# Zorginkoopovereenkomst: De rechtsverhouding tussen de zorgverzekeraar en de zorgaanbieder in contractenrechtelijk perspectief

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# Summary

## Healthcare Purchase Agreement

*The legal relationship between the health insurer and the care provider from a contract law perspective*

*1 Introduction, background, research design*

This thesis studies the rights and obligations of health insurers and care providers in healthcare purchase agreements relating to care covered by the Dutch Health Insurance Act (Zvw). Health insurers may conclude healthcare purchase agreements with care providers – which include hospitals, independent health centres, mental health institutions, pharmacies, general practitioners, physiotherapists and speech therapists – for the purposes of offering and implementing healthcare insurance. In a healthcare purchase agreement, the health insurer and the care provider agree which care the care provider will deliver to persons insured with the health insurer for the account of the health insurer, under what conditions and at what price. A healthcare purchase agreement usually has a term of one or more years. Health insurers and care providers are private legal persons. The healthcare purchase agreements they conclude are agreements under civil law.

These agreements and the role allocated to health insurers under these agreements are of major importance for the operation of the health insurance system introduced in 2006. The aim of the government when introducing the health insurance system is to provide the entire population with effective access to necessary care on acceptable terms. When the system was introduced, the government wanted health insurers to act as 'efficient, customer-oriented directors of the care system' and increasing freedom of contract in the relationship between health insurers and care providers to contribute to the accessibility, affordability and quality of health care. The Dutch government considers itself to be 'systemically responsible' for these public interests, in part given its human rights obligations pursuant to the Constitution and international arrangements. It therefore takes regulatory and supervisory action where it deems such action to be necessary. In recent decades, a system of regulated competition has replaced the system in which the government exerted central control over supply. Section 1.2 describes this development and concludes with a description of the current regulations applying to the healthcare system.

The aim of the present study was to understand how the healthcare purchase agreement can fit into the prevailing hybrid framework of public and private law and how that framework should be applied to the agreement.

Answers are given to the following research questions:

1) *In what way and to what extent do regulations have an impact on, and should regulations impact, the contractual relationship between the health insurer and the care provider?*
2) *Do the involvement of public interests and the capacity of the health insurer affect the rights and obligations of the health insurer and the care provider in healthcare purchasing agreements, and should that be the case?*

In order to answer these questions, a review was conducted to determine what emerges from the legal text and what has been decided by the courts regarding the effect of regulations relating to, and the influence of, the involvement of public interests and the capacity of the health insurer on the healthcare purchasing relationship. I also investigate how regulations have an effect and what effect the involvement of public interests and the capacity of the health insurer should have, on the basis of an analysis of the purpose and purport of the regulations in question, the system enshrined by the law and the operation of private-law mechanisms through which regulations can have an effect on contractual rights and obligations.

The basic principle when answering the research questions is that the decision to introduce competition implies a decision to apply contract law. Contract law helps to shape the market and how it works. Sector-specific regulations and public interests may influence the rights and obligations of contracting parties under contract law. In addition, the general law of obligations requires contracting parties to take into account the social and personal interests involved in the given case, and the application of contract law varies depending on the capacity of the contracting parties.

*2 Regulations for the healthcare system: capita selecta*

Chapter 2 discusses in greater detail some regulations relating to the healthcare system that are relevant for a number of the subsequent chapters. Section 2.2 discusses the main features and the regulation of health insurance, for the implementation of which health insurers may conclude healthcare purchase agreements. It is argued that the health insurer's obligation to the insured person with an entitlement to benefits in kind, as referred to in Section 11(1)(a) Zvw, can be defined as the obligation towards the insured to effectively provide and supply equal, financial and geographical access to appropriate care of good quality. The implementation of Section 11(1) of the Health Insurance Act by health insurers therefore contributes to the realisation of the insured's right to health care vis-à-vis the government. With regard to the quality of care, the health insurer's obligation relates solely to the provision of good care in an abstract sense, in other words to the proper selection of care providers. The health insurer does not have to vouch for the quality of the care that is actually provided. The health insurer's obligation to the insured with an entitlement to reimbursement as referred to in Section 11(1)(b) Zvw, is an obligation of result to reimburse costs for care

and – should the insured make a request to that effect – an obligation of best endeavour to mediate in the obtention of care. The care provider to which the health insurer refers the insured person must provide good-quality care in the abstract sense. When the health insurer limits the entitlement to reimbursement for the costs of care to care provided by contracted care providers, it follows from that limitation that the insurer is subject to the same obligation as a health insurer which offers an entitlement to benefits in kind.

