Multi-Principal Agency and the Compliance with Professional Guidelines in Health Systems: Economic and Regulatory Perspectives

Meervoudige principaal-agentrelatie en de naleving van professionele richtlijnen in gezondheidsstelsels: economische en regelgevende perspectieven

Thesis

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Ayman Mohamed Metwalli Ali Fouda
born in Alexandria, Egypt.

Erasmus University Rotterdam

Doctoral Committee:

Promotors:	prof.dr. M.G. Faure LLM
	prof.dr. G. Fiorentini
Other members:	prof.dr. E. Kantorowicz - Reznichenko
	prof.dr. L.B. Connelly
	prof.dr. M. Eliantonio

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LIST OF ABBREVIATIONS

ACA	Affordable Care Act
AGENAS	The National Agency for Regional Healthcare Systems, *Agenzia nazionale per i servizi sanitari regionali*
AHRQ	Agency for Healthcare Research and Quality
AIFA	*Agenzia Italiana del Farmaco* (Italian Agency for Pharmaceuticals)
AMWF	The Association of the Scientific Medical Societies, Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften
ASA	Assistanze Specialistica Ambulatoriale or Regional Ambulatory Dataset
ASL	Local Health Authorities, *Aziende Sanitarie Locali*
ATC	Anatomical Therapeutic Chemical
ÄZQ	German Agency for Quality in Medicine, Ärztliches Zentrum für Qualität in der Medizin
BÄK	The German Medical Association, *Bundesärztekammer*
CAP	Capitation payment
CCI	Charlson Comorbidity Index
CDM	Chronic Disease Management
CeVEAS	The Centre for the Evaluation of the Effectiveness of Health Care, *Centro per la Valutazione della Efficacia della Assistenza Sanitaria*
CHIP	The Children's Health Insurance Program
CKD	Chronic Kidney Disease
CPG	Clinical Practice Guidelines
DBC	Diagnosis Treatment Combination,
DiD	Difference-in Difference
DRGs	The diagnosis-related groups scheme
EBM	Uniform Value Scale, Einheitlicher Bemessungsmassstab
EU	European Union
FFS	Fee-For-Service

GDP	Gross Domestic Product
GFR	Glomerular Filtration Rate
GP	General Practitioner
HHI	Herfindahl–Hirschman Index
HHS	The U.S Department of Health and Human Services
HR	Hazard Ratio
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
ISS	The National Institute of Health, *Istituto Superiore di Sanità*
KiMS	The Knowledge Institute of Medical Specialists
KNMG	The Royal Dutch Medical Association
LATE	Local Average Treatment Effect
LPM	Linear Probability Model
NGC	The National Guideline Clearinghouse
NHS	National Health Service
NICE	The National Institute for Health and Care Excellence
NVL	The National Disease Management Guidelines, *Nationale VersorgungsLeitlinien*
OECD	Organisation for Economic Co-operation and Development
OOP	Out-Of-Pocket Payment
P4P	Pay for performance
PDRE-PSA	Panel data random-effects survival model
PHI	Private Health Insurance
PIRP	Prevenzione della Insufficienze Renale Progressiva
PTT	Parallel Trend Test
QOF	Quality and Outcomes Framework
RD	Regression Discontinuity
RDiT	Regression Discontinuity in Time
RRT	Renal Replacement Therapy
SDO	*Scheda di Dimissione Ospedaliera* or Regional Hospitalization Dataset
SGB	The Social Code Book, *Sozialgesetzbuch*

SHI	Social Health Insurance
SNLG	The National Guideline System, *Sistema Nazionale Linee Guida*
SSN	National Health Service system, *Servizio Sanitario Nazionale*
UK	The United Kingdom
USA	The United States of America
VHI	Voluntary Health Insurance
WHO	World Health Organization
WLZ	Long-term care, Wet Langdurige Zorg
ZVW	curative care, Zorgverzekeringswet

