal liability encompassing a punishment for an offence. Civil liability implies the liability for payment of damages. In order to establish civil liability, the plaintiff needs to prove fault, damage and a causal link between the elements. Sometimes there is a presumption of liability. Pursuant to articles 1641 to 1649 of the Civil Code, the seller guarantees the buyer for the hidden defects in the product sold. This article can also be applied to physicians in their use of defective products or devices for a patient.[ooo] The injured party does not need to prove the fault, but has to prove the defect, the existence of the defect at the moment of the use, that the defect rendered the product/device inappropriate for its intended use and the severity of the defect. The presumption of liability can solely be refuted if the defendant can prove that he could not be aware of the defect.

Patients having occurred an injury by a medical accident have two ways of recourse. They can choose to appeal to the health care professional's civil liability before court. They can also ask for advice to the Medical Accidents Fund on the liability and on the gravity of the harm. Medical accidents without liability having caused damage with a certain gravity are eligible for

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mmm See for a general overview of liability law: S. CALLENS en J. PEERS, Organisatie van de gezondheidszorg, Antwerpen-Oxford, Intersentia, 2008, p. 590 e.v.; T. VANSWEEVELT, *De civielrechtelijke aansprakelijkheid van de geneesheer en het ziekenhuis*, Maklu, Antwerpen - Bruylant, Brussel, 1997, 960 p.

nnn S. CALLENS, "Medische hulpmiddelen en aansprakelijkheid", *Acta Hosp.* 2005, afl. 2, 37-46. For an extensive overview of the liabilty of physicians for defective products see T. VANSWEEVELT, *De civielrechtelijke aansprakelijkheid van de geneesheer en het ziekenhuis*, Antwerpen - Bruylant, Brussel, Maklu, 1997, 960 p.,

ooo A. VIJVERMAN, "Hergebruikvan voor eenmalig gebruik bestemde medische hulpmiddelen: nood aan een duidelijke regeling", *T. Gez.* 2008-2009, p.22; W. DIJKHOFFZ, "Organisatiefouten in ziekenhuisverband", *T. Gez.* 2006-2007, p. 253

compensation by this fund. [ppp][21-24] Damage is deemed grave if the patient has a permanent invalidity rate equal to or higher than 25%, a six-month temporary invalidity, suffered particularly serious perturbations (including economic) in his life conditions, or is deceased (art. 5);

Health care interventions with an aesthetic purpose that are not reimbursed by the national health and disability insurance (NIHDI) are excluded from the scope of the law (art. 3 §1, 2°). So is the damage resulting from pre- and aftercare related to non-reimbursed aesthetic interventions. The rationale of exclusion is that national solidarity cannot be deemed to sponsor unnecessary medical interventions initiated by patients' choice.[qqq] According to Vansweevelt the argument of the patient's initiative also applies for medical interventions resulting from patient's choice for a lifestyle such as smoking, drinking etc. Other arguments can be raised in favour of the inclusion of medical aesthetic non reimbursed interventions in the law: reducing aesthetic interventions to interventions initiated by patients' choice does not take into account psychological suffering of the patient, there is no evidence that aesthetic interventions cause more (or more costly) damage than other interventions,...[rrr] In the preparatory parliamentary discussions, Schamps argued that the exclusion is insufficiently justified and could lead to a claim for violation of the principal of equality at the Constitutional Court.[sss]

4.2.5.8. The EU Directive 2011/24/EU on Patients' Rights to Cross Border Healthcare

The Patients' Rights Directive applies to health care professionals, independent of the setting they work in (cfr. Supra).

5. PARTICULARITIES OF REFRACTIVE EYE SURGERY AND OTHER OPHTHALMOLOGIC INTERVENTIONS PERFORMED IN EXTRAMURAL CENTERS

5.1. No registration of refractive eye surgery in extramural centers

Currently, the number of refractive surgical interventions in Belgium is a black box.

Refractive eye surgery performed in an extramural eye surgery center is not reimbursed except for the pre- and postoperative consultations. Often pre- and postoperative consultations are included in the package price of the intervention. Even if the consultations are charged to the NIHDI for reimbursement, there is no indication of the setting where the consultation took place. Since there is no registration of the setting where refractive eye surgery was performed, there are no data on the number of complications.

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ppp Act of 31 March 2010 on the compensation of damage resulting from healthcare, *B.S./M.B.* 2 April 2010; see also I. BOONE en S. LIERMAN (eds.), *Vergoeding van slachtoffers van medische ongevallen. Praktijkgerichte analyse van de wet van 31 maart 2010*, Antwerpen, Intersentia 2011, 116 p.; G. SCHAMPS, M. DERESE, A. SQUIFFLET, J. HAUSMAN, *Nouvelle réglementation relative à l'indemnisation des dommages résultant de soins de santé*, Waterloo, Kluwer, 2011, 375 p.; T. VANSWEEVELT, "De Wet Medische Ongevallen: eindelijk de goede keer voor de no fault in België?", *T. Gez*. 2010-11, afl. 1, 2-3; T. VANSWEEVELT, "De Wet Medische Ongevallen", *T.Gez*. 2010-11, afl. 2, 84-134

qqq Bill of law regarding the compensation of damage resulting from healthcare, *Parl. St*. Kamer 2009-2010, 52-2240/001, p. 31

rrr T. VANSWEEVELT, "De Wet Medische Ongevallen", *T.Gez*. 2010-11, afl. 2, 84-134

sss *Parl. St*. Kamer 2009-2010, 2240/006, p. 27

5.2. No registration of reimbursed Ophtalmologic interventions in extramural eye surgery centers

To be eligible for reimbursement, interventions with a value equal to or exceeding K 120, N 200 or I 200 need to be practiced in a recognized hospital having at least a C or D service, except for circumstances beyond one's control. The respective interventions, however, can be practiced in extramural centers without any reimbursement of the obligatory health insurance.

A particular exception is foreseen if the architectural norms of a function surgical day hospital are respected[ttt] and if the operation is performed with local or topical anesthesia, without sedation and if no post-operative surveillance is required[uuu]. In application of this exception, cataract operations for instance can be performed extra muros. Physicians performing such interventions in extramural centers need to introduce a form indicating compliance with the criteria of a surgical day hospital as mentioned in the law.[vvv] The Belgian Working Group of Extramural Eye Surgery additionally asks all extramural eye surgery centers in Belgium to sign a declaration of conformity. In principle, the NIHDI can trace if the cataract operation took place in a hospital or in an extramural center via the reimbursed posts. Since the day care lump sum in extramural eye surgery centers is not reimbursed, identification of the type of setting is possible.

In the near future the traceability of implants will be enhanced[www]. All implants will have to be registered and an implant passport will be granted to the patient. This will also apply to implants used in extramural centers.

5.3. Several auto regulatory initiatives of health care professionals in the extramural eye surgery sector

5.3.1. Voluntary Certification and registration of extramural centers for opthalmology

Although extramural eye surgery centers do not have to comply with the legal recognition norms and other quality and safety norms applicable to hospitals, some clinics voluntarily obtain surgery room recognition certificates. The certificate guarantees compliance with norms predefined by the Belgian working group for extramural eye surgery. This working group was set up by the Belgian Society for Cataract and Refractive Surgeons, the Belgian professional association for ophthalmologists (BBO UPBMO) and the Ophthalmologic trade union (SOOS). The conformity assessment is carried out by an independent instance (ISS, accredited by the Belgian Accreditation Organisation BELAC) specialized in hygiene and expertise. The audit concerns architecture, equipment, sterility, personnel and responsibilities (checklist see Appendix 1). The criteria are different according to the interventions (intra ocular - eye lid - intravitreale injections (reimbursed by NIHDI), LASIK (not reimbursed by NIHDI). Currently, there is a list of certified clinics that is updated every 4 months (list see Appendix 2). This information is going to be published on a publicly accessible website.

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ttt articles 2 to 6 of the Royal Decree of 25 November 1997 regarding the definition of norms which the function "surgical day hospital" needs to comply with to be recognised, *B.S./M.B.* 5 December 1997

uuu art. 15 § 2 last section of the Royal Decree of 14 September 1984 on the nomenclature of medical interventions regarding the obligatory healthcare Insurance , *B.S./M.B.* 29 September 1984; Royal Decree of 16 February 2009 modifying art. 15, § 2, of the annex of the Royal Decree of 14 September 1984 on the nomenclature of medical interventions regarding the obligatory healthcare Insurance *B.S./M.B.* 16 March 2009

vvv According to personal communication of the NIHDI, this was never formalised however.

www See implantatenplan Onkelinx

5.3.2. Other voluntary quality initiatives

Apart from the norms that need to be complied with to obtain certification, norms are sometimes inserted in insurance contracts. Some insurers restrict reimbursement by complementary insurance of the costs of refractive eye surgery to interventions performed in certified clinics. Indirectly this has an impact on the non-certified centers. Yet, it has to be noted that not every citizen has a complementary insurance and thus will not necessarily experience the incentive to have an operation in a certified center.

The certification is sometimes a precondition for ophthalmologists working in an extramural eye surgery center to get a civil liability insurance. Other norms in civil liability insurance contracts of opthalmologists are for instance the compliance with the predefined minimal content of the medical patient file and the obligation for extramural eye surgery centers to notify their activities to the emergency department of a hospital.

6. THE NETHERLANDS AND DENMARK: SOURCES OF INSPIRATION?

The preceding sections highlighted the lack of a sound legal framework setting minimal criteria for quality and safety for extramural centers in Belgium. In the next section we zoom in to the models of the Netherlands and Denmark. These countries were selected as illustrative examples because they have a sound regulatory system in place for the guarantee for quality and safety of healthcare provided in extramural centers can serve as inspiring options.

6.1. The Netherlands

In the Dutch healthcare system, independent treatment centers (zelfstandige behandelcentra's – ZBC) and private clinics are two types of healthcare institutes where non-urgent care is provided (ZBCs and private clinics are also called "particuliere klinieken"). Independent treatment centers are institutions that are specialized in one type of care independent of hospitals. The centers provide day care by medical specialists. Their function is delivering non-acute care, for which the patient does not have to stay overnight. Some treatments provided in ZBCs are eligible for reimbursement by the statutory health insurance. ZBCs need a Wet Toelating Zorginstellingen (WTZi)-license to operate.

Private clinics are defined as treatment institutions without WTZi license that offer health care, for which costs cannot be claimed to the health insurance[xxx]. In 2011, the market share of the "particuliere klinieken" in curative care was about 2 % [yyy]. [25]

[xxx] art. 6 General Act Particular Medical Costs of 14 December 1967, *Staatsblad* 1967, nr. 617.

[yyy] Inspectie voor de Gezondheidszorg. *Het resultaat telt. Particuliere klinieken 2011, verbeterde kwaliteit, normontwikkeling komt op gang*. http://www.rijksoverheid.nl/documenten-en-publicaties/rapporten/2012/10/30/het-resultaat-telt-particuliere-klinieken-2011.html

6.1.1. General minimal framework on quality in care institutions: the "Quality Act"

The "Quality Act" is a general legal framework setting minimal quality norms for care establishments, included private clinics. According to the law, care establishments need to

- deliver qualitative care (verantwoorde zorg)
- ensure quality management
- set up a quality system
- and draft an annual report.

Care establishments are free to fill in these general quality norms. Professional and scientific associations have a major role in the elaboration of guidelines on the contents of those quality norms.

6.1.2. Registration of private clinics

Since 29 May 2010[zzz] private clinics and ZBCs are obliged to register in the Care register. The register is publicly accessible and contains the name, the address and the specialism.[aaaa] The register, however, does not contain any information on the quality of care offered in these clinics.