Section 2.3 briefly discusses the prohibition of the abuse of a dominant economic position as described in Section 24(1) of the Dutch Competition Act (Mw) and Article 102 of the Treaty on the Functioning of the European Union (TFEU). As yet, the civil courts have not ruled that a health insurer has abused a dominant economic position with respect to a care provider or vice-versa. The civil courts have taken the health insurer's dominant position into consideration in their decisions on a number of occasions but it is not always clear here whether the courts were referring to a dominant economic position in the sense of the Mw.

Section 2.4 discusses the enforcement competences of the Dutch Healthcare Authority (NZa) in the event of one or more health insurers or care providers having a significant market position (Sections 47-49 of the Healthcare Market Regulation Act (Wmg)), and also how the NZa implements its enforcement competences pursuant to the policy rule relating to Significant Market Position (AMM) in the healthcare system and its case practice. The NZa can impose a range of obligations that may have implications for precontractual and contractual relationships but it cannot intervene directly in the legal relationship between parties using its AMM instrument and determining their reciprocal rights and obligations. When applying its AMM instrument, the NZa does not focus on the balance of power between health insurers and care providers as such. It investigates whether their market conduct furthers the general interests of consumers. The NZa's AMM supervision has so far resulted in few enforcement decisions that affect a healthcare purchase agreement. This study does not examine the question of whether AMM supervision is working well. It does suggest, however, that the NZa's thinking about the purchasing power of health insurers and the NZa's limited options to assess the impacts of market conduct on the accessibility and affordability of care may have played, and indeed are playing, a role in the small number of decisions to date. The transfer of market supervision from the NZa to the ACM as envisaged in the proposed *Adjustments to tariff and performance regulation and market supervision in the field of health care* legislation would not seem to lead to any change in these areas.

In Section 2.5, I discuss the NZa's competence pursuant to Section 45 Wmg to set out rules relating to the establishment of, and conditions in, agreements, including healthcare purchase agreements. The only regulation affecting the healthcare purchase agreement so far on the basis of Section 45 Wmg is the Regulation on the Transparency of the Healthcare Purchasing Process Zvw, which is discussed in Chapter 4.

The subsequent chapters follow the 'life cycle' of the agreement: the establishment, determination of the content, and execution/performance of the agreement.

*3 Are health insurers contracting authorities?*

In Chapter 3, I examine whether health insurers qualify as bodies governed by public law in the sense of the Dutch 2012 Procurement Act (Aw 2012) and the European Public Procurement Directive (Directive 2014/24/EU). Until now, different decisions have been made by some Dutch courts about the questions of whether health insurers meet the criterion that the needs they serve are of a non-commercial nature and whether they meet any of the dependency requirements.

I have made an assessment of whether health insurers fulfil the financing criterion. In my opinion, they do fulfil this criterion because the equalisation contribution paid to them by the National Healthcare Institute from the Health Insurance Fund must be considered government funding and this source of income, due to the operation of the 50% rule in Section 45(4) and (5) Zvw, amounts to more than half of health insurers' income.

In addition, the public interest served by health insurers is of a non-commercial nature since several factors point to the non-commercial nature of the needs served by health insurers. For example, health insurers are financed more than half by the government, profit cannot be considered to be their main objective, they do not operate in normal market conditions because of the provisions of the Zvw and Wmg, and, in practice, there is no highly competitive situation. I argue that a strict application of the 'non-commercial' criterion should be assumed. I also argue that the exception derived from the Àgora and Excelsior ruling[1] – that a profit motive can be equated with the operation of the legal entity according to the criteria of performance, efficiency and cost-effectiveness – should not be applied broadly.

I conclude that health insurers are bodies governed by public law and that they are therefore contracting authorities in the sense of Section 1.1 Aw 2012.