CHAPTER ONE: INTRODUCTION

1. BACKGROUND AND PROBLEM STATEMENT

Before and after the COVID-19 pandemic, the rising trend in health expenditure remains one of the major issues for policymakers and scholars in many countries worldwide, especially those with advanced economies (OECD, 2015). Escalating health expenditure constitutes a dilemma for policymakers as it poses real and looming threats to the sustainability of health systems, and therefore, it might as well hinder the endeavors to achieve universal health coverage that has been a global objective led by the World Health Organization (WHO) in the last few decades. Several studies were conducted to analyze the reasons behind the escalating health expenditure globally (Altman et al., 2003; Tang et al., 2012; Chye et al., 2021; Maharana & Ladusingh, 2021). Among the main factors of the escalating health expenditure, this literature underlines supply-side economic factors which are related to costs (service providers' payments and administrative costs) and especially technological factors such as innovations in drugs, biomedical devices, and other technologies; medico-legal factors such as professional malpractice and defensive medicine; demand-side factors such as unhealthy lifestyles or demographic factors such as population aging and the associated chronic disease burden; (Sorenson, 2013; Sheiner, 2014; OECD, 2015).

Such a trend in health expenditure led some health systems to rethink their structure and healthcare delivery model. A shift from the care models that solely focus on the health outcomes of an individual when in need of medical intervention towards more preventive and pre-emptive care services and towards a population health management model is marked as a potential gateway towards optimization of the health expenditure (Hennessy et al., 2015; Merchant et al., 2016; Jacko et al., 2021). With population health management models, health systems emphasize the health outcomes of larger communities, entire populations, or population subgroups. By doing so, with the seemingly inevitable

rising trend in health expenditure, policymakers try to optimize expenditure by re-allocating available resources to clinically appropriate services that serve broader populations and thus improve the population health outcomes and mitigate the financial burden in the future.

At the very heart of the process of changing the structure of the health systems is the tripartite interaction between policymakers or service regulators (sometimes also funders), service providers (professionals), and service users (patients). This interaction can be investigated as a multi-principal agent relationship ubiquitous in most regulated health systems. In such a relationship, service providers (physicians) act as agents of two principals: the patients and the regulators or funders. In a multi-principal agent setting, several economic and regulatory problems emerge and pose challenges to regulators with regard to the implementation of the population health models and the optimization of health expenditure. Among the problems is the information asymmetry between the principal(s) and the agents, where the agents conventionally are more informed than the principals with regard to health and medical information. Therefore, principals delegate health- and medical-related tasks to agents or service providers. In the absence of contractual agreements and regulatory framework, potential moral hazards, arising from the information asymmetry, can lead service providers (agents) to produce inefficient and unnecessary services that might maximize their utility and the utility of service users or patients while undermining the utility of the service regulators - especially when the objectives of both the providers and users are aligned against the regulators (Buchanan, 1988; Mooney & Ryan, 1993; Forgione et al., 2005; Schneider & Mathios, 2006).

Several strategies have been devised in domains such as corporate governance and public economics to mitigate and solve the problems of the multi-principal agent setting and design optimal contracts that maximize the utility of the principal or regulator. In health markets, among the most widely investigated strategies are:

1. Financial incentives imposed by the regulator or funders to service providers and patients.
2. Regulatory arrangements aiming at influencing the providers' clinical decisions.

The use of financial incentives alone by regulators or funders in health markets to influence the providers' clinical choices is challenging, and the results shown in the relevant literature are mixed at best. For instance, Quinn et al. (2019) found no association between different provider payment mechanisms and the volume of patients' visits, and the overall cost of care. Other studies revealed that financial incentives to providers could be too powerful to the extent that they can negatively affect the fiduciary role of the providers towards their patients (Armour et al., 2001; Heider & Mang, 2020). Other studies questioned the practice of incentive-induced cream-skimming of patients by the providers, leading to fairness problems (Kjøstolfsen et al., 2021). Overall, financial incentives are, at best useful tools to induce some change in the behavior of health professionals but cannot alone provide a solution to the allocative problems due to multi-principal agent settings.

Regulatory arrangements such as soft law tools and different degrees of mandate provide a promising alternative for regulators to induce behavioral changes in providers while maintaining a balance in the multi-principal agent relationship. Such a balance is paramount to regulators trying to maximize the health outcomes of their population. In principle, soft law tools such as clinical practice guidelines offer evidence-based information that mitigates the asymmetry gap between the principal and the agent and thereby contribute to a more efficient allocation of healthcare resources. However, the question of compliance by providers and adherence by patients to soft law tools in healthcare remains unconcluded. Several determinants play a role in the compliance with guidelines, whether they are local, national, or international guidelines, including individual characteristics of service providers, regional differences, differences across medical specialties, and in the trust relationships between practitioners and patients (Aarts et al., 2012; Lugtenberg et al., 2009; Zerbo et al. 2020). However, the

interplay between regulatory tools and financial incentives in healthcare markets is still largely understudied, broad, and open to further research.