6.1.3. Inspection by "Inspectie voor de Gezondheidszorg"

The Dutch Healthcare Inspectorate (IGZ) is responsible for monitoring quality and safety in Dutch hospitals as well as in private clinics (and ZBCs). Each clinic needs to send the results of predefined quality indicators annually to the IGZ[bbbb]. Based on this information, clinics with the highest risk profile are selected for visitation. Tests at random are carried out at non selected centers. The results of the inspections are public. Furthermore the IGZ also analyses reported accidents in patient care.

There are two types of quality indicators: general quality indicators (e.g. availability of accreditation, severity of care, number of patients and treatments, etc.) for all institutes and particular indicators for specific interventions such as amongst others refractive eye surgery. These norms are integrated in an assessment tool for the inspection of private clinics. The norms included in this tool stem from legislation[cccc] and norms formulated by scientific associations. For instance, according to requirement to provide "verantwoorde zorg" as stated in the Kwaliteitswet Zorginstellingen "particuliere klinieken" are not allowed to perform surgery on patients with ASA class 3 or higher unless the clinic performs local anesthesia conform to the norms of the scientific association or in case of derma-surgival treatment.The concept of "verantwoorde zorg" is thus further interpreted by the IGZ. Additional norms are drafted by the IGZ for clinics in general and for clinics focusing at particular interventions, such as for instance clinics where refractive eye surgery is performed.[dddd][26] Furthermore there are separate norms for specific processes, e.g. preventions of infections, operative care processes, intensive care norms.

The inspection tool contains 13 topics on which private clinics are scored. General policy - Personnel and organization – Accessibility – Patients' rights - Care process - Quality management - Quality management professionals - Patient safety - Infection prevention policy - Pharmaceuticals policy - Medical devices - Building and facilities.

There are 4 possible scores: not available, available (but not respected or no specific operational procedures), operational (norms are respected, specific procedures to guarantee this), guaranteed (evaluation). Scores are based on conversations with the direction and representatives of the medical

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zzz art. 4b Act of 18 January 1996 regarding the quality of care institutions, *Staatscourant* 1996, nr. 185 (Kwaliteitswet zorginstellingen)

aaaa www. zorgregister.nl

bbbb http://www.igz.nl/onderwerpen/handhavingsinstrumenten/gefaseerd-toezicht/basissetiinsinsters/index.aspx

cccc De Kwaliteitswet zorginstellingen (Kwzi), de Wet op de beroepen in de individuele gezondheidszorg (Wet BIG), Wet Toelating Zorginstellingen (WTZi), de Wet op de geneeskundige behandelingsovereenkomst (WGBO), de Wet klachtrecht cliënten in de zorgsector (WKCZ), de Geneesmiddelenwet (Gnw) en de Wet op de medische hulpmiddelen (Wmh))

dddd Inspectie voor de Gezondheidzorg, *Report refractiechirurgie "Kwaliteit van behandeling in ooglaserklinieken meestal goed, maar infectiepreventie kan beter*", 2009

staff and assisting collaborators and on the available management documents and protocols.

If clinics do not comply with the requirements for qualitative care, follow –up visit are scheduled. If no or insufficient improvement was achieved, unplanned visits take place during a limited period. The ultimate sanction is an order for closure.

On the individual medical specialist level, quality control is implemented in the re-registration requirements. In order to get re-registered a specialist needs to participate to the visitation program organized by the respective scientific association of medical specialists.[eeee]

6.1.4. Particularities for refractive eye surgery

6.1.4.1. Setting

Refractive eye surgery is solely practiced in private clinics. In 2009, 41.202 refractive interventions were carried out in 46 clinics. In 2012, 28 (of 319 in total) were performing refractive eye surgery[ffff].

6.1.4.2. Quality assurance

The Nederlands Oogheelkundig Gezelschap (NOG) checks via a peer visitation whether a refractive surgeon complies with their predefined norms (consensus guideline). The visitation is organized on a voluntary basis, every three years. Names of accredited refractive surgeons are published on the NOG website. [gggg]
The consensus guideline describes;

- The indications for refractive eye surgery
- Basic requirements for result- and complication registration
- Requirements for effective and safe treatment of patients
- Basic requirements for training and registration of the opthamologist:

Refractive eye surgery needs to be performed by an ophthalmologist

- having a BIG registration
- enrolled in the register of the Medical Specialist Registration Commission Member of the NOG
- having sufficient accreditation points in the scope of post graduation training
- having followed training in theory and treatment of the procedure, post operative care and the knowledge and treatment of complications of refractive eye surgery
- furthermore practical training is required. Opthalmologists need to assist to refractive eye surgery procedure performed by another ophthalmologist.
- they need to have performed at least 10 refractive eye surgical interventions, pre- and postcare included, under supervision of a NOG accredited and registered supervisor
- having a NOG registration
- being visited once every 3 years by the NOG visitation commission
- updating knowledge by literature and post graduate training.

In addition there is an accreditation by the association Zelfstandige Klinieken Nederland (ZKN http://www.zkn.nl/consumenten/over-zkn/). The quality and professionalism of the medical personnel, the intake and the treatment, safety of the apparatus, infection prevention, waiting times, after care and patient satisfaction are checked.
If a refractive surgeon has a positive evaluation by the NOG and an accreditation is granted to the clinic, this is considered by IGZ as compliance with the requirement for qualitative care (verantwoorde zorg) as set in the

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[eeee] Decision of 9 February 2004 regarding the general requirements for training, registration and reregistration of medical specialists en for the recognition of trainers, replacing trainers, training coaches and training institutes, *Staatscourant* of 14 December 2004, nr. 241.

[ffff] Personal communication IGZ

[gggg] Nederlands Oogheelkundig Gezelschap: http://www.oogheelkunde.org/uploads/f8/jd/f8jdmH5zMSIhhDpxtedKKg/gecertificeerde-refractiechirurgen-APRIL-2013.pdf

Quality Act. IGZ additionally checks the lasers (production year, last validation report, last maintenance report).[hhhh] [27]

A global overview of the results can be found on the IGZ website[iiii].

6.2. Denmark

The majority of the hospitals in Denmark are owned and financed by the regions. In 2010, there were 19 405 beds, 95% of which were located in publicly owned hospitals. In 2010 there were 401 beds in for profit privately owned hospitals. Measured in production value, private hospitals constituted 2.2% of the total hospital activity in 2010, compared with 1.1% in 2006. In the same period, the number of private hospitals and clinics with registered activity rose from 175 to 249, corresponding to a 42% increase[jjjj].[28]

6.2.1. Registration of private clinics

Private clinics need an authorization to operate and from 1 October 2011 registration at the Danish Health and Medicines Authorities is required[kkkk]. This register is public and not only contains the identification data, but also the supervision report from the inspection visits. So far, approximately 1000 clinics are registered in 4 categories: a) Clinics/hospitals with beds, b) Clinics no beds, more than one doctor, c) Clinics no beds, one full time doctor, d) Clinics no beds, one doctor not full time.

6.2.2. Inspection

The regional Public Health Medical Officers conducts the supervision in a 3 year cycle. Inspection can also be reactive if there were complaints or information about concrete events or concerns (e.g. if there was a disproportionate amount of registered complications). The evaluation is based on predefined criteria on hygiene, medication management, post operation surveillance, aftercare, complication and emergency management, medication error and medication storage management, etc. developed by the Danish Health and Medicines Authorities for every medical specialization. The professional organizations have been invited to participate and have done so actively.

If standards are not in place in a clinic this is reported in the results, which are made publically available on Danish Health and Medicines Authorities' homepage. If the clinic fails to improve to acceptable standards, re-visit takes place, which costs a considerable fee for the clinic (2250 euro). Once the clinic has reached the required standard this is reported in the published report. Furthermore, if the inspection visits reveal problems with specific doctors, standard sanctions such as for instance intensified supervision, mandatory change of professional performance, restriction in registration and revocation of registration can be imposed.

6.2.3. List of Physicians – "bad performers"

Complaints on physicians' interventions are listed by name on the website of the Danish Health and Medicines Authorities. The complaint is only listed if confirmed malpractice took place.

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hhhh Inspectie voor de Gezondheidszorg. *Basisset risico-indicatoren particuliere klinieken 2013*: http://www.igz.nl/Images/2012-08-16%20IGZ%20basisset%20particuliere%20klinieken%202012_tcm294-332426.pdf p. 37

iiii Inspectie voor de Gezondheidszorg. *Het resultaat telt. Particuliere klinieken 2011, verbeterde kwaliteit, normontwikkeling komt op gang*, http://www.rijksoverheid.nl/documenten-en-publicaties/rapporten/2012/10/30/het-resultaat-telt-particuliere-klinieken-2011.html

jjjj Siciliani, L., M. Borowitz and V. Moran(eds.) (2013),Waiting Time Policies in the Health Sector: What Works?, OECD Health Policy Studies, OECD Publishing.doi: 10.1787/9789264179080-en; National Board of Health, 2011

kkkk Danish Health and Medicines Authority. http://www.sst.dk/Tilsyn%20og%20patientsikkerhed/Private%20behandlingsteder.aspx

6.2.4. Particularities for refractive eye surgery

6.2.4.1. Setting

Refractive eye surgery is performed in public and private hospitals as well as in private clinics. Currently 169 extramural eye surgery centers are registered.

6.2.4.2. Additional requirements for refractive eye surgery

There are specific documentation requirements for refractive eye surgery
An assessment of visual acuity in both eyes, indicating the optimal refraction, has to be performed and documented in the patient journal. When an indication is for correction present it needs to be stated whether the patient wish to avoid glasses, whether the patient is a case of refractions anomaly where the use of glasses / contact lenses is not possible, or whether there is an economic/work-related threat to the use of glasses.
It has to be stated in the patient file that the patient is informed about the following:

- There is no guarantee that the sight will get better after surgery
- In 1-2 % of the patients the sight will get significantly worse after the surgery
- There is a risk of reduced night vision
- There is a risk of getting dry eyes
- It is very likely that the patient at a later stage will need reading glasses because of presbyopia

The assessment of this norm is dichotomous (fulfilled or not fulfilled). The clinic will get “fulfilled” if stated in all patient cases, otherwise “not fulfilled”.

Keypoints

- **In Belgium, the number of extramural centers, the number and the character of the interventions and physicians practising in extramural centers is a black box.**
- **Today many legal guarantees for quality and safety for healthcare interventions in hospitals do not apply to healthcare provided in extramural centers. This does not imply that extramural centers operate in a legal vacuum. General rules such as regulations related to fire prevention or environmental regulations with regard to sewage apply. Moreover medical devices used in these centers need to be CE marked and ISO norms are available for medical devices or systems such as for instance airflow systems in operation rooms. Health care professionals working in extramural centers need to comply with general rules linked to the exercise of the profession such as patients’ rights, duties included in the deontological code, the Royal Decree concerning the exercise of health care professions and the law on processing of personal data. Furthermore general civil and criminal liability rules apply to extramural centers as well as to the health care professionals working there.**
- **The general legal framework applying to extramural centers and the physicians working there offers certain guarantees for quality and safety of care in extramural centers but compliance can only be verified posterior to the intervention, i.e. when potential harm has already been caused to the patient. Furthermore, some general rules are solely further elaborated for the hospital setting (e.g. central liability, minimal content of the patient file).**

- **Quality and safety requirements have been drafted and certification of extramural centers where refractive eye surgery takes place was set up by initiatives of professionals. There is no legal obligation, however, to satisfy therequirements or to get a certification to operate and the value of the certification is not internationally guaranteed. Yet, the currently existing quality and safety requirements in extramural centers can serve as a valuable input for the interpretation and specification of possible future legal norms.**
- **Patients having occurred an injury by a medical accident have two ways of recourse. They can choose to appeal to the health care professional's civil liability before court. They can also ask for advice to the Medical Accidents Fund on the liability and on the gravity of the harm. Medical accidents without liability having caused damage with a certain gravity are eligible for compensation by this fund. Patients suffering from injuries caused by aesthetic medical interventions that are not reimbursed by the NIHDI cannot benefit from the latter option.**
- **Other advantages, such as the hospitals' central liability, facilitating for the patient who to direct the claim at are not applicable for patients suffered harm due to an intervention in an extramural center. There are voluntary initiatives of health care professionals to include the central liability in the insurance contracts of the respective extramural center.**
- **In countries such as the Netherlands and Denmark extramural centers have to register and comply with predefined norms regarding safety and quality. The professional organizations are involved in the elaboration of the specialism- specific norms. Visitations are organised to control the conformity.**

7. OPTIONS TO REGULATE QUALITY AND SAFETY OF HEALTHCARE IN EXTRAMURAL CENTERS IN BELGIUM

The sole existence of general rules and regulations of the field is insufficient to guarantee qualitative care in all extramural centers. In the following section some options to regulate quality and safety in extramural centers clinics are be presented and discussed. At the time of writing some initiatives are pending. The report reflects the state of affairs in June2014.