*4 Pre-contractual phase*

In practice, it is currently assumed that health insurers are not subject to procurement obligations. Chapter 4 focuses on the rights and obligations of health insurers and care providers with respect to the establishment of the agreement on the basis of this assumption. The perspective selected here is the freedom the health insurer has to design and implement the purchase procedure. Where applicable, I distinguish between the different ways in which healthcare purchase agreements are concluded: on the basis of an equal, non-negotiable offer offered to multiple care providers; on the basis of negotiations; or as a result of a tender process, whether or not this is considered to be a voluntary tender procedure.

1 CJEU 10 May 2001, C-223/99 and C-260/99, ECLI:EU:C:2001:259 (*Agorà and Excelsior*).

It has been pointed out that the basic principle is that 'ordinary contract law' can be applied in the pre-contractual healthcare purchasing relationship. The application of 'ordinary contract law' implies that a health insurer has the freedom of contract to make an identical, non-negotiable, offer to multiple care providers. When a health insurer and a care provider enter into negotiations with one another, general case law with respect to aborted negotiations can be applied. If the health insurer opts for a voluntary tender procedure, the legal rule provided by the Dutch Supreme Court in *KLM/CCC*[2] should be used to establish whether the health insurer should observe the principles under procurement law of equality and transparency.

Section 4.2 looks in more detail at how sector-specific regulations, soft law and enforcement by the NZa and ACM determine the rights and obligations of contracting parties. I set out the main findings. Section 12 Zvw gives the government the competence to designate care or services that health insurers may provide solely on a contracted basis for the protection of the public interest and to impose a duty to conclude a contract on health insurers and care providers. The provision has not yet been applied since the Zvw came into force.

It follows from the *VGZ c.s./Nutricia c.s.*[3] ruling that the norms contained in the Zvw system regarding the duty of care of health insurers referred to in Section 11(1) of the Zvw can also serve to determine the rights and obligations of health insurers and care providers in the pre-contractual phase.

The same applies to the NZa's Regulation on the Transparency of the Health Insurance Purchasing Process, although it has so far been invoked in only a few civil court proceedings. I conclude that the main purpose of the regulation is to streamline the establishment process, without implying that transparency and the related equality standards apply as they may in procurement law and on grounds of reasonableness and fairness. However, it would be advisable for the NZa to clarify how the regulation relates to the principles of procurement law and general principles of proper administration.

The quantitative significance of AMM supervision for the pre-contractual phase is limited. The NZa has taken enforcement action in only two cases: the imposition of a duty to conclude a contract in both cases and a transparency obligation as well in one case. In both decisions and the subsequent appeals, the NZa and the Trade and Industry Appeals Tribunal (CBb) refer to the importance of the health insurer being able to exercise its steering role in the healthcare system.

The importance of the Code of Conduct for Good Health Insurance Practice for the rights and obligations of parties alongside regulation is grounded in particular in Article 2.3.2 of that code. This provision requires

2 HR (Supreme Court) 3 May 2013, ECLI:NL:HR:2013:BZ2900, *NJ* 2013/572 m.nt. C.E.C. Jansen (*KLM/CCC*).

3 HR (Supreme Court) 6 November 2015, ECLI:NL:HR:3241:2015, *NJ* 2016/474, m.nt. J. Legemaate and H.B. Krans (*VGZ c.s./Nutricia c.s.*).

health insurers, even if they are not in a dominant position, to use public, objective criteria when selecting care providers and to state grounds for any refusal to conclude an agreement.

Administrative Agreements can also affect parties' pre-contractual rights and obligations. In the decisions published until now, they played a role mainly in determining the parties' legitimate reciprocal expectations in a negotiation context.

Section 4.3 examines whether, because of the involvement of public interests and the capacity of the health insurer, the courts impose special due care requirements on the health insurer in the pre-contractual phase. It proves difficult to discern a clear line in the case law. A basis in case law for imposing further due care requirements is whether the health insurer has a dominant position. This may be a dominant economic position in the sense of the Mw, or a dominant position that is otherwise relevant to the application of contract law, for example because the care provider is dependent on the health insurer. I recommend that the courts should make it clear in their grounds for decisions what sort of dominant position is involved. In addition, it has emerged that the courts also consider the interests of insured persons, of public health in general and the public interest of good-quality care at the lowest possible price in their decisions about the applicable due care requirements. The civil courts also refer regularly to 'settled case law' as the basis for the requirement that a health insurer's healthcare purchasing policy should be verifiable, transparent and non-discriminatory. However, there are also decisions in which freedom of contract is paramount and decisive.