Hence, in this thesis, I examine the determinants of (non-)compliance with different regulatory tools in light of the tripartite interaction of the multi-principal agent relationship between service providers, patients, and regulators or funders. More precisely, I will focus on the effects of financial incentives and professional competition on the (non-)compliance with different local and national regulations, soft law tools, and degrees of mandate. The thesis aims to:

1. Reveal the different institutional, economic, and regulatory settings that influence the multi-principal agent relationship in different health systems.
2. Propose a theoretical or conceptual framework of the potential (non-)compliance with soft law tools issued by regulators.
3. Study the effect of intra- and inter-professional competition among healthcare professionals on the (non-)compliance with soft law tools.
4. Examine the effect of different degrees of mandate on the providers.

2. RESEARCH QUESTIONS

The main research question of this thesis is:

> What are the determinants of the (non-)compliance with different regulatory tools in light of the multi-principal agent relationship between the three main economic players in the healthcare systems: service providers (professionals), regulators (funders), and users (patients)?

Furthermore, four sub-questions are used to answer the main research question as follows:

1. What are the different institutional, economic, and regulatory settings which govern the multi-principal agent relationship in healthcare in different countries representing a wide array of governance, economic, and regulatory considerations? How can such different settings affect the multi-principal agent relationship?
2. In light of the multi-principal agent framework, what role can soft law tools such as clinical practice guidelines play in regulating the medical practice and providers' decisions?
3. How do intra-professional competition between GPs and inter-professional competition between different medical specialties affect the (non-)compliance with clinical practice guidelines of enrollment into a chronic disease management program?
4. In a setting where physicians act as agents of multiple principals: patients, and regulators, under which conditions are different degrees of mandate an effective implementation and regulatory tool?

3. OUTLINE OF THE CHAPTERS AND RESEARCH METHODOLOGY

This subsection provides the main outline and the methodology of the following chapters.

Chapter Two: The Regulation of Professional Healthcare Services: A Comparative Analysis

In this chapter, a comparative analysis is carried out to reveal different governance, economic, and regulatory determinants of the multi-principal agent relationship in five different countries. The analysis focuses on the implementation of similar regulatory and contractual solutions that allows service regulators or funders to change their service delivery model or structure. The chapter focuses on five countries, which represent different health systems as for funding and provision of services. The countries of choice are Italy, the United Kingdom (UK), Germany, the Netherlands, and the United States (USA). The comparative analysis delves into the typology of the health system, financing

system, and the trends of health expenditure in general. Then the analysis tackles directly the tools to regulate the multi-principal agent interactions in health markets, such as the provider payment schemes and the regulatory arrangements of soft law tools used in the five countries to optimize service provision and their enforcement and compliance status.

Chapter Three: Economic and Regulatory Arrangements of Multi-Principal Agent Relationship in Healthcare: A Theoretical Framework

This chapter is concerned with the second research sub-question: In light of the multi-principal agent framework, what role can soft law tools such as clinical practice guidelines play in regulating the medical practice and providers' decisions? Therefore, this chapter analyzes the principal-agent model in general and the multi-principal agent in healthcare in particular, discussing:

1. The different roles of cost-sharing arrangements posed by the regulators on service providers
2. The role of soft law tools such as clinical practice guidelines in influencing the clinical choice of service providers

After this discussion, a theoretical framework of the behavioral interactions between service providers, payers, and users when confronted with soft law tools such as clinical practice guidelines is developed. The framework draws testable implications on how different legal or professional rules and different economic settings affect the (non-)compliance of service providers with the soft law tools.