7.1. Powers of the Federal State and the Communities

In the past, some attempts have been made to create a framework for safe health care in extramural centers. A bill, based on the French model (for details on this model see report KCE on plastic surgery[llll])[29] was proposed to submit extramural centers to certain registration requirements and in some cases an obligation to have a license[mmmm]. Moreover a number of architectural, organizational and functional obligations are inserted.

According to the bill proposal, invasive cosmetic interventions can solely be performed in institutes complying with particular norms. Invasive cosmetic interventions are defined as interventions where the skin or the mucous is cut or punctured for purely cosmetic reasons.

The interventions are categorized according to the type of anesthesia. For each category, norms regarding the obligatory availability of pharmaceuticals, the medical equipment, the characteristics of the place where the interventions is performed and the personnel is defined in general wording. The institutes where these interventions take place need to be registered with the Federal Public Service Public Health. The institutes where the 2 most invasive categories of interventions are carried out need a license awarded after a visitation by the Community.

[llll] K. De Gauquier, A. Senn, L. Kohn, I. Vinck. Internationale vergelijking van terugbetalingsregels en juridische aspecten van plastische heelkunde. Health Services Research (HSR). Brussel: Federaal Kenniscentrum voor de Gezondheidszorg (KCE). 2008-07-14. KCE Reports 83A. wettelijk depot D/2008/10.273/43

[mmmm] Bill of law regarding the regulation of institutions outside the hospitals where invasive aesthetic interventions take place, *Parl. St.* Senaat 2010, 5-63.

The Council of State commented extensively on the issue of competences of the Federal Government and the Communities in this matter[nnnn]. In principle, the Communities are competent for policy setting of health care provision in and outside the care institutes.[oooo] An exception to this general rule regards the regulations regarding the basic legislation for hospitals such as Hospital Law or basic regulations regarding care institutions aiming at the preventions or diminishing of hospital stays (organieke wetgeving) which remains to the competence of the Federal Government.[pppp] The Council of State concluded, however, that the regulation of care institutions having no link or a non-binding link to hospitals cannot be considered as an application of this exception. Another relevant exception could have been the federal government's competence to set national recognition norms[qqqq] but as these need to relate to financing of the exploitation, healthcare insurance or the basic rules regarding the programming and the financing of the infrastructure, which is not the case in the bill, this exception does not apply either. The Council of State concluded that in order to fall within the federal government's competence, the bill needs to be reformulated in terms of obligations for health care professionals exercising medicine outside a hospital rather than in terms of obligations for the health care institutes. As such the federal government would also competent to control these obligations and to regulate their registration or license.

In 2012 the Flemish Community issued a Decree based on which institutions (or the responsible person of the institution) in the Flemish region or in the Brussels region falling within the competence of the Flemish Community, except for the recognized hospitals, where a risky medical intervention is performed, needed to declare to the ""Vlaams Agentschap Zorg en Gezondheid" which persons carry out the interventions, the character of the interventions and the measures taken to guarantee the quality of care and the safety of the patient. Depending on the character of the risky intervention, the respective institutes could be submitted to an external quality control. In an advice on the bill decree, the Council of State clarified that the communities are competent for the non-medical issues such as the setting of the framework and the non-medical prerequisites (e.g. reception, relation with non- medical professionals, the patient file as far as non-medical).[rrrr] The definition of quality and safety requirements, as foreseen in the bill decree, implied, according to the Council of State that obligations related to the practice of medicine were imposed to the health care professionals which would imply that the competence of the Federal government regarding the regulation of the practice of medicine would be overridden. The decree has been annulled by the Constitutional Court.[ssss]

The federal state remains competent for the regulation of the practice of medicine, even though the powers to organise primary health care, the support of the primary care professionals and the recognition of health care professionals within the boundaries of the recognition norms defined by the federal state are allocated to the Communities due to the sixth state reform. The Communities are also competent for setting the quota of the respective health care professionals, taking into account the global quantity that can be set per community for the access of each of the health care professions. Furthermore, due to the 6th state reform the Communities will be – on top of the existing powers – be competent to define the norms hospitals and the services (including the psychiatric hospitals and the psychiatric divisions in a general hospital), the care programs, the hospital services, etc. will have to comply with to be recognised. It concerns the recognition as defined in art. 66 and following of the Hospital law. Hereto the exception f) article 5, §

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nnnn Advice n°49.795/VR/3 Council of State of 28 June 2011 related to the bill decree regarding the obligatory notification of risky medical interventions, *Parl. St.* Senaat 2010-2011, 5-62/2, p. 7

oooo Art. 5, §1, I, 1° Special Law of 8 August 1980 regarding the reform of the institutions, *B.S./M.B.* 15 August 1980

pppp Art. 5, §1, I, 1°, a) Special Law of 8 August 1980 regarding the reform of the institutions, *B.S./M.B.* 15 August 1980

qqqq Art. 5, §1, I, 1°, f) Special Law of 8 August 1980 regarding the reform of the institutions, *B.S./M.B.* 15 August 1980

rrrr Advice Council of State n° 49/739/VR of 28 June 2011 related to the bill decree regarding the obligatory notification of risky medical interventions, *Parl. St.* Vl. Parl. 2011-2012, 1568/1; see also 2nd advice on the same bill decree confirming this position Advice Council of State n° 50.825/3 of 24 Januari 2012, *Parl. St.* Vl. Parl. 2011-2012, 1568/1

ssss Constitutional Court, 19 December 2013, nr. 170/2013 http://www.const-court.be/public/n/2013/2013-170n.pdf

1, I, 1°, of the special law of 8 August 1980 was abrogated. Consequently the Communities are competent for the matters included the texts enumerated in the explanation of article 6 of the bill of law of the special law regarding the sixth state reform.[tttt] The Communities need to respect the organic federal legislation and the federally defined programming criteria. Furthermore the financing of the hospitals, except A1 (budget for the construction and renovation of the hospitals) and A3 (investment costs for heavy medical equipment (MRI, PET-scan, radiotherapy) of the budget financial means, as well as the rules related to the definition and the calculation of the budget financial means of the hospitals remains the competence of the federal government. Yet, a procedure to evaluate the impact of draft legislation related to the definition of recognition norms or hospitals and the services, the care programs and hospital functions on the budget of the federal government and social security is foreseen and if necessary a veto can be imposed by the competent federal minister or by the council of ministers.[uuuu]

7.2. Minimal framework of quality and safety norms for health care professionals providing care intra and/or extra muros in the pipeline?

As mentioned earlier, at the moment of the writing of this report a bill of law regarding practice in healthcare has been approved by the Council of Ministers (dd. 25 April 2014) and advice of the Council of State is foreseen by the 7th of July 2014 (expiration date). The idea is to create a minimal framework for quality and safety of medical practice. As the federal government is not competent to extend the quality norms for hospitals to extramural settings, quality and safety requirements need to be linked to the federal government's competence to regulate the exercise of medicine. In the draft bill quality– and safety requirements are elaborated according to the potential risks related to the diagnostic and/or therapeutic interventions (general quality norms and quality norms for surgical interventions). The norms are applicable to the respective health care professionals, regardless the setting they work in. The general requirements and norms relate to the expertise and experience of the health care professional, particular requirements for interventions with anxiolysis, hypnose or anaesthesia, the assistance of the necessary personnel, continuity of care, sanitary requirements, electronic data exchange, use of evidence based information distribution and storage of pharmaceuticals and medical devices. Furthermore, based on the character of the invention and the patient characteristics the draft bill limits some interventions to the hospital setting.

Particular safety requirements are set for healthcare professionals performing surgery; these relate to collaboration with a hospital for the organisation of urgency care, modalities of the information duty and informed consent, the quality framework the professional works in, internal and external ad hoc quality control by peers and registration of general information regarding individual health care professionals, the setting they work in and the character of the interventions. In order to be registered, accreditation by an accreditation instance is necessary. It should be noted that the bill foresees the disposition regarding the requirement of accreditation prior to the registration is foreseen to enter into force by the 1st of January 2020.

In the bill of law the responsibility to perform medical interventions in a "safe and qualitative" environment remains with the healthcare professional, as the federal government is not competent to transfer the hospital recognition norms to extramural centers. For the hospitals, technical and sanitary norms are incorporated in the recognition norms (in addition to the generic legislation regarding quality and safety as for instance Vlarem legislation). The recognition norms for hospitals do not apply to the extramural centers, however. This may lead to legal uncertainty for the physician since it is not clear whether the same medical intervention performed in a hospital or in an extramural center needs to comply with the same minimal requirements for quality and safety. Turned otherwise, it can be questioned whether the safety and quality requirements included in the hospital recognition norms will implicitly be considered as the standard for medical interventions in another setting, which is a particularly important question when judging the physician's eventual liability. Furthermore, the bill of law foresees an external quality assessment by peers. It is not clear, however, who will draft the quality and safety requirements for this assessment or to what extent

[tttt] Bill of law of the special law regarding the sixth state reform, *Parl. St.* Senaat, 2012-2013, 5 - 2232/1, p. 28

[uuuu] Special law of 6 January 2014 regarding the sixth state reform, *B.S./M.B.* 31 January 2014

these will be similar or relate to the quality and safety requirements included in the hospital recognition norms. The advice of the Council of State will probably clarify several issues.

It was also noted in the explanatory memorandum of the bill that it is not obvious for health care professionals who work as an employee or statutory at the hospital (or an extramural center) to force the hospital managers to guarantee the sanitary and technical requirements. Since the health care professionals are considered to verify whether they practice in a qualitative and safe environment hospital, they are supposed to discuss lacking or insufficient technical or sanitary conditions with the hospital manager and if necessary they need to refuse to perform the medical intervention. This issue also seems difficult when the health care professional is at the same time the manager of the care setting, for instance an extramural center.

7.3. Other options

7.3.1. Recognition of the extramural centers

An option to regulate extramural centers could be to recognise these centers, by granting them a license to operate. The recognition should be specific to the practice profile of the extramural center. For the definition of the recognition norms for the centers, collaboration between the Communities and the Federal State is primordial to avoid discussions regarding their respective competences, especially when these norms also relate to the practice of medicine. The currently existing norms for quality and safety in extramural centers drafted by the professional associations can serve as a valuable input for the interpretation and specification of the general as well as the specialty-specific norms. The supervision of these norms (e.g. by visitations) can be organized in a systematic and cyclic way as well as in a reactive (based on ad hoc complaints) way. It would be also worthwhile, to consider to what extent the existing autoregulation, such as for instance in the example of the accreditation model of refractive eye surgery (cfr. supra) could complement the supervision activities.