I argue that the legislator's intended role for the health insurer and its capacity implies that a health insurer should exercise a certain degree of due care in the pre-contractual phase. The interpretation of these due care requirements seems to me to depend largely on the circumstances of the case. Nevertheless, they relate to objectivity, verifiability, transparency and non-discrimination. I have provided guidelines for some situations in this chapter.

*5 Description, characteristics and qualification*

Chapters 5, 6 and 7 comprise a trinity relating to the legal effects of the healthcare purchase agreement. In Chapter 5, I explicate how healthcare purchase agreements can generally be defined, the principal obligations of the parties and the general characteristics of those agreements. Guidelines are also given for the qualification of healthcare purchase agreements as either contracts of the kind regulated in Book 7 of the Netherlands Civil Code, or as innominate contracts. The analyses is partly based on a comparison of health insurers' procurement terms and conditions and standard provisions drafted by sector associations and others (the 'contract documents studied')[4].

4 For a description and justification of the approach used in the comparison, see Section 5.2.

In my opinion, the healthcare purchase agreement can be described as:

*The agreement in which the care provider undertakes to the health insurer to provide the care and/or other services described in the agreement to persons who, pursuant to the healthcare insurance policy (and supplementary healthcare insurance) concluded with that health insurer, are entitled to the provision or reimbursement of that care, and in which the health insurer undertakes to the care provider to pay the agreed rate for the care provided.*

The healthcare purchase agreement is a reciprocal agreement that, in my view, should be classified as a continuing performance agreement with a fixed term, also when a health insurer and a care provider conclude successive continuing performance agreements with a fixed term with each other over a period of several years. It is neither an auxiliary agreement nor a preliminary agreement or framework agreement.

When describing a healthcare purchase agreement as a specified, innominate or hybrid contract, the scope of Part 7.7.5 of the Netherlands Civil Code regarding the medical treatment agreement – a category of the agreement to provide services – can be used as a guide. The healthcare purchase agreement is not itself a medical treatment agreement. However, if the care provider is obliged under the healthcare purchase agreement to perform acts that, in the relation with that insured person, fall within the scope of application of Part 7.7.5 of the Netherlands Civil Code for the medical treatment agreement (acts in the field of medicine), the care provider undertakes vis-à-vis the health insurer to perform activities that qualify as services. This applies to the majority of healthcare purchase agreements. Most of the provisions of Part 7.7.1 of the Netherlands Civil Code for agreements to provide services also lend themselves to application to healthcare purchase agreements. However, healthcare purchase agreements and applicable regulations often provide specific arrangements for issues regulated in Part 7.7.1.

Healthcare purchase agreements between health insurers and pharmacies, suppliers of medical devices, providers of seated patient transport and agreements relating to ambulance care include elements of other contracts regulated in Book 7 of the Civil Code. This is addressed in Sections 5.5.3 and 5.5.4 in greater detail.

*6 The relationship of the healthcare purchase agreement to health insurance and the medical treatment relationship*

Chapter 6 focuses on the relationship of the healthcare purchase agreement to the health insurance agreement and the medical treatment agreement. These agreements link the health insurer, care provider and insured patient in a triangular relationship. It is argued that there is no multi-party agreement between health insurer(s), care provider(s) and insured persons. The sides of the triangle constitute three separate legal relationships that can be considered linked contracts. In specific circumstances, the parties will have

to take into account each other's legitimate interests. How they should do so is coloured to some extent by regulations.

In response to the debate about this matter in the literature, I argue that any medical treatment agreement is concluded between the care provider/medical practitioner and the insured person, not between the health insurer and the insured person, even when the insured has an entitlement to benefits in kind from a health insurer. The medical treatment agreement is concluded if there is an offer and that offer is accepted.