Chapter Four: Determinants of Compliance with Clinical Practice Guidelines: The Case of Patient Enrollment in a Chronic Disease Management Program

Chapter four of this thesis tackles the third research sub-question: How do intra-professional competition between GPs and inter-professional competition between different medical specialties

affect (non-)compliance with clinical practice guidelines of enrollment into the chronic disease management program? The chapter investigates the case of inappropriate (non-)enrollment of chronic kidney disease (CKD) patients into a CKD management program called PIRP that has been implemented in Emilia-Romagna, Italy. The enrolment of patients into PIRP should follow clinical practice guidelines developed by the local health authorities in Emilia-Romagna. The chapter examines the effects of different factors affecting the (non-)compliance with the guidelines, namely the intra-professional competition between GPs and the inter-professional competition between different medical specialists who interact with CKD patients. Using panel data from 2009 to 2016 from PIRP, a panel data survival analysis is used to reveal the effect of different characteristics of the service providers and the service users on the (in-)appropriate referral of CKD patients to PIRP in light of the locally issued clinical practice guidelines of concern. Furthermore, the chapter provides a description of the PIRP program and its guidelines. In addition, it provides a conceptual framework for the motivations of the agents or providers.

Chapter Five: The Compliance of Healthcare Professionals to Different Regulatory Degrees for the Prescription of Generics Medications

This chapter answers the fourth and last research sub-question: In a setting where physicians act as agents of multiple principals, under which conditions are different degrees of mandate an effective implementation and regulatory tool? Precisely, the effects of two national laws targeting the prescription behavior of service providers are examined. The two laws have different degrees of mandate to physicians as prescribers. Using the PIRP panel data, firstly, the effect of the two laws on the policy outcome of interest, promoting generic medications, is examined using the regression discontinuity in time (RDiT) causal inference method. Secondly, two difference-in-difference models: canonical and dynamic, are used to analyze the effect of the second law from the RDiT model, explore

the long-term effect of the soft law, and reveal conditions that lead to heterogeneity in the treatment effect.

Chapter Six: Conclusion

The final chapter provides a summary and the main conclusions of the thesis - and how they relate to the research question(s). In addition, it discusses the limitations of the thesis along with avenues for future research.

4. RESEARCH SIGNIFICANCE

This thesis is chiefly concerned with studying the multi-principal agent relationship and the determinants and driving factors of (non-)compliance with soft law tools and different degrees of mandate in healthcare systems. More specifically, the thesis investigates how the (non-)compliance with soft law tools and different degrees of mandate at a micro-level depends on the interaction between three main economic agents: the service providers, service users as in patients; and service regulators or funders. Studying the characteristics and attributes of each agent might give important insights into how soft law tools and different degrees of mandate work in different regulatory and institutional settings.

The research will therefore contribute to the literature of applied health economics and regulation in terms of understanding the (non-)compliance with soft law tools and different degrees of mandate, or better, of disentangling the causal relations between the characteristics of the service providers, receivers and funders and the effectiveness of those regulatory tools. Such analysis is of paramount importance for scholars and policymakers as it will provide insights for designing more sustainable health systems to achieve better health outcomes and to open the door for further validation and testing in other institutional settings.

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CHAPTER SIX: CONCLUSIONS

This thesis primarily attempted to investigate the determinants of the (non-)compliance with different regulatory tools in light of the multi-principal agent relationship between the three economic players of healthcare service providers (professionals), regulators (funders), and users (patients). In addition, insights on the different institutional, economic, and regulatory settings, which govern the multi-principal agent relationship in healthcare in different countries, were provided. Furthermore, a conceptual framework of the possible (non-)compliance by service providers (physicians) to different regulatory tools issued by the service regulator or funder was provided and tested empirically. The main conclusions of the thesis are as follows:

1. MAIN CONCLUSIONS

In a Multi-Principal Agent Setting, the Utilization of Financial Incentives to Align the Objectives of Service Providers and the Regulator/Funder is Important but Not the Only Solution

As shown in Chapter 2, different health systems employ different financial incentives in the form of provider payment mechanisms to achieve their own policy objectives. Each health system has unique financial incentive features that fit its policy agenda. Such heterogeneity does not provide a one-size-fits-all model of financial incentives to optimize the multi-principal agent relationship. Furthermore, with the current trend on regulated and mature health systems to shift focus onto population health management models, regulators and funders often provide financial incentives to providers to increase services and improve health outcomes through preventive and primary care and limit or economize financial incentives to optimize the costly and specialized health services in secondary and tertiary care. Although some studies showed that the role of financial incentives in a multi-principal agent

setting is weak or without effects, the general consensus is that financial incentives are important and can influence the service providers' clinical choices.