7.3.2. Extension of the criteria to maintain recognition status of health care professionals with quality and safety requirements for medical practice

Today the exercise of medicine is submitted to recognition by the federal government. General and specialty-specific recognition norms are set to obtain as well as to maintain the recognition status of health care professionals. Currently, several quality criteria are already included in the criteria to maintain recognition. For general practitioners for instance, the participation to the organized after-hours duty, the guarantee for continuity and duties regarding the patient file are inserted as criteria to maintain recognition.[vvvv]

In line with this practice additional general as well as specific quality and safety norms related to the character of the medical activities (e.g. surgery) could be inserted as criteria to maintain recognition of the health care professionals. This option requires the elaboration of the consequences of the non-compliance with the recognition norms and criteria for the re-recognition after possible withdrawal.

The advantage of this solution (compared with the option of the bill regarding practice in healthcare) is that the creation of supplementary control mechanisms (as is proposed in this) is avoided as the existing control mechanism related to the (maintenance of) recognition of health care professionals could be used. Due to the sixth state reform, the control of the recognition norms set by the federal government and the granting of the recognition belongs to the competence of the communities.[wwww] It has to be noted, however, that the competence of the federal government to regulate the practice of medicine is larger than the definition of recognition norms and also enhances for instance the regulation of patients' rights,…

[vvvv] Ministerial Decree of 1 March 2010 regarding the definition of recognition criteria for general practitioners, *B.S./M.B.* 4 March 2010

[wwww] Art. 6 Special Law of 6 January 2014 related to the Sixth State Reform, *B.S./M.B* 31 January 2014

7.4. Does the regulation of extramural centers imply public financing?

7.4.1. Reimbursement often linked to hospital setting - no financing of operational costs in extramural centers

In order to avoid costs for the health insurance related to unnecessary hospital admissions, an entitled patient can be admitted to a hospital, if it is not possible to diagnose, apply a therapy or isolate an infectious disease.[xxxx] Yet, reimbursement of invasive interventions by the compulsory health insurance is legally by large linked to the hospital setting, in the idea of safeguarding quality and safety. To be eligible for reimbursement, interventions with a value equal to or exceeding K 120, N 200 or I 200 need to be practiced in a recognized hospital having at least a C or D service, except for circumstances beyond one's control. For some interventions, a particular exception is foreseen[yyyy]. If the architectural norms of a function surgical day hospital are respected[zzzz] and if the operation is performed with local or topical anaesthesia, without sedation and if no post-operative surveillance is required, the intervention can be performed extra muros.[aaaaa] In application of this disposition, cataract operations can be performed extra muros (see table 1). It would be possible for the NIDHI to identify the number of cataract operations in the different settings because the posts that were reimbursed to each setting differ. One report from the independent sickness Fund suggested different costs according to the setting, with lower prices for extra-muros interventions.[bbbbb][31] The difference between in hospital care and the intervention extra muros is mainly caused by the absence of financing for the operational costs[ccccc] in extramural centers, in contrast with public or private not for profit hospitals. The patient day price covering the working cost of an extramural center is directly charged to the patient and can legally be freely set. A maximum tariff has been set, however, in a convention between several private insurers covering costs as part of a complementary health insurance and the Werkgroep Extramurale Oogheelkunde.[ddddd]
Still the comparison between intervention prices in the different settings is not relevant. First the profile of the patients may vary between hospitals and extra-muros settings. Second the price of ambulatory care before or after the intervention (biology, anesthesist consultation) is not included in the costs calculation.

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xxxx art. 7 §1 Order of 28 July 2003 executing article 22, 11° of the Law related to the compulsory health insurance for medical care and reimbursements, coordinated 14 July 1994, *B.S./M.B*. 29 August 2003

yyyy art. 15 § 2 last section of the Royal Decree of 16 February 2009 modifying art. 15 § 2 of the annex of Royal Decree of 14 September 1984 on the nomenclature of medical interventions regarding the obligatory healthcare Insurance , *B.S./M.B.* 16 March 2009

zzzz articles 2 to 6 Royal Decree of 25 November 1997 regarding the definition of norms which the function "surgical day hospital" needs to comply with to be recognised, *B.S./M.B.* 5 December 1997

aaaaa Royal Decree of 16 February 2009 modifying art. 15 § 2 last section of the Royal Decree of 14 September 1984 on the nomenclature of medical interventions regarding the obligatory healthcare Insurance *B.S./M.B.*. 16 March 2009

bbbbb R. Van Tielen en I. Umbach, Opération de la Cataracte. La chirurgie extra hopitalière: une troisièmre voie défendable?, Health Forum Décembre 2012, n° 12, p. 22-23

ccccc Operational costs include amongst others the day price, utilities, consumables, intensive care, emergency department, the continuity of care during night and day, costs for infrastructure….

ddddd If these tariffs are not respected by certified extramural ophthalmologic centers (cfr. supra) reimbursement of the intervention performed in the respective center to the patient by the complementary health insurance can (after current reminders) be refused. Indirectly this also impacts the center. There is, however, no legal sanction if those tariffs were not respected.

Table 1 – Fractions in extramural centre (EM) for conventional (246595) and US/Laser cataract surgery (246912), 2010-2012

	Fiscal years		
	2010	2011	2012
Care site **Case 246912**			
Extramural	1.280	1.763	2.547
Intramural	103.507	106.745	112.017
Fraction EM	**1,22%**	**1,62%**	**2,22%**
Care site **Cases 246595**			
Extramural	23	89	105
Intramural	442	565	559
Fraction EM	**4,95%**	**13,61%**	**15,81%**
Subtotals			
Extramural	1.303	1.852	2.652
Intramural	103.949	107.310	112.576
Fraction EM	**1,24%**	**1,70%**	**2,30%**

source: Doc P – RIZIV-INAMI

7.4.2. The EU State Aid rules

It can be questioned whether public financing of the operational cost in public or private not for profit hospitals for interventions that are reimbursed by the NIHDI (such as ophthalmologic interventions e.g. cataract) whereas it is not if the intervention is performed in an extramural center can be justified if the same minimum requirements for quality and safety would be set. Even if the minimum requirements will not be formulated as norms that need to be accomplished to get financing from the federal government, such as in the hospital law and even if quality and safety norms will be linked to the practice of the healthcare professional instead of the establishment, there will be some overlap with the existing norms for hospitals.

The EC Treaty prohibits any aid that distorts or threatens to distort competition in the common market (Article 107(1) TFEU). Based on this, the State aid rules generally only apply where the recipient of an aid is an "undertaking". As health care is (usually) provided for economic consideration, doctors and other health care providers (such as public and private hospitals and extramural centers) are engaged in economic

activities.[eeeee] The Treaty allows some exceptions where the proposed aid may have a beneficial impact in overall Union terms. State aid measures can sometimes be effective tools for achieving objectives of common interest such as services of general economic interest (SGEI) defined in EU competition law as economic activities that public authorities identify as being of particular importance to citizens and that would not be supplied (or would be supplied under different conditions) if there were no public intervention. Medical interventions can be considered as services of general economic interest[fffff].

The European Commission is entrusted with the task to control state aid, which is fundamentally about balancing whether the presumed advantages for the common interest outweigh the negative effect of the distortion of competition. Basically, the legality of SGEI is tested based on necessity and proportionality. The State Aid SGEI package consists of four instruments applicable to all authorities (national, regional, local) to assess whether compensation for SGEI granted by those authorities can be considered as illegal state aid.[ggggg] Without going into a sound analysis of all applicable instruments, we will focus on the core requirements of transparency and proportionality of the compensation that are reflected in several instruments. According to the Altmark criteria, for instance, based on which the granting of an advantage can be excluded, the recipient undertaking must actually have public service obligations to discharge, the obligations must be clearly defined and the parameters on the basis of which the compensation is calculated must be established in advance in an objective and transparent manner.[hhhhh] One of the compatibility conditions of the Decision is that the compensation must not exceed what is necessary to cover the costs incurred in discharging the public service obligations including a reasonable profit; a calculation of all costs as well as any kind of revenue received is necessary to this end.

7.4.3. Need for transparency in the Budget Financial Means

According to art. 2 Hospital law, hospitals have a mission to fulfill services of general interest. It is doubtful, however, if this notion is sufficiently well described. According to the Commission the act of entrustment has to specify the nature and duration of the public service obligations, the entities entrusted with the provision of the services, the parameters for calculating the compensation and the safeguards to avoid overcompensation. Furthermore it was also specified that the act of entrustment must allow the correct allocation of costs between the SGEI and non-SGEI activities which the service provider may offer.[iiiii] In the definition of the notion of hospital, the

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eeeee See Joined Cases C-180-184/98, Pavlov [2000] *ECR* I-6451 and case C-475/99, Ambulanz Glöckner [2001]*ECR* I-8089

fffff NN54/2009 Financing of public hospitals of IRIS network in the region Brussels-Capital, *JOCE* C/74/2010, Arrest van 12 juli 2001 in zaak C-157/99, Smits en Peerbooms, *Jurispr*. 2001, blz. I-5473, punt 53, arrest van 31 januari 1984 in gevoegde zaken 286/82 en 26/83, Luisi en Carbone, *Jurispr*. 1984, p. 377, punt 16; arrest van 4 oktober 1991 in zaak C-159/90, Society for the Protection of unborn children (IVG), *Jurispr*. 1999, p. I-4685, punt 18; Arrest van 12 juli 2001 in zaak C-368/98, Abdon Vanbraekel, *Jurispr.* 2001, blz. I-5363, punt 43; arrest van 11 juli 2007 in zaak T-167/04, Asklepios Kliniken, *Jurispr*. 2007, p. II-2379, punten 49-55.

ggggg European Commission staff working document. Guide to the application of the European Union rules on state aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest of 29 April 2013 SWD(2013) 53 final/2 http://ec.europa.eu/competition/state_aid/overview/new_guide_eu_rules_procurement_en.pdf. The Decision block exempts public service compensation from notification. The Framework sets the rules for the compatibility check of public service compensation for large commercial SGEI that do not fall under the scope of the Decision, and thus have to be notified to and assessed by the Commission. The Framework sets the rules for the compatibility check of public service compensation for large commercial SGEI that do not fall under the scope of the Decision, and thus have to be notified to and assessed by the Commission.

hhhhh Case C-280/00 Altmark Trans [2003] ECR I-7747, paragraph 87 to 95. The Commission spelt out these conditions in its Communication on the application of the EU State aid rules to compensation granted for the provision of services of general economic interest, *O.J.* C 8, 11.01.2012, p. 4

iiiii European Commission staff working document. Guide to the application of the European Union rules on state aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest of 29 April 2013 SWD(2013) 53 final/2, p. 44

aspects of continuity of care (after hours and emergency care), multidisciplinarity and the possibility to stay overnight, in particular are not available in extramural centers. The compensation for these services in hospitals is included in the Budget Financial Means (BFM). Today, it is not feasible, however, to differentiate these different aspects in the BFM and to calculate the amounts that were granted for each element. Furthermore, other aspects such as the obligation to accept all patients render a sound assessment of the appropriateness of compensation for medical services in public or private not for profit hospitals difficult. In the past, the European Court of Justice (ECJ) had to judge a few times on the topic of state aid for hospitals[jjjjj]. Based on these cases, it must be noted that so far the ECJ has not delivered a judgment that clearly settled disputes resulting from tensions between health care objectives and state aid. Nevertheless, anticipating to this, it is important that the national legislator clearly designates the missions of hospitals and the parameters for the calculation of the amounts granted for the compensation of these missions in a clear and transparent way.[kkkkk][32] This might imply a change in Belgian hospital financing rules since today parameters to calculate appropriate compensation for the different missions reflecting SGEI of hospitals are not available.