Whether a healthcare purchase agreement contains a third-party beneficiary clause for the benefit of the insured person is a matter that should be determined by interpretation. Section 11(1)(a) Zvw does not, in my view, oblige health insurers to stipulate for the benefit of persons insured for benefits in kind an enforceable entitlement to care from the care provider in the form of a third-party beneficiary clause. Section 6.3 discusses the potential benefits of a third-party beneficiary clause and the insured person's options in the event of a discrepancy between the contents of the third-party beneficiary clause and what the insured person has understood on the basis of the statements and conduct of the care provider. I recommend that, when opting for a third-party beneficiary clause, the health insurer and the care provider should also determine whether a multiparty agreement will be concluded after the acceptance of the third-party beneficiary clause and, if so, that they should regulate their mutual relationships, particularly with respect to the possibility of termination of the agreement.

Alternatively, as part of or in addition to the healthcare purchase agreement with the care provider, the health insurer has the option of concluding a preliminary agreement with the care provider, on behalf of the insured person, in which it is stated that the care provider will conclude a treatment agreement with the insured person if the insured person turns to it. It is noted that this concept does not seem to be applied in practice because no power of representation is seen in health insurance policies. Nor, in my opinion, does such a power of representation derive from the Zvw.

The linked contracts in the healthcare triangle may raise the question of which claim(s) the health insurer must pay to the care provider under the healthcare purchase agreement and what the health insurer's obligation to pay involves in light of the relationships in the triangle and the legal framework. The answer to these questions may be important, for example, in terms of the legal defences the health insurer may invoke and the determination of when the claims arise or payment of the claims is due. This issue is addressed in Section 6.6, where a distinction is made between claims for payment for care granted to insured persons with a policy for benefits in kind and to insured persons with a reimbursement policy.

Health insurers, care providers and insured persons will have to make agreements among themselves regarding the patient contribution that the insured person must pay for certain forms of care under and pursuant to the Zvw. The law does not specify who should collect the patient contribution from the insured person or withheld it. Any collection of the deduct-

ible should, in my opinion, given the purpose and scope of the statutory arrangements in this respect, be for the account and risk of the health insurer (Section 6.7).

*7 Effect of regulations on principal obligations and interpretation*

Chapter 7 examines in further detail the contents of the healthcare purchase agreement and the manner in which those contents should be determined, given the regulatory context. The chapter focuses on the principal obligations of the parties.

Section 7.2 addresses the interpretation of the healthcare purchase agreement. The rules of interpretation developed in case law under general contract law can be applied to a healthcare purchase agreement. The Haviltex standard serves as the guiding principle. The objectification of this standard may be required first when the provision to be interpreted is part of an adhesion contract or of general terms and conditions and should be interpreted in the same way in relationships of a health insurer with different care providers. This is in particular the case if the provision comes from the health insurer's policy for healthcare purchasing and constitutes a general rule or procedural rule or a provision that corresponds word for word to the content of tender documents. In addition, the fact that a healthcare purchase agreement by its nature involves a predictably large number of insured persons whose legal position the healthcare purchase agreement aims, to some extent, to influence and regulate in a uniform way, constitutes grounds for the application of a more objectified Haviltex standard. Whether this is the case depends in part on the extent to which insured persons are affected by the provision to be interpreted. The mere presence of a third-party beneficiary clause does not necessitate the objectification of the interpretation standard.

A contra proferentem interpretation is particularly reasonable in the case of a provision in an adhesion contract offered to a care provider who is in a dependent position. On the other hand, in specific circumstances, a duty to investigate unclear provisions in an agreement may be incumbent on the professional, expert and/or powerful care provider in particular. For the purposes of considering for whose risk ambiguities in a healthcare purchase agreement should be, I believe it is important to determine the extent to which the health insurer and care provider have complied with the Regulation on the Transparency of the Healthcare Purchasing Process Zvw when the agreement was concluded.