Nevertheless, financial incentives suffer from different problems related to moral hazards and ethicality in managing the relationship between providers and patients. For instance, some financial incentives to providers easily become too strong to the extent that they lead to inappropriate care and to opportunistic behavior. Provider's cost-sharing mechanisms can indeed lead to fewer health services provided and cream-skimming of patients, while other financial incentives can lead to service accessibility issues for the patients. In such cases, financial incentives might have large adverse effects and backfire on the regulators' objectives to improve the population's health outcomes. To this end, the utilization of financial incentives in a multi-principal agent setting is important but cannot be the only policy tool to regulate the multi-principal agent relationship.

Soft Law and Clinical Practice Guidelines are Important Tools to Mitigate the Problems of the Multi-Principal Agent Setting in Health Markets

Soft law tools such as clinical practice guidelines can indeed offer service regulators or funders a complementary or substitutive role to financial incentives. The evidence-based principle of the clinical practice guidelines decreases the information asymmetry gap between the service providers and the regulators or funders. Therefore, they mitigate the classic multi-principal agent problems of information asymmetry and moral hazard. By doing so, they provide avenues for a greater alignment of the objectives of the regulators and the agents.

Furthermore, the non-binding nature of soft law tools such as clinical practice guidelines is beneficial as they preserve to a significant extent the professional autonomy of the agents (service providers), which is an important component of the medical practice. The non-binding nature also provides

ground to providers for flexible clinical decision-making, especially when faced with complex medical conditions that cannot be treated *ex-ante* even by carefully designed guidelines.

Soft Law Tools (Clinical Practice Guidelines) are Complex and Heterogeneous

Although soft law tools (clinical practice guidelines) in healthcare are important in a multi-principal agent setting, similar to financial incentives, they face several challenges. These challenges relate to the heterogeneous nature of their development process. For instance, as shown in Chapter 2, there are different models for developing clinical practice guidelines. On the one hand, in some countries, guidelines are developed centrally, such as the case in the UK. On the other hand, in other countries, the development of guidelines is decentralized and carried out by several agencies or institutions. Moreover, the heterogeneity in clinical practice guidelines extends to their scope; while local or regional health authorities issue some guidelines, others are issued by national or federal authorities. Chapter 4 showed that compliance with regional and international soft law tools could vary significantly in relation to specific economic characteristics of the regulatory settings and market conditions. Additionally, the scientific evidence that inspires the drafting of clinical practice guidelines can stem from local, national, or international research. Overall, therefore, adaptation to the local context and to the local healthcare delivery model is paramount for compliance, as shown in Chapter 4 with the adaptation of the international KDIGO guidelines into a regional version in Emilia-Romagna.

Furthermore, the heterogeneous nature of soft law tools or clinical practice guidelines extends to the (non-)compliance of service providers. Several factors have been associated with non-compliance with clinical practice guidelines. Chapter 2 showed that there are individual, organizational, and professional factors that may hinder compliance. For instance, at the individual level, the age of providers or

physicians is among the factors that negatively affect compliance with CPGs. On the organizational level, the lack of trust, inappropriate governance, conflicts of interest, and lack of coordination and awareness are associated with non-compliance. Finally, at the professional level, the lack of unambiguous scientific evidence and the competition between different professional specialties - each with its specific cultural identity – are among the drivers of non-compliance.

Soft Law Tools and Clinical Practice Guidelines Work but Under Conditions

Findings from Chapter 4 suggest that soft law tools are effective. Indeed, the clinical practice guidelines aiming at organizing the enrollment of patients into the PIRP program were found to be partially complied with by the specialists. However, some factors such as intra-professional competition between GPs were found to negatively affect compliance with the PIRP guidelines. Where the economic arrangements between the regulator and the GPs in Emilia-Romagna provide GPs with the incentive to maximize the number of their affiliated patients, GPs might end up inappropriately referring their patients to an advanced level of care. Such a referral, which keeps patients co-managed by GPs and specialists, can be some form of quality signaling by GPs to satisfy their patients. In contrast, no evidence for the effect of inter-professional competition between specialists (nephrologists, cardiologists, and endocrinologists) was found to negatively affect compliance with the PIRP guidelines. Such contrasting findings suggest that different monitoring devices, training, and communication may play a role in the (non-)compliance with clinical guidelines.

Different Degrees of Mandate have Different Effects on Providers' Compliance

Chapter 5 studies two different degrees of mandate aiming to promote the prescription of generic medications. The two laws have different degrees of mandate. Results have shown that the stronger the mandate, the stronger the effect on the prescribing behavior of the agents or the service providers.