8. IMPACT OF THE PRACTICE OF CARE IN EXTRAMURAL CENTERS ON THE PUBLIC HEALTHCARE SYSTEM

Apart from the concern for ensured quality and safety of care for the individual patient in extramural centers, the practice in extramural centers may have implications on the organization of health care on the macro level.

In the next sections the impact of care provision in extramural centers on the public health care sector is addressed.

8.1. Financial accessibility: those willing to pay, pay non urgent care

Some interventions are eligible for reimbursement regardless whether they are carried out intra or extra muros (cfr. supra). There is no difference in the reimbursement tariff according to the setting where the interventions took place. The price paid by the patient can differ, however. Some doctors are partly conventioned and charge for instance the conventional tariff when working in a recognized hospital and their proper tariff at the extramural center.

For interventions that are not eligible for reimbursement, tariff setting is free, independent of the setting. The patient day price covering the working cost of an extramural center is directly charged to the patient and can legally be freely set. In general there is no price guarantee for the patient. Today policy does not intend to build a parallel system of private health care provision available to those with a better ability to pay. Extramural centers mainly provide aesthetic, non-urgent care, for those who are willing to pay for it. Although financial accessibility for patients in need of urgent or curative care

jjjjj Case T-167/04, Asklepios Klinken v Commission [2007] ECR II-2379, European Commission, Decision 28.10.2009, NN 54/2009 Financing of public hospitals of IRIS network in the region Brussels-Capital, *Official Journal* C/74/2010 (http://ec.europa.eu/competition/elojade/isef/case_details.cfm?proc_code=3_nn54_2009),

kkkkk J.W. Van de Gronden, "Financing Health Care in EU Law: Do the European State Aid Rules Write Out an Effective Prescription for Integrating Competition Law with Health Care?", *The Competition Law Review* 2009, Volume 6 Issue 1 pp 5-29 http://www.clasf.org/CompLRev/Issues/Vol6Issue1Article1vandeGronden.pdf;

is not immediately at risk, there are indirect drawbacks for patient care in public and private not for profit hospitals.

8.2. Continuity of care: risk for brain drain and no after hours for patients

Extramural centers are particularly attractive for some medical specialties. Most of the interventions in extramural centers allow a time schedule from 9 to 5, and after-hours duty or duty during weekends is sometimes not included. Moreover, specialists in extramural centers can make more money than in recognized hospitals. As often solely the best patients (in terms of severity of the illness and co-morbidities) are selected, the working costs are predictable and there is hardly compensation of the more expensive patients by the less expensive ones. Moreover, the predictability of the patient populations limits the risk for budgetary deficits. Physicians' contributions to such deficit will thus be limited or non-existing. Free tariff setting allows even more profit.

These advantages may lead to a brain drain to extramural centers of some medical specialties. Some specialists opt to work exclusively in a extramural center, others combine salaried, public (or private not for profit) sector clinical work with a fee for service private clientele.

This may lead to a shortage of these specialties in recognized hospitals. This may be more problematic for those disciplines where there is already a shortage of specialists and where the number of specialists in training does not cover the need. For the near future there does not seem to be a shortage of ophthalmologists in terms of number of graduating students. However, the attractivity of the options extra muros for this specialty and the increasing feminization of the specialty may have an impact on the availability of manpower in hospitals.[IIIII]

The possible brain drain is not limited to the medical specialists. Paramedical personnel working in extramural centers may also be attracted by the advantageous working hours and the salary.

8.3. Risk for risk selection

Extramural centers are often owned by physicians that also work in a recognized hospital. Competition problems can arise if the services offered in the recognized hospital are similar to those offered in the private practice or the extramural center. Mostly physicians decide on the referral of patients. Some physicians may take the opportunity to refer the most favourable patients to the extramural center. If the number of extramural centers grows, a possible consequence is that recognized hospitals will have to treat patients with a heavier pathology; patients in need of medical help after 5 pm, or those suffering from complications due medical interventions performed in extramural centers. Since these hospitals loose the more advantageous patients, there will be no longer any compensation for the heavier pathologies which may lead to financial losses. As today there is no registration of interventions performed in extramural centers, the magnitude of the above-mentioned potential problems cannot be estimated.

[IIIII] J. Pauwels et. Al. Naar een geneeskunde met kantooruren? Voorstellen voor het waarborgen van de continuïteit van acute zorg. Zorgnet Vlaanderen 2012, p. 29

9. OPTIONS TO REGULATE PRACTICE IN EXTRAMURAL CENTERS?

In the next section possible options to rationalize health care provision in extramural centers and the possible brain drain are discussed on a macro level. Then the possible conformity with EU law of this kind of restrictions is addressed.

9.1. Listing the interventions that obligatory need to be performed in recognized hospitals?

Today there is no regulation on which interventions can be practiced intra- or extra muros. Even interventions requiring sedation can in principle be practiced extra muros. Via the reimbursement regulations, an attempt has been made by limiting "more invasive" interventions to the hospital setting. To be eligible for reimbursement, interventions with a value equal to or exceeding K 120, N 200 or I 200 need to be practiced in a recognized hospital having at least a C or D service, except for circumstances beyond one's control. The respective interventions, however, can be practiced in extramural centers without any reimbursement of the obligatory health insurance. Furthermore, as the above mentioned disposition was never updated according to newer techniques of sedation, the rule does not completely achieve its initial intention. For interventions that are not eligible for reimbursement by the obligatory health insurance a possible solution to rationalize their delivery in extramural centers could be brought by Article 81 of the Hospital Law, as mentioned earlier. Pursuant to this article, it is possible to define by Royal Decree which kind of health care has to be delivered within hospitals (as defined by the Hospital Act i.e. excluding extramural centers) and, conversely, which care can be delivered outside hospitals. In the past, several attempts to draw up such a list have been made by the working group within the National Council of Hospital Services. They concluded, however, that it was impossible to do so because of the fast evolution of medical techniques and the continuous stream of new techniques[mmmmm]. It could be an option, however, to exclude some interventions from the extramural setting based on the risk for complications for which a specialized approach is necessary. In the Netherlands risk selection of patients is amongst others done based on the ASA class and BMI. Patients with ASA class superior to 3 and patients with BMI ≥35 are treated by preference in a hospital.

The Patients' Rights Directive brings this issue to the attention again. According to the Directive, the possibility for member states to require a prior authorization for reimbursement of costs of cross-border healthcare is restricted. One of the categories for which a system of prior authorization is however allowed is planned care, which must be understood as treatments "*requiring at least one stay in a hospital and/or expensive or specialized equipment or infrastructure*" (art. 8, 2 a, i and ii). This list must be handed over to the European Commission. For the implementation in Belgium, this could have indirectly implied the execution of art. 81 of the Hospital Law and thus the drawing up of a list with interventions that can only be performed in a hospital. As mentioned earlier the bill regarding practice in healthcare limits some interventions, based on the character of the invention and the patient characteristics to the hospital setting.

[mmmmm] Nationale Raad voor Ziekenhuisvoorzieningen, Jaarverslag 2007, p. 13 http://www.health.belgium.be/eportal/Healthcare/Consultativebodies/NationalcouncilforhospitalfaciI/708701

9.2. Regulating dual practice

Another option to rationalize practices in extramural centers is to regulate dual practice. Dual practice refers to the holding of more than one job by a health professional, mostly a job in a public or private not for profit hospital in combination with a job in a private practice or hospital. Various countries have regulated the dual practice. In 2011 a systematic review was conducted to identify the various methods governments have used worldwide to address this issue[nnnnn].[33]

9.2.1. Banning.

Countries like China and Canada completely ban dual practice, Portugal[ooooo] and Greece[ppppp] attempted total banning of dual practice, but did not succeed to implement this successfully.[34, 35] Moreover, banning dual practice in some countries has been associated with the migration of health workers, especially specialists, from the public to the private sector as well as an international brain drain.[qqqqq][33]

9.2.2. Financial restrictions

Several countries introduced financial restrictions including limiting private sector earnings, providing incentives to limit private sector activities, salary increases for public sector workers and performance-based payments.

Spain, Portugal and Italy, among others, have offered public physicians salary supplementations or promotions if they do not engage in private practice in exchange. The restriction of private earnings of publicly employed physicians has been implemented in the UK and in France. In the UK, full-time NHS consultants, who are mostly senior specialists, are permitted to earn up to 10% of their gross income from private practice in addition to their NHS earnings. Similarly, in France, public hospitals employ both full-time and part-time physicians who can also provide private services in the public hospital subject to the restriction that income from private fees is limited to 30% of physicians' total income.[rrrrr][33] The advantage is that this creates an incentive for specialists to stay in public hospitals. On the other hand, it might create a gap between those who are willing and able to pay to avoid waiting times and those who are not.

Countries like Austria, Ireland and Italy limit dual practice through government specification of the maximum time involvement in private activities.

The use of competitive public sector salaries to discourage private practice has been tested in Norway.[sssss][36] This experiment revealed that increased public sector wages led to an increase in work hours committed to the public sector.

Key success factors to implement such measures are a well-established and adequate health financing systems to fund and monitor public and private sector activity.[ttttt][33]

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nnnnn S.N. Kiwanuka, A.A. Kinengyere, E. Rutebemberwa, C. Nalwadda, F. Ssengooba, G.W. Olico-Okui, Pariyo (2011) Dual practice regulatory mechanisms in the health sector: a systematic review of approaches and implementation. London: EPPI-Center, Social Science Research Unit, Institute of Education, University of London.

ooooo M.D. Oliveira, C.G. Pinto (2005) Health care reform in Portugal: an evaluation of the NHS experience. Health Economics 14(S1): S203-S220.

ppppp E. Mossialos, S. Allan, K. Davaki (2005) Analysing the Greek health system: a tale of fragmentation and inertia. Health Economics 14:151-168.

qqqqq J. Buchan, J. Sochalski J. (2004). The Migration of nurses: trends and policies. Bulletin of the World Health Organization 82: 587-594.

rrrrr S.N. Kiwanuka, A.A. Kinengyere, E. Rutebemberwa, C. Nalwadda, F. Ssengooba, G.W. Olico-Okui, Pariyo (2011) Dual practice regulatory mechanisms in the health sector: a systematic review of approaches and implementation. London: EPPI-Center, Social Science Research Unit, Institute of Education, University of London.

sssss E.M. Saether (2003) A discrete choice analysis of Norwegian physicians' labour supply and sector choice, Working Paper 19. Oslo: University of Oslo.

ttttt S.N. Kiwanuka, A.A. Kinengyere, E. Rutebemberwa, C. Nalwadda, F. Ssengooba, G.W. Olico-Okui, G.W. Pariyo (2011) Dual practice regulatory mechanisms in the health sector: a systematic review of approaches and implementation. London: EPPI-Center, Social Science Research Unit, Institute of Education, University of London, p. 26

In Belgium, Zorgnet Vlaanderen[uuuuu] and the Strategische Adviesraad voor het Welzijns-, Gezondheids- en Gezinsbeleid[vvvvv] recommended to establish a more reasonable relation between the income of the physician and his/her workload. In order to do so they recommended differentiating the fees of hospital doctors participating to afterhours duty and emergency service and doctors (in extramural centers) who do not. Moreover, they also suggested linking the participation of the physician to after hours and emergency service to the reimbursement of the NIHDI for their patients.[37, 38]

9.2.3. *Licensure restrictions*

Kenya, Indonesia, Zambia and Zimbabwe[wwwww] implemented mandatory licenses to engage in dual practice, a restriction of dual practice to more experienced senior practitioners, a restriction of time spent on private sector activities and allowed minimal dual practice within public facilities.[39-41]

9.2.4. *Promotional incentives by offering career or recognition incentives*

In Italy, job promotions in hospitals were extended exclusively to full-time public sector workers.