Sections 7.3 to 7.8 examine whether, and if so how, regulations have an effect on the content of healthcare purchase agreements. To that end, Section 7.3 first describes in general how regulations can affect healthcare purchase agreements. The analysis in Sections 7.4 to 7.8 shows that the freedom of contract of health insurers and care providers with respect to the content of healthcare purchase agreements is significantly limited by regulations for the quality of care, the care offered and the insured package, and for rates, performance and the invoicing process. The level of the restriction of

freedom of contract depends on the type of care covered by the agreement. Performance regulation (Section 7.4) constitutes a restriction on the freedom of health insurers and care providers to determine which care they include in their contracts and how they define 'performance units' they include in their contracts. Regulations for the quality of care and care offered (Section 7.5) limit the freedom of the health insurer and care provider to agree about how the care must be provided, by whom the care must be provided, and which requirements must be met by the care provider or its employees. Which care must be purchased or reimbursed by health insurers is determined by and pursuant to the Zvw (Section 7.6). Rate regulation (Section 7.7) limits the freedom of health insurers and care providers to determine the price for care provided. Invoicing rules (Section 7.8) may limit the freedom of health insurers and health care providers to determine when to charge for care, in what way, and whom to charge. Healthcare purchase agreements are therefore concluded in a highly regulated context that significantly influences the content of those agreements.

The vast majority of these regulations are not ascribed to the contractual relationship between health insurer and care provider. These are rules for the health insurance policy, the medical treatment agreement, the actual provision of care, characteristics of the care provider, or the actual billing and payment for care. With the exception of Part 7.7.5 of Book 7 of the Netherlands Civil Code on the medical treatment agreement, these are regulations that are enforced in administrative law, criminal law and sometimes disciplinary law. However, compliance with the regulations does require healthcare purchase agreements to include a certain content, and therefore to proceed with the subsequent implementation of that content. In line with this, it has therefore emerged from the analysis of the contract documents studied that health insurers and care providers generally bind themselves to these regulations in contractual terms. Further, it is argued that the regulations provide a context that should be considered when interpreting healthcare purchase agreements.

Because the regulations are not ascribed to the contractual relationship between the health insurer and care provider, it is not always clear whether the regulations have consequences under contract law and, if so, what those consequences are. In the Sections referred to here, I look in detail at the validity of an agreement that violates regulations for the quality of care, the Care Provider Accreditation Act (Wtza) and the Special Medical Procedures Act (Wbmv). I also conclude that an agreement that violates Section 35 Wmg in terms of content or purport may, in specific circumstances, be void on the grounds of Art. 3:40(1) of the Netherlands Civil Code because it is contrary to public order. In my opinion, NZa's generic application of the capping instrument (Section 7.7.2) limits the content of healthcare purchase agreements in an indirect and de facto way only. The purport of the invoicing rules based on Section 37 Wmg, in particular for diagnosis-treatment combinations, is not to determine when the claim for the payment of care provided arises. Nor, in my view, do those rules determine when those claims fall due.

I advise the legislator, when issuing regulations that directly affect the content or performance of healthcare purchase agreements, to take the possible interaction between those regulations and relationships under contract law into consideration to a greater extent. The legislator could explicitly regulate the contract-law implications by statute but could also, for example in the explanatory memorandum accompanying a regulation, explicitly state that the contract-law implications must be determined on the basis of civil law, with or without the consideration of specific principles associated with the regulation.

Section 7.9 points out that supervision by both the ACM and NZa has so far resulted in few enforcement decisions touching on the content of a healthcare purchase agreement. Accordingly, the NZa's supervision activities do not address (dis)proportionality between reciprocal performances as such. However, an AMM obligation can have far-reaching effects on the contractual relationship, as seen in a case in which the NZa imposed a duty to conclude a contract that extended to all the terms of the agreement.

*8 Audit and non-fulfilment*

Chapter 8 discusses the rights and obligations of health insurers and care providers in the event of a failure to fulfil healthcare purchase agreements. The chapter begins with an exploration of the legal and practical relevance of possible types of non-fulfilment of a range of principal obligations incumbent on parties to the healthcare purchase agreement. In the rest of the chapter, the focus is on non-fulfilment by the care provider in the provision and invoicing of care when a) that care is not included in the services insured by and pursuant to the Zvw and b) the invoicing of care contravenes the tariff and performance rules in and pursuant to the Wmg – together referred to as 'unlawful invoices' – and the legal consequences thereof. The discussion also addresses the identification of unlawful invoices by formal audits, substantive audits and fraud investigations.

