Contents

List	of Figures	page xi
List	of Tables	xiii
List	of Contributors	XV
Ackı	nowledgments	xvii
	Introduction Carmel Shachar, Julia Adler-Milstein, Daniel B. Kramer, and I. Glenn Cohen	1
	PART I QUESTIONS OF DATA GOVERNANCE FOR DATA FROM DIGITAL HOME HEALTH PRODUCTS	11
	Introduction Carmel Shachar	11
1	In the Medical Privacy of One's Own Home: Four Faces of Privacy in Digital Home Health Care Barbara J. Evans	15
2	Patient Access to Health Device Data: Toward a Legal Framework Charles Duan and Christopher J. Morten	27
3	Challenges of Remote Patient Care Technologies under the General Data Protection Regulation: Preliminary Results of the TeNDER Project Danaja Fabcic Povse	38
4	Renegotiating the Social Contract for Use of Health Information: Lessons Learned from Newborn Screening and Implications for At-Home Digital Care Jodyn Platt and Sharon Kardia	50

viii Contents

	PART II DIGITAL HOME DIAGNOSTICS FOR SPECIFIC CONDITIONS	61
	Introduction Daniel B. Kramer	61
5	Patient Self-Administered Screening for Cardiovascular Disease Using Artificial Intelligence in the Home Patrik Bächtiger, Mihir A. Kelshiker, Marie E. G. Moe, Daniel B. Kramer, and Nicholas S. Peters	65
6	The Promise of Telehealth for Abortion Greer Donley and Rachel Rebouché	79
7	Monitoring (on) Your Mind: Digital Biomarkers for Alzheimer's Disease Claire Erickson and Emily A. Largent	92
	PART III THE SHAPE OF THE ELEPHANT FOR DIGITAL HOME DIAGNOSTICS	105
	Introduction I. Glenn Cohen	105
8	Physician and Device Manufacturer Tort Liability for Remote Patient Monitoring Devices David A. Simon and Aaron S. Kesselheim	109
9	Post-Market Surveillance of Software Medical Devices: Evidence from Regulatory Data Alexander O. Everhart and Ariel D. Stern	123
10	Labeling of Direct-to-Consumer Medical Artificial Intelligence Applications for "Self-Diagnosis" Sara Gerke	139
11	"Internet Plus Health Care" as an Impetus for China's Health System Reform Zhang Yi and Wang Chenguang	156
	PART IV REIMBURSEMENT CONSIDERATIONS FOR DIGITAL HOME HEALTH	169
	Introduction Julia Adler-Milstein	169

Contents ix

12	A Pathway for High-Value Home Hospital Care in the United States: Statutory, Reimbursement, and Cybersecurity Strategies in the Age of Hybrid Care Stephanie Zawada, Nels Paulson, Margaret Paulson, Michael Maniaci, and Bart Demaerschalk	173
13	Digitally Enabled Medicaid Home and Community-Based Services Kathryn Huber and Tara Sklar	185
14	EU In-Home Digital Diagnostics – Cross-Border Patient Reimbursement under Threat? Kaat Van Delm	196