9.3. Financial restrictions in general

The regulation of dual practice does not have any impact on physicians working exclusively in extramural centers. Therefore, measures on a broader level could be envisaged. Capping the fee supplements of reimbursed care in extramural centers (and by extension in general) could be an option. This might only work if a sound control system is implemented.

As demonstrated by a study of the Christian Sickness Fund[xxxxx], today physicians even do not always respect the convention tariffs.[42]

9.4. Limiting reimbursement by NIHDI for interventions by non conventioned physicians

In France, differentiation of reimbursement rates by social security according to the convention status is implemented. Reimbursement by social security for interventions performed by non conventioned physicians is very limited.[yyyyy] In that way, patients opting to consult non conventioned physicians pay almost the entire amount. This measure is solely effective for reimbursed care, though.

9.5. Possibility to regulate the provision of care in extramural centers according to the European Legislation?

Regulation in the field of health care is scrutinized regarding its conformity with EU law. The European Court of Justice screens this conformity, based on a claim of any person or in answer to a prejudicial question of a court.

The question raises to what extent the provision of health care in private settings can be restricted according to the European legislation.

The EC Treaty rules on free movement encompass the principles of free provision of services and the free establishment of providers are which are of particular interest for the issue of extramural centers. Healthcare, being qualified as an economic service implies that national regulatory measures could be considered as unjustified restrictions to free movement. The scrutiny includes regulations directly governing access to national health care service markets as well as the exercise of the health care activity itself.

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uuuuu J. Pauwels et. Al. Naar een geneeskunde met kantooruren? Voorstellen voor het waarborgen van de continuïteit van acute zorg. Zorgnet Vlaanderen 2012.

vvvvvvvvv Advies van de Strategische Adviesraad voor het Welzijns-, Gezondheids- en Gezinsbeleid, *Hand*. Vlaams Parlement 2011-2012, 1568/1, p. 27 e.v.

wwwww P. Ferrinho, W. Van Lerberghe W, I. Fronteira, F. Hipólito, A. Biscaia (2004). Dual practice in the health sector: review of the evidence. Human Resources for Health 2(1): 14; S. Jan, Y. Bian, M. Jumpa, Q. Meng, N. Nyazema, P. Prakongsai (2005) Dual job holding by public sector health professionals in highly resource-constrained settings: problem or solution? Bull World Health Organ. Oct 2005; 83(10): 771–776; J. Macq, P. Ferrinho, V. De Brouwere, W. Van Lerberghe (2001) Managing health services in developing countries: between the ethics of the civil servant and the need for moonlighting: Managing and moonlighting. Human Resources for Health Development Journal 5(1-3): 17-24.

xxxxx Christelijke mutualiteit. “Tariefonderzoek: “Wat betaalt u bij de specialist?”, http://www.cm.be/binaries/tariefonderzoek_tcm375-130483.pdf

yyyyy tariff d’authorité - Article L162-5-10 du code de la Sécurité Sociale

Several European Courts of Justice cases illustrate this[zzzzz]. [43]Member states are allowed to maintain barriers to free movement, however, provided they are justified in the public interest. The justification consists of a **necessity** test and a **proportionality** test.

Member States need to prove that the measure is necessary to attain a public interest objective (necessity) and that the measure does not exceed what is necessary to attain the objective nor that the same can be achieved by a less restrictive measure (proportionality). The objective to protect public health is a Treaty based objective. Apart from this, the Court adopted in its jurisprudence **the rules of reason** to justify measures that serve the public interest, such as for instance the risk of seriously undermining the financial balance of the social security system.

In the past, the Court already ruled with respect to hospitals, that planning the provision of health care can be allowed if certain conditions are fulfilled.[aaaaaa] As such, establishments providing outpatient care such as doctors' surgeries or extramural centers might also be the subject of planning if justified. Case law proves that the hardest part of the justification procedure for Member States is not the definition of a public interest objective but to prove proportionality. In the Stamatelaki case, for instance, the Court concluded that excluding reimbursement of any treatment in a foreign private hospital was a disproportionate measure in order to preserve a financial balance in social security, because less restrictive alternative measures were available, such as for instance the implementation of a prior authorization scheme[bbbbbb].

In the assessment of the justification, the Court often uses the criterion of the "consistent and systematic" character of the pursuit of the alleged justification ground. This implies that the restricting measures taken by the Members States need to be applied consistently and systematically. In the case Hartlauer Handelsgesellschaft mbH v Wiener Landesregierung and Oberösterreichische Landesregierung, national legislation required a prior authorization based on an assessment of the needs of the market for setting up and operating new independent outpatient dental clinics[cccccc], The Court concluded that the national legislation at issue did not pursue the stated objectives in a consistent and systematic manner, since it does not make the setting up of group practices subject to a system of prior authorisation, as is the case with new outpatient dental clinics.

9.6. Regulating dual practice in Belgium?

In Belgium, dual practice is not regulated. Some hospitals adopt clauses prohibiting the referral or the simultaneous work in a public and a private practice or in an extramural center during the period of their contract or even longer. It is doubtful, however, whether such clauses are in accordance with the rules of competition law[dddddd].[44]

The question can be raised whether effective general restricting measures can be justified and are (legally) feasible.

Different possible measures can be considered. A rewarding policy such as an exclusivity premium intended to induce some physicians to work solely in the public or not for profit private hospitals does not seem to be an optimal solution since such a policy risks to attract in particular specialists being able to work in private settings because of their specialism (e.g. ophthalmologists, paediatrician,..). Limiting the earnings from private practices for physicians employed in public or not for profit private hospitals could induce that physicians being able to maximize their earnings in private settings, permanently quit the public circuit. A policy of restriction of the hours performed in private practices or limiting the income from private practice are only feasible if registration and monitoring of the hours and the

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zzzzz See cases enumerated p. 208 W. Gekiere, R. Baeten en W. Palm, *Free movement of Services in the EU and Health Care, in Health Systems Governance in Europe: the role of EU law and Policy,* 2010, Cambridge University Press

aaaaaa Case C‑157/99 Smits and Peerbooms, 2001*, ECR* I‑5473, paragraphs 76 to 80, and Watts, paragraphs 108 to 110

bbbbbb Case C -444/05 Stamatelaki, 2007*, ECR* I-3185

cccccc Case C-169/07 Hartlauer Handelsgesellschaft mbH v Wiener Landesregierung and Oberösterreichische Landesregierung, 2009, *ECR* I-01721

dddddd in particular art. IV. 1 § 1 Code Economic law of 28 February 2013, *B.S./M.B.* 26 April 2014; D. Fornaciari, S. Callens, E. Schokkaert, *Ziekenhuizen, mededingingsrecht en recht op kwaliteitsvolle zorg*, 2010, Antwerpen – Oxford, Intersentia, p. 124 e.v.

incomes is organized. Performance based payments, rewarding the working time, continuity of care, inclusion of all patients, multidisciplinary approach, etc., could be another solution.

Regardless of their specific features, restricting measures regulating the care provided in extramural centers, the professionals working in extramural centers or the establishment of extramural centers needs to be conform to the EU regulations. The financial accessibility and the necessity for continuity of care (cfr. supra) are clearly objectives that can be accepted as public interest objectives. Member States need to provide evidence, however, that the non- application of the measure would jeopardize the public interest objective. Therefore accurate registration of who does what and in which setting, the monitoring of the available manpower in public and private not for profit hospitals and waiting lists are primordial to support the implementation of the appropriate restricting measures. Furthermore, the above mentioned risks and threats are not solely linked to the existence of extramural centers but need to be assessed within the context of the broader organisation and remuneration of the medical profession and the hospital landscape. In that scope, the underlying causes of scarce human resources and high burden of disease need to be addressed. An assessment of the restricting measure in a wider context and the application of the measure in the broader regulatory framework is thus necessary.

Keypoints

- **The risks and threats associated with the existence of extramural centers need to be assessed within the context of the broader organisation and remuneration of the medical profession and the hospital landscape. The underlying causes of scarce human resources and high burden of disease need to be addressed. In that scope the available manpower in public and private not for profit hospitals and waiting lists need to be monitored.**
- **Restricting measures regarding the care provided in extramural centers or the professionals working in extramural centers can only be implemented if they are necessary to protect the public (health) interest objectives and if they are proportional to achieve their aim.**

APPENDICES

APPENDIX 1. CHECKLIST FOR CERTIFICATION

RECOMMENDATIONS POUR UN CENTRE DE CHIRURGIE EXTRAMURALE *Groupe de travail chirurgie des yeux extra muros*									
Identification			Description	intraoculair	paupiere	inj intrav	lasik	Remarque	Période de correction (mois)
A. Architecture	A.2	A.2.1	Plusieurs zones de service raccordées à la salle d'opération	❑	❑				6
		A.2.2	Salle d'attente pour patients et accompagnants	❑	❑	❑	❑		6
			Dressing séparé de la salle d'opération	❑	❑				6
			Toilettes et lavabo séparés de la salle d'opération	❑	❑	❑	❑		6
			Système d'appel interne des infirmier(e)s	❑	❑				6
		A.2.3	Zone scrub (rinçage et désinfection)	❑	❑	❑	❑		6
			Produits (savon chirurgical, désinfectants)	❑	❑	❑	❑		6
		A.2.4	Espace de rangement	❑	❑	❑	❑		6
	A.3		bloc opératoire séparée de l'espace de consultation	❑	❑	❑	❑		6
	A.4		Accessibilité des locaux (pas d'escaliers)	❑	❑	❑	❑		6
	A.5		Détection incendie	❑	❑	❑	❑		6
			Système d'extinction incendie	❑	❑	❑	❑		6
B. Equipement	B.1		Système électrique de secours (groupe électrogène)	❑	❑	❑	❑		6
			Certificat de controle (tous les 3 ans)	❑	❑	❑	❑		3
	B.2		Système de chauffage moderne sans échapement de gaz ou fumée	❑	❑	❑	❑		3
			Système de purification de l'air de la zone d'opération post-2011 (classe 6)	❑					6
			Système de purification de l'air de la zone d'opération pre-2011 (classe 8)	❑	❑	❑	❑		6
	B.3		Téléphone avec numéros d'urgences clairement visibles	❑	❑	❑	❑		3
			Numéro de contact post-opératoire	❑	❑	❑	❑		3
	B.4		Système d'archivage (fiches, base de donnée informatique)	❑	❑	❑	❑		1

RECOMMENDATIONS POUR UN CENTRE DE CHIRURGIE EXTRAMURALE *Groupe de travail chirurgie des yeux extra muros*								
Identification		Description	intraoculair	paupiere	inj intrav	lasik	Remarque	Période de correction (mois)
		Type d'intervention	❑	❑	❑	❑		1
		Déroulement chirurgical de l'intervention	❑	❑	❑	❑		1
		Médication pre, per et post intervention	❑	❑	❑	❑		1
		Nom et adresse du patient	❑	❑	❑	❑		1
		Mention du médecin traitant	❑	❑	❑	❑		1
	B.5	Recovery: possibilité de communication avec le médecin ou l'infirmier	❑	❑	❑	❑		1
		Chariot de réanimation présent	❑	❑	❑	❑		1
	B.6	Zone scrub	❑	❑	❑	❑		6
		Autoclave (type B) dans un espace séparé	❑	❑	❑	❑		6
	B.7	Zone de rangement fermée par rapport aux accès des couloirs						
	B.8	Certification d'entretien annuel des lasers de réfraction, rapports liés	❑	❑	❑	❑		6
B.9	B.9.1	Salle d'opération : instruments stériles	❑	❑	❑	❑		3
		Salle d'opération : éclairage adapté au type d'intervention	❑	❑	❑	❑		3
	B.9.2	Chariot de réanimation : Oxygène, masque à oxygène	❑	❑	❑			6
		Matériel d'intubation	❑	❑	❑			1
		Ambu de respiration	❑	❑	❑			1
		Défibrilateur avec monitoring : ECG, saturation en oxygène et tensiomètre	❑	❑	❑			1
		Seringues, aiguilles, catheters IV, perfusion et solutions d'entretien	❑	❑	❑			1
		Canule de Mayo et ouvre-bouche	❑	❑	❑			1
		Ambu de respiration avec masque et connection pour oxygène	❑	❑	❑			1
		Médication IV : ephedrine, atropine, succinylcholine, adrenaline, phenergan, solu-medrol, diazepam, cordarone.	❑	❑	❑			1
		Carbonate de sodium	❑	❑	❑			1