It emerges that the rights and obligations of the health insurer and the care provider under contract law during the execution of, and cooperation with, audits of contract compliance and fraud investigations are influenced to a major extent by regulation and the public, general and societal interests involved with that regulation. The same applies to the contractual and extra-contractual legal effects to be attached to the results of that audit or those fraud investigations. The relevant regulations consist of the Zvw, Chapter 7 of the Health Insurance Regulations (Regeling zorgverzekering), the Wmg and the Protocol for the Substantive Auditing of the Dutch Health Insurers (Protocol materiële controle van Zorgverzekeraars Nederland). The regulations referred to here were not written with a view to the contractual or post-contractual relationship between the health insurer and the care provider. However, broadly speaking, they do effectively address (among other things) the contractual relationship between the health insurer and the care provider, and they apply when the parties have concluded an agreement. In practice, health insurers and care providers generally bind each other con-

tractually in healthcare purchase agreements to those regulations. Significance can also be attached to this regulatory framework when interpreting what they have agreed upon. In addition, it is possible that provisions from these regulations supplement the agreement, or that care providers and health insurers are bound by these regulations on the basis of reasonableness and fairness. Furthermore, these regulations may be significant in the case of claims by the health insurer for the reimbursement of invoices on the grounds of tort or undue payment, as well as for determining the size of the claim based on the extrapolation of a sample from invoices and for the assessment of a care provider's invocation of forfeiture of rights. Regulations can also affect the contract indirectly by forcing parties to be bound by their own acts. This applies in particular to the audit plan that health insurers must draw up pursuant to Articles 7.6 to 7.8 (incl.) of the Health Insurance Regulations.

The Zvw, Wmg, Health Insurance Regulations and the Protocol for the Substantive Auditing of the Dutch Health Insurers – with the exception of Section 35(4) Wmg – do not state the implications under contract law of any violation of those rules. The Protocol for the Substantive Auditing of the Dutch Health Insurers does provide a direction for how to determine which subsequent action or legal effect should be attached to the outcome of audits and states which sanctions the care provider can, in any case, reasonably expect. The basis for remedies in the case of the violation of these regulations should always be sought in the contract or in a provision under general civil law, such as Section 6:74, 6:162 or 6:212 of the Netherlands Civil Code. Case law does show that the aforesaid regulations are important for the assessment of any invocation of these principles.

Case law research has shown that civil courts do not always state the grounds for the meaning they assign to regulations and how those regulations relate to the healthcare purchase agreement. I advise the civil courts to do so, at least more explicitly, for the sake of legal development and the possible review of decisions.

The provisions in the Further Regulations for the Auditing and Administration of health Insurers (Nadere regel Controle en administratie zorgverzekeraars) relating to the organisation and administration of audit activities are of a slightly different nature. In particular, these provisions serve to make accountability to, and supervision by, the NZa possible and they are not intended to supplement the healthcare purchase agreement.

The case law from the lower courts relating to the legality of invoices and audits of invoices assigns significance to the health insurer's statutory duty or obligation to audit invoices and verify that funds (public and otherwise) and premiums paid by insured persons are spent efficiently and/or effectively and lawfully. It also considers the general and/or societal interest of ensuring that the costs of care should not rise too high at the expense, ultimately, of the people who pay premiums and the national budget, and that payment should be made only for care that is provided efficiently and lawfully. In all these cases, the stated interests and the statutory duty or

obligation supported the health insurer's position. In the case law from the lower courts, this is one of the ways in which substance is given to the way in which health insurers are allowed to fulfil their role in society and to the expectations with regard to the care provider in terms of claims procedures and cooperating with audits. On a number of occasions, the importance of preventing the wrongful recovery of invoice payments was taken into consideration, as was the shared responsibility of the health insurer for the importance of the continuity of care.

I note that the use of the term 'statutory duty' in case law from the lower courts is not entirely correct. In my opinion, the courts should use this term only if the law actually stipulates the duty in question. However, health insurers are not explicitly entrusted with the statutory duty of checking whether the national budget and premiums are spent efficiently, effectively and lawfully, or at least not in the sense that health insurers have been granted public authority as referred to in Section 1(b) Awb. The legal system has been designed in such a way that health insurers are effectively encouraged to fulfil a certain public duty, but they are not directed to do so. Section 35 Wmg therefore prohibits the payment of invoices and benefits in violation of the Wmg and, in order not to violate this provision, health insurers will have to audit invoices. However, the Wmg does not include an explicit obligation or duty incumbent on the health insurer to audit invoices. In my view, it is correct that the courts do consider the public duty of the health insurer arising from or embedded in the system enshrined by the law.