On the one hand, a softer mandate in which prescribers were required to inform their patients about the availability of generic medications did not have a significant effect on the average percentage of generic medications prescribed by individual GPs. On the other hand, a stricter mandate, which requires prescribers to opt for generic medications for newly diagnosed chronic patients, had a significant effect on the average percentage and on the probability of prescribing generic medications by GPs. The contrast in the monitoring and documentation tools of the GPs' prescribing behavior could be the driver behind such differences in compliance with different mandates.

Nevertheless, some supply-side factors played a role in the compliance with the tougher mandate. Intra-professional competition between GPs was found to negatively affect compliance – a result that is similar to the findings of Chapter 4. GPs operating in more competitive settings complied less with the mandate to prescribe generic medications; a potential explanation is that branded medications, which are widely perceived superior to generic alternatives, are prescribed by GPs to satisfy their patients. Furthermore, Chapter 5 provides findings that confirm that patients who are co-managed by GPs and hospital specialists are more likely to receive more generics. This result confirms that hospital specialists possess a greater influence on the patients and that such influence affects the GPs' prescribing behavior as well.

2. LIMITATIONS

In this subsection, the limitations of the thesis are addressed by the chapter content. Chapter 2 provided a comparative analysis of the economic and regulatory arrangements governing the multi-principal agent relationships in five different health systems. Although the comparison between the economic arrangements of the provider payment mechanisms and the development of the clinical practice guidelines between the five countries of choice are thematic and consistent, the comparative

analysis between the statuses of (non-)compliance with the guidelines is not fully inconsistent. This inconsistency reflects the heterogeneous nature of the clinical practice guidelines research in general, where thematic comparative research on specific guidelines (sorted by medical specialty, management programs, or specific medication) is lacking – to the best of the author's knowledge. For instance, Chapter 2 did not provide a consistent and thematic comparative analysis of the (non-)compliance with Chronic Kidney Disease programs in the five countries due to the lack of literature.

Furthermore, in Chapter 4, although the results point to important insights on specialists' and GPs' referral and enrollment behavior of patients by deploying two categories of inappropriateness, the study design could not capture a specific CKD stage (stage 3b), which qualifies patients for enrollment in the PIRP program according to KDIGO and PIRP guidelines. In addition, in both Chapters 4 and 5, upcoding and downcoding practices, if present, are not accounted for in the econometric analysis and cannot be discerned using the available data. Finally, the scope of the thesis focuses on regulated and mature health systems. Therefore, findings, especially from the empirical analysis, should be extrapolated to less or unregulated markets with caution due to the different institutional, financial, and regulatory settings.

3. FUTURE RESEARCH

The intersection between applied health economics and law and economics as applied to the analysis of the implementation of soft laws and different degrees of mandate in healthcare systems provides avenues for future research. Further research to better understand the effectiveness of soft law tools and different degrees of mandate in the multi-principal agent settings and the (non-)compliance with the professional guidelines can entail several comparative empirical analyses. First, an expansion of the body of the literature in terms of vertical comparative analysis of (non-)compliance with local or

regional, national, and international clinical practice guidelines. Such an analysis can add to our understanding of the service providers' attitudes towards regional or national guidelines with a stronger degree of enforcement and professionally adopted guidelines with less degree of enforcement but with more degree of professional peer pressure and professional identity.

Second, a cross-country or cross-system comparative empirical analysis between specific guidelines in different countries or different health systems. Based on this thesis, a premise for future research is to compare policies of promoting generic medications in several countries or several health systems. Such research would require the availability of comparable data. Third, future research should address a comparative empirical analysis of (non-)compliance with soft law tools and clinical practice guidelines between regulated, less regulated, and unregulated health markets.

Fourth, in addition to the aforementioned comparative empirical studies, identifying new determinants and reasons that led soft law tools and softer degrees of mandate to be (in)effective in the multi-principal agent relationship is another avenue for future research. For instance, although in Chapter 5 of this thesis, the January 2012 law did not turn out to be effective, the reason behind this non-compliance is not known nor investigated in Chapter 5 due to data limitations. Such an avenue for future research would shed highlight on the source of the non-compliance, whether it is from the physicians (the agents) or from the patients (the second principal). By doing so, this research can advance our understanding of how soft law tools and different degrees of mandates could work and how they should be designed.

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Ayman Mohamed Metwalli Ali Fouda

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