RECOMMENDATIONS POUR UN CENTRE DE CHIRURGIE EXTRAMURALE *Groupe de travail chirurgie des yeux extra muros*								
Identification		**Description**	**intraoculair**	**paupiere**	**inj intrav**	**lasik**	**Remarque**	**Période de correction (mois)**
		Matériel d'aspiration : pompe et canule "yankauer" et tuyau d'aspiration	❑	❑	❑			1
		Pour l'anesthesie générale :						1
		Matériel pour intubation difficile (guides d'intubation, masque, laryngoscope, pince de Magill)	❑	❑	❑			1
		Dantrium pour utilisation de vapeur anesthésiante	❑	❑	❑			3
	B.9.3	Soins infirmiers : table d'opération, armoire avec trousse et champs opératoires stériles, compresses stériles, chariots, plan de travail, plan de travail pour l'infirmier (transcriptions)	❑	❑	❑	❑		3
C. Stérilité	C.1	Surfaces de la salle d'opération lavables	❑	❑	❑	❑		
		Enregistrement de la fréquence des nettoyages	❑	❑	❑	❑		
		Enregistrement des produits de nettoyage	❑	❑	❑	❑		
	C.2	Autoclave : controle chaque semaine	❑	❑	❑	❑		
		Autoclave : entretien annuel	❑	❑	❑	❑		
		Archivage outprint stérilisateur et (min 1 an)	❑	❑	❑	❑		
		Sterilisation au gaz : certificat de stérilité	❑	❑	❑	❑		
D. Personnel	D.1	Personnel employé dans la salle d'opération : 1 chirurgien, 1 assistante médical (ou instrumentiste), anesthésiste (uniquement pour sédation profonde ou anesthésie générale) - enregistrement	❑	❑	❑	❑		
E. Responsabilités	E.1	Consentement formel du patient	❑	❑	❑	❑		
	E.2	Assistant médical sous la responsabilité du chirurgien	❑	❑	❑	❑		
	E.3	Information pour le patient (video, brochure, flyer, …)	❑	❑	❑	❑		
	E.4	décharge de patiënt - documents d'instruction postop	❑	❑	❑	❑		
	E.5	Enregistrement annuel des exercices de situation d'urgence	❑	❑	❑			
	E.6	Enregistrement annuel des exercices d'évacuation	❑	❑	❑	❑		

RECOMMENDATIONS POUR UN CENTRE DE CHIRURGIE EXTRAMURALE AUTONOME AMBULATOIRE *Groupe de travail chirurgie des yeux extra muros*								
Identification		**Description**	**intraoculair**	**paupière**	**inj intravitr**	**lasik**	**Remarque**	**A corriger en-déans (mois)**
A. Architecture	A.1	Structure distincte	❑	❑	❑	❑		6
B. Devoir de l'établissement	B.1	Absence de bactéries de l'hopital en OK	❑	❑	❑	❑		6
D. Responsabilités	D.1	Consentement formel du patient	❑	❑	❑	❑		1
E. Relations externes	E.1	Services d'urgences au courant de l'activité chirurgicale	❑	❑	❑	❑		1
	E.3	Centre disponible 24/7	❑	❑	❑	❑		1
	E.4	Médecin traitant du patient informé par écrit de l'intervention chirurgicale	❑	❑				1

AANBEVELINGEN VOOR EEN CHIRURGISCH CENTRUM *Werkgroep Extramurale Oogheelkunde (WEO)*									
Identificatie			**Omschrijving**	**intraoculair**	**ooglid**	**intravitr inj**	**lasik**	**Opmerkingen**	**Correctie termijn (maand)**
A. Architectuur	A.2	A.2.1	Meerdere aansluitende dienstzones bij operatiezaal	❑	❑				6
		A.2.2	Wachtzaal patiënten en begeleiders	❑	❑	❑	❑		6
			Kleedhokje - afgescheiden van operatiezaal	❑	❑				6
			Toiletten + lavabo - afgescheiden van operatiezaal	❑	❑	❑	❑		6
			Intern oproepsysteem met verpleegkundige	❑	❑				6
		A.2.3	Scrub zone (reinigen en desinfectie)	❑	❑	❑	❑		6
			Producten (chirurgische zeep, desinfectieproducten)	❑	❑	❑	❑		6
		A.2.4	Bergingsruimte	❑	❑	❑	❑		6
	A.3		Chirurgisch centrum gescheiden van consultatieruimte	❑	❑	❑	❑	☐	6
	A.4		Toegankelijkheid van lokalen (geen trappen)	❑	❑	❑	❑		6
	A.5		Branddetectie	❑	❑	❑	❑		6
			brandbestrijdingsmiddelen	❑	❑	❑	☐		6
B. Uitrusting	B.1		Elektrisch voedingssysteem - noodsituatie	❑	❑	❑	❑		6
			Certificaat 3 jaarlijkse controle	❑	❑	❑	❑		3
	B.2		Modern verwarmingsysteem zonder gas of rookuitlaat in het OK	❑	❑	❑	❑		3

AANBEVELINGEN VOOR EEN CHIRURGISCH CENTRUM *Werkgroep Extramurale Oogheelkunde (WEO)*								
Identificatie		**Omschrijving**	**intraoculair**	**ooglid**	**intravitr inj**	**lasik**	**Opmerkingen**	**Correctie termijn (maand)**
		Luchtzuiveringssysteem operatieruimte bouw vanaf 2011 ISO class 6	❑					6
		Luchtzuiveringssysteem operatieruimte bouw ISO class 8	❑	❑	❑	❑		6
	B.3	Telefoon met duidelijk zichtbare noodnummers	❑	❑	❑	❑		3
		Ontslagfiche patiënt met telnummer urgentie	❑	❑	❑	❑		3
	B.4	Archiveringssysteem (fiches, computerdatabase)	❑	❑	❑	☐		1
		Type interventie	❑	❑	❑	❑		1
		Chirurgisch verloop van ingreep	❑	❑	❑	❑		1
		Pre, per, post operatieve medicatie	❑	❑	❑	❑		1
		Naam en adresgegevens van de patiënt	❑	❑	❑	❑		1
		Vermelding huisarts	❑	❑	❑	☐		1
	B.5	Recovery: communicatie mogelijkheid met arts of verpleging	❑	❑	❑	❑		1
		Reanimatiekar aanwezig, inhoud lager beschreven	❑	❑	❑	❑		1
	B.6	Scrub zone	❑	❑	❑	❑		6
		Autoclaaf (type B) in aparte ruimte	❑	❑	❑	❑		6
	B.7	Bergingsruimte afgesloten van wandelgangen	❑	❑	❑	☐		6
	B.8	Certificaat jaarlijks onderhoud refractieve lasers, bijhorende rapporten				▫		
B.9	B.9.1	Operatiezaal: Steriele chirurgische instrumenten	❑	❑	❑	❑		3
		Operatiezaal: Verlichting aangepast aan type ingreep	❑	❑	❑	❑		3
	B.9.2	Reanimatiekar: Zuurstof Zuurstofmasker Intubatiemateriaal Beademingsballon Defibrillator met monitoring: ECG, zuurstofsaturatie en NIBP Spuiten, naalden, IV-catheters, infusen en onderhoudsinfuusoplossingen Mondpijpjes (mayo) en mondsperder Beademingsballon met maskers en aansluiting voor	❑	❑	❑			3

Identificatie		AANBEVELINGEN VOOR EEN CHIRURGISCH CENTRUM *Werkgroep Extramurale Oogheelkunde (WEO)* Omschrijving	intraoculair	ooglid	intravitr inj	lasik	Opmerkingen	Correctie termijn (maand)
		zuurstof IV medicatie: efedrine, atropine, succinylcholine, adrenaline, phenergan, solu-medrol, diazepam, cordarone. Natriumbicarbonaat Aspiratiemateriaal: pomp en yankauer en aspiratieslangen Bij algemene anesthesie: Materiaal voor moeilijke intubatie (intubatiegeleiders, larynxmasker, Magill) Dantrium bij het gebruik van anesthesie-dampen						
	B.9.3	Verpleegkundige zorgen: operatietafel, kasten met trousses en steriele operatievelden, steriele kompressen, karretjes, werkplan, plan voor verpleegkundig schrift	❑	❑	❑	❑		3
C. Steriliteit	C.1	Reinigbare oppervlakken operatiezaal	❑	❑	❑	❑		6
		Registratie poetsbeurten	❑	❑	❑	❑		1
		registratie poetsproducten	❑	❑	❑	❑		1
	C.2	Autoclaaf: wekelijkse controle	❑	❑	❑	☐		1
		Autoclaaf: tweejaarlijks onderhoud	❑	❑	❑	❑		1
		Archivering outprints (min 1 jaar)	❑	❑	❑	❑		1
		Gassterilisatie - bewijs van steriliteit	❑	❑	❑	❑		1
D. Personeel	D.1	Personeel per in gebruik zijnde operatiekamer: Chirurg, medisch assistent (instrumentist), anesthesist (enkel voor diepe sedatie of volledige anesthesie) - registratie	❑	❑	❑	❑		1
E. Verantwoordelijkheden	E.1	Informed consent patiënt	❑	❑	❑	❑		1
	E.2	Medisch assistent valt onder verantwoordelijkheid chirurg voorleggen BA	❑	❑	❑	❑		1
	E.3	Informatie voor patiënt (video, foto's, brochures …)	❑	❑	❑	❑		1
	E.4	Ontslag patiënt - instructie documenten	❑	❑	❑	❑		1
	E.5	Registratie tweejaarlijkse oefening noodsituatie	❑	❑	❑			3
	E.6	Registratie tweejaarlijkse oefening ontruimingsplan	❑	❑	❑	❑		3

AANBEVELINGEN VOOR EEN ONAFHANKELIJK AMBULANT EXTRAMURAAL HEELKUNDIG CENTRUM *Werkgroep Extramurale Oogheelkunde (WEO)*								
Identificatie		**Omschrijving**	**intraoculair**	**ooglid**	**intravitr inj**	**lasik**	**Opmerkingen**	**Correctie termijn (maand)**
A. Architectuur	A.1	Afgescheiden structuur	❑	❑	❑	❑		6
B. Plicht van het extramuraal centrum	B.1	Afwezigheid van ziekenhuisbacteriën in OK	❑	❑	❑	❑		6
D. Verantwoordelijkheden	D.1	Informed consent patiënt	❑	❑	❑	❑		1
E. Externe relaties	E.1	Spoedgevallendienst op de hoogte van chirurgische activiteit bevestiging voorleggen	❑	❑	❑	☐		1
	E.3	Centrum is 24/7 bereikbaar	❑	❑	❑	❑		1
	E.4	Behandelende arts van patiënt schriftelijk op de hoogte brengen van chirurgische ingreep	❑	❑	☐	☐		1