In view of the responsibility arising from this duty, a certain degree of care may be expected from the health insurer during audits and fraud investigations. Due care requirements have been included in the Health Insurance Regulations and the Protocol for the Substantive Auditing of the Dutch Health Insurers. The interpretation of these rules should also grant significance to the public duty and capacity of the health insurer. For the purposes of the development or ongoing elaboration of open standards for audits and fraud investigations, the courts could look for inspiration to the general principles of proper administration and, if the case also involves the contractual phase, to the principles of procurement law.

Section 8.6 studies the conditions under which healthcare providers can invoke Section 13(5) of the Zvw. Pursuant to this provision, the insured person who is receiving care from the care provider at the time of the termination of an agreement between a health insurer and a care provider will remain entitled to care from the care provider after termination of the agreement for the account of the health insurer.

*9 Concluding remarks*

In the concluding remarks, I discuss the principal findings of the study. I also place the healthcare purchase agreement in the hybrid public-private legal framework and evaluate the application of that legal framework to the healthcare purchase agreement.

In Section 9.3, I discuss the mechanisms through which regulations affect the contractual relationship. I then provide a summary of how the healthcare purchase agreement, because of the involvement of public interests, is situated in a highly regulated context. The basic principle underlying the healthcare system is that freedom of contract applies between health insurers and care providers, with that freedom being limited by the law of obligations and competition law. Nevertheless, this study has shown that the rights and obligations of the health insurer and the care provider are, to a significant degree, determined in part by sector-specific regulations and soft law – and that those rules have an effect on the law of obligations. This law of obligations is, in turn, coloured – or at least it should, in my view, be so – by the capacity of the health insurer and the public interests involved in the healthcare purchase agreement.

I note that private law provides health insurers, care providers and the civil courts with a legal framework to determine retrospectively, after sector-specific regulations enter into force, the effects of regulation on the application of private law and to resolve questions of interaction between those regulations and private law. Justice can be done here to individual cases. Nevertheless, in order to prevent legal uncertainty about the effects of sector-specific regulations on the application of contract law, I recommend that the legislator considers the possible implications of those regulations in advance when drafting regulations that directly affect the establishment, content or implementation of healthcare purchase agreements. The legislator can also do this by, for example, explicitly stating that the regulations in question are not intended to determine rights and obligations under private law or by explicitly leaving the determination of the significance of the regulations under contract law to the civil court. For the purposes of implementing this recommendation, I suggest that Instruction 2.9 of the Drafting Instructions for Legislation (Aanwijzingen voor de regelgeving) explicitly mention private law as an area of law in which any secondary effects of new regulations should be identified.

The civil courts can, even when the decision is tailored to the circumstances of the case, contribute to the development of law about the effect of regulations on the application of private-law rules by explicitly stating in its grounds which sector-specific regulations they apply and which meaning they attribute to them in the application of private-law rules.

In Section 9.4, I discuss the meaning the case law has assigned to public interests and the capacity of the health insurer. I then argue that it follows from the system enshrined by the law that health insurers have a special capacity or position, even though no competence under public law has been granted to them. I refer to the directive role granted to the health insurer in the parliamentary history, the duty of care regulated in Section 11(1) Zvw and the regulation of the insured package that creates the conditions for the proper functioning of the healthcare system and regulates the size of the market for insured care, the dominant economic position resulting from the public duty, which arises from the statutory system, to audit invoices and

the significant level of government funding. In my view, the instrumental basis of the health insurer's freedom of contract also implies precisely that the freedom of contract should be limited because this freedom of contract is supposed to contribute to the fulfilment of public interests and serves the capacity of the health insurer. This capacity and these public interests require the imposition of special due care requirements on the statements and conduct of health insurers with respect to care providers during the establishment, determination of the content and execution of healthcare purchase agreements. I briefly state which kind of due care requirements are involved and offer some pointers for further research.