APPENDIX 2. LIST CERTIFIED EXTRAMURAL EYE SURGERY CENTERS

Oogarts	rizivnr	Naam EMOC	gelegen te
De Wilde Fernand	**1-44266-52-370**	**Eyecenter Latem**	**Sint-Martens-Latem**
van Egmond Joke	1-45894-91-370	Policlinic, Oogkliniek Okulus	Kortrijk
Callebert Ineke	1-07688-79-370	Policlinic, Oogkliniek Okulus	Kortrijk
Jadnanansing Jayant	1-07689-79-370	Policlinic, Oogkliniek Okulus	Kortrijk
Samain Henri	1-31601-28-370	Policlinic, Oogkliniek Okulus	Kortrijk
Haverbeke Gregory	1-18658-70-370	Policlinic, Oogkliniek Okulus	Kortrijk
Cardyn Caroline	1-33962-92-370	Policlinic, Oogkliniek Okulus	Kortrijk
Claeys Marnix	**1-45881-07-370**	**Policlinic, Oogkliniek Okulus**	**Kortrijk**
De Leye Alberte	1-32812-78-370	Policlinic, Oogkliniek Okulus	Kortrijk
Brouckaert Joseph	1-32103-11-370	Policlinic, Oogkliniek Okulus	Kortrijk
Dekimpe Nicole	1-33107-74-370	Policlinic, Oogkliniek Okulus	Kortrijk
Huyghe Philippe	**1-44805-16-370**	**Hippocrates**	**Sint-Niklaas**
De Wilde Gerda	1-45361-42-370	Hippocrates	Sint-Niklaas
Van Winden Marianne	1-76824-07-370	Hippocrates	Sint-Niklaas
Van De Moere Ann	1-09938-60-370	Laser Refractie Centrum	Sint-Martens-Latem
Schauwvlieghe Pierre	1-44181-58-370	Laser Refractie Centrum	Sint-Martens-Latem
Boven Geert	1-14497-60-370	Laser Refractie Centrum	Sint-Martens-Latem
Brouckaert Joseph	1-32103-11-370	Laser Refractie Centrum	Sint-Martens-Latem
Reynders Stefaan	1-36435-44-370	Laser Refractie Centrum	Sint-Martens-Latem
Guy Sallet	1-45799-89-370	Laser Refractie Centrum	Sint-Martens-Latem
Kempeneers Henri	1-45843-45-370	Laser Refractie Centrum	Sint-Martens-Latem
Van Hijfte Rudy	0-44392-41-370	Laser Refractie Centrum	Sint-Martens-Latem
Adank Antonius	1-08320-29-370	Laser Refractie Centrum	Sint-Martens-Latem
Vincke Bruno	1-58344-57-370	Laser Refractie Centrum	Sint-Martens-Latem
Derous Danny	1-34096-55-370	Laser Refractie Centrum	Sint-Martens-Latem

Van den Dooren Erik	1-41891-20-370	Laser Refractie Centrum	Sint-Martens-Latem
Van den Dooren Karl	1-09257-62-370	Laser Refractie Centrum	Sint-Martens-Latem
Poelman Jan	**1-45008-07-370**	**Laser Refractie Centrum**	**Sint-Martens-Latem**
Kesteloot Frank	1-33417-55-370	Laser Refractie Centrum	Sint-Martens-Latem
Vermeulen Paul	1-15772-46-370	Laser Refractie Centrum	Sint-Martens-Latem
Breusegem Roger	1-42240-59-370	Laser Refractie Centrum	Sint-Martens-Latem
Cardoen Line	1-09381-35-370	Laser Refractie Centrum	Sint-Martens-Latem
Goes Frank Jr	**1-17993-56-370**	**Goes Oogcentrum**	**Antwerpen**
van Laethem Jean	**1-43462-01-370**	**BOLC**	**Drongen**
Vereecken Guy	1-45931-54-370	BOLC	Drongen
Huygens Marc	1-33896-61-370	BOLC	Drongen
Van Slycken Steven	1-45905-80-370	BOLC	Drongen
Vandamme Dirk	1-32964-23-370	BOLC	Drongen
De Hilde Gerda	1-45361-42-370	BOLC	Drongen
Huyghe Philippe	1-44805-16-370	BOLC	Drongen
Golenvaux Benoît	1-85296-71-370	BOLC	Drongen
Ryckaert Sofie	1-43997-48-370	BOLC	Drongen
Schulte Augustinus	1-35914-80-370	BOLC	Drongen
Muylaert Lutgard	1-14398-62-370	BOLC	Drongen
Meersschaert Ann	1-36387-92-370	BOLC	Drongen
Deman Christian	1-34991-33-370	BOLC	Drongen
Renier Steven	1-98070-04-370	BOLC	Drongen
Heintz Bernard	1-34151-97-370	BOLC	Drongen
Golenvaux Benoît	1-85296-71-370	BOLC	Drongen
Callebert Ineke	1-07688-79-370	BOLC	Drongen
De Wilde Gerda	1-45361-42-370	BOLC	Drongen
De Wilde Fernand	1-44866-52-370	BOLC	Drongen
Wille Christiana	1-42427-66-370	BOLC	Drongen
Platteeuw Fedor	1-43655-02-370	BOLC	Drongen

Luyssaert Luc	1-42416-77-370	BOLC	Drongen
Verhaeghe Isabelle	1-46650-14-370	BOLC	Drongen
Verstrynge Katrien	1-36203-82-370	BOLC	Drongen
Leroux Kathleen	1-76047-08-370	Brussels Eye Doctors	Brussel
Vryghem Jérôme	**1-05317-25-370**	**Brussels Eye Doctors**	**Brussel**
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Reiter Marc	1-25340-81-370	Brussels Eye Doctors	Brussel
Mertens Erik	**1-17065-14-370**	**Medipolis**	**Wilrijk**
Schraepen Patrick	1-18984-35-370	Medipolis	Wilrijk
Mesplede Jean Jacques	1-86618-10-370	Medipolis	Wilrijk
Zen Jane	1-14348-15-370	Oogkliniek Antwerpen	Berchem
Van der Hauwaert Nathalie	1-08205-47-370	Oogkliniek Antwerpen	Berchem
Van Tenten Yasmine	1-18473-61-370	Oogkliniek Antwerpen	Berchem
Van Horenbeeck Robert	**1-14509-48-370**	**Oogkliniek Antwerpen**	**Berchem**
Collaer Nanny	1-76174-75-370	Oogkliniek Antwerpen	Berchem
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Robberecht Kirsten	1-76979-46-370	Ooginstituut Aalst	Aalst
Schelfhout Veerle	1-46655-09-370	Ooginstituut Aalst	Aalst
Buysse Sophie	1-08423-23-370	Oculus, Eye & Refractive Center	Ieper
Bastin Ingeborg	1-08245-07-370	Oculus, Eye & Refractive Center	Ieper
Mulliez Evelyne	1-09473-40-370	Oculus, Eye & Refractive Center	Ieper
Blanckaert Johan	**1-34247-01-370**	**Oculus, Eye & Refractive Center**	**Ieper**
Callens Caroline	1-58446-52-370	Oculus, Eye & Refractive Center	Ieper

Wery Vincent	**1-86464-67-370**	**Clinique de la Vision**	**Charleroi**
Chaves Alessandra	1-96223-08-370	Clinique de la Vision	Charleroi
Demuynck Joelle			
Wery Vincent	**1-86464-67-370**	**Clinique de la Vision**	**Waterloo**
Chaves Alessandra	1-96223-08-370	Clinique de la Vision	Waterloo
Dubois Isabelle	1-57322-12-370	Clinique de la Vision	Waterloo
Demuynck Joelle		Clinique de la Vision	Waterloo
Nerinckx Fanny		Clinique de la Vision	Waterloo
Haustrate Francois	**1-15360-70-370**	**Eye Clinic Sharper Image**	**Antwerpen**
Nietvelt Staf	1-17307-63-370	Eye Clinic Sharper Image	Antwerpen
Reyntjens Bruno	1-94047-69-370	Eye Clinic Sharper Image	Antwerpen
Evens Peter	**1-07179-06-370**	**Focus Eye Clinic**	**Brussel**
Verdonck Nancy	1-76008-47-370	Focus Eye Clinic	Brussel
Evens Pascale	1-06585-17-370	Focus Eye Clinic	Brussel
De Doncker Rita	1-45638-56-370	Dr. Van Langenhove	Aalst
Van Langenhove Luc	**1-46025-57-370**	**Dr. Van Langenhove**	**Aalst**
Galand Albert	**1-62104-80-370**	**Cataract and Intraocular Implant Clinic**	**Liège**
Stadion Paul	1-24958-75-370	Cataract and Intraocular Implant Clinic	Liège
Hubert Cristina	**1-81478-09-370**	**Hubert Vision**	**Arlon**
Fanourakis Stélios	**1-86278-59-370**	**Clinique Ophtalmologique Mieux Voir**	**Fleurus**
Barlet Tania	1-89028-25-370	Clinique Ophtalmologique Mieux Voir	Fleurus
De Clerq Christophe	1-89901-25-370	Clinique Ophtalmologique Mieux Voir	Fleurus
Koch Philippe	1-89304-40-370	Clinique Ophtalmologique Mieux Voir	Fleurus

Kolyvras Nicolas	1-89783-46-370	Clinique Ophtalmologique Mieux Voir	Fleurus
Golub Eléna	1-96764-49-370	Clinique Ophtalmologique Mieux Voir	Fleurus
Serpe Jean-Nicolas	1-68135-63-370	Clinique Ophtalmologique Mieux Voir	Fleurus
Mustaka Lindita	1-20624-44-370	Clinique Ophtalmologique Mieux Voir	Fleurus
Bouzekri Alami Rayan	1-20649-19-370	Clinique Ophtalmologique Mieux Voir	Fleurus
Mistrih Salah	1-96328-97-370	Clinique Ophtalmologique Mieux Voir	Fleurus
Andriantafika Raberahona	1-89506-32-370	Centre Medical de l'Alliance	BRAINE L'ALLEUD
Kallay Oscar	**1-85154-19-370**	**Centre Medical de l'Alliance**	**BRAINE L'ALLEUD**
Lefebre Pierre	1-88857-02-370	Centre Medical de l'Alliance	BRAINE L'ALLEUD
Sevilla Estelle	1-88261-16-370	Centre Medical de l'Alliance	BRAINE L'ALLEUD
Ravet Olivier	1-67515-04-370	Centre Medical de l'Alliance	BRAINE L'ALLEUD
Heintz Bernard	**1-34151-97-370**	**Oogcentrum Brugge**	**Brugge**
Claeskens Walter	**1-15366-64-370**	**Oogcentrum Kapellen**	**Kapellen**
Jansen Guy	**1-6159-47-370**	**Oogheelkunde Centrum Jansen**	**Turnhout**
Jansen Jozef	1-5013-29-370	Oogheelkunde Centrum Jansen	Turnhout
Haustermans Ann	**1-17785-70-370**	**Oogkliniek Brasschaat**	**Brasschaat**
Verhelst Dominique	1-19162-51-370	Oogkliniek Brasschaat	Brasschaat
Leysen Inge	1-19613-85-370	Oogkliniek Brasschaat	Brasschaat
Bartholomeussen Els	1-49048-41-370	Oogkliniek Brasschaat	Brasschaat
Mélard Jean-luc	**1-2-7794-52-370**	**Centre Ophtalmologique Le Verseau**	**Wavre**
Termote Hervé	**1-83014-25-370**	**Advanced Laser Eyesurgery Center (ALEC)**	**Grez Doiceau**
Van Cleynenbreughel Hugo	**1-09666-41-370**	**Mediclinic**	**Oud-Heverlee**

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