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KEY ISSUES IN MEDICAL DEVICE COMPLIANCE: ADAPTING TO CHANGE AND INNOVATION

MONA PETERSON ROSOW
SR. COMPLIANCE DIRECTOR
RESTORATIVE THERAPIES GROUP

LAVONNE PULLIAM
SR. COMPLIANCE PROGRAM MANAGER
RESTORATIVE THERAPIES GROUP

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KEY ISSUES IN MEDICAL DEVICE COMPLIANCE
AGENDA

1	Overview of Medical Device Regulation
2	New World for Medical Device
3	Building Compliance Programs to Keep Up with Innovation

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OVERVIEW OF MEDICAL DEVICE REGULATIONS

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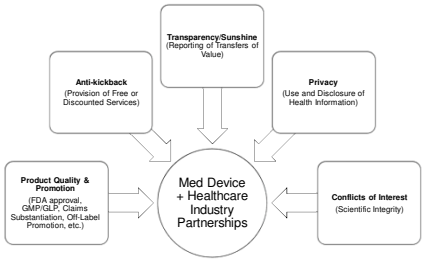
MEDICAL DEVICE
UNIQUE RISKS TO MANAGE



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EACH MODEL PRESENTS UNIQUE RISKS
DEVICE V. SERVICE MODELS

Services		
Conflict of Interest	Separation of Data	Organizational Structure
Off-Label/Claims	Transparency	Fair Market Value
Clinical Independence	Beneficiary Inducement	Debarment
AKS	Billing/Coding	Practice of Medicine
BCS Applicability	Segregation of Systems	Licensure

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NEW WORLD FOR MEDICAL DEVICE

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CHALLENGES IN OUR GLOBAL HEALTHCARE SYSTEM
HEALTHCARE IS NOT SUSTAINABLE AS IS

$7.2 TRILLION [1]	▪ **2x** variation in 30-day mortality rate from heart attack in U.S. ▪ **18x** variation in reoperation rates from radical prostatectomies in the Netherlands ▪ **20x** variation in mortality after colon cancer surgery in Sweden [2]		▪ Consumer-driven healthcare ▪ Evidence-based medicine ▪ Prior authorization for expensive services [4]
Healthcare costs are skyrocketing	There's wide variation in care and delivery of meaningful outcomes	The need for care is only growing	Incremental "solutions" have had limited impact

1. Source: Deloitte. 2015 Global Health Care. Accessed September 8, 2015.
2. Source: ICHOM analysis, Martin Makary, *How Health Care's Successes Became Distractions"*, Health Affairs August 2014
3. World Health Organization. The Impact of Chronic Disease in High Income Countries. Accessed September 1, 2015 / UNC Carolina Population Center. Mortality and Cause of Death, 1900 v. 2010. June 16, 2014. Accessed September 1, 2015., 4. Source: Michael Porter ICHOM 2016

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HEALTHCARE INDUSTRY IS CHANGING FUNDAMENTALLY
REIMBURSEMENT CONTINUES TO EVOLVE

FEE FOR SERVICE **(e.g. DRGs)**	PAY FOR **PERFORMANCE**	INTEGRATED CARE/ **BUNDLED PAYMENT**	ACCOUNTABLE CARE/ **SHARED SAVINGS**	CAPITATION/ **GLOBAL PAYMENT**
Reimbursed for volume of services, not value	Fee for service at risk for bonuses/penalties based on performance measures	Single payment for all services provided for an episode of care	Capitated payment for a defined population for some, but not all, services	Capitated payment for a defined patient population for all services provided

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VOLUME-BASED SYSTEM ISSUES GLOBALLY

EPISODIC	DISCONNECTED	INCONSISTENT	LACKING DATA
HEALTHCARE PROVIDERS ARE PAID FOR THE **VOLUME** OF SERVICES, NOT **VALUE**	**PATIENT CARE IS NOT COORDINATED** ACROSS THE CARE CONTINUUM	**CARE CAN VARY GREATLY** FROM PATIENT-TO-PATIENT FROM FACILITY TO FACILITY (AND SOMETIMES EVEN AT THE SAME FACILITY)	**DATA NOT SHARED** ACROSS THE SYSTEM

This challenge creates opportunities for new solutions and new partnerships between players in the healthcare industry. With new solution offerings, comes new risks and challenges that often our compliance programs were not designed to address.

OUR FOCUS:

THERAPY OPTIMIZATION	EPISODIC CARE BUNDLES	CHRONIC CARE MANAGEMENT
Products/ technologies that by design impact outcomes and cost	Routine treatment delivered typically includes our product	Impacting care over a more sustained period of time (beyond the product sale)

BUILDING COMPLIANCE PROGRAMS TO KEEP UP WITH INNOVATION

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SO I HAVE THIS GREAT IDEA….
HOW NEW IDEAS COME ACROSS OUR DESK

Business Leader: So I have this great idea ….

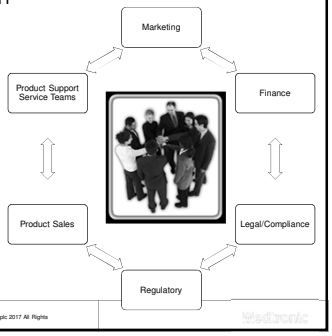
Compliance Leader: Really, tell me more

Business Leader: So I want to solve my customer's problems by providing them with a new service offering that we have never done before. I have no idea what to charge for the service or even if that is necessary. I was in a meeting yesterday with Dr. Key Opinion Leader and he told me that if we provide this service, our device sales will go through the roof! What are our next steps?

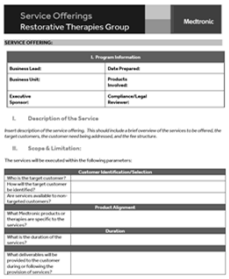
Compliance Leader: (in their head) What are the next steps…

DEVELOPING AND LAUNCHING NEW BUSINESS MODELS
A CROSS-FUNCTIONAL TEAM APPROACH

- **Get everyone into a room together!**
  - If the business lead is going to each team individually, volunteer to pull the functions together.
  - Changes to one area often impact how we control the compliance risks
  - If you don't have the full picture, you may not be controlling the right risks.
- **Find alignment with other functions**
  - "Free services" also raise concerns for finance
- **Set the right expectations with your business team**
  - If your organization has never done this type of initiative before, it will take longer to work through the issues
- **Look to other parties**
  - Partner with hospital compliance/legal teams
  - Who has dealt with this in the past? Reach out and collaborate



WRITE IT DOWN
KEEP EVERYONE ON THE SAME PAGE


Service Offerings
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SERVICE OFFERING:

I. Program Information	
Business Lead:	Date Prepared:
Business Unit:	Products Involved:
Executive Sponsor:	Compliance/Legal Reviewer:

I. Description of the Service

Insert description of the service offering. This should include a brief overview of the services to be offered, the target customers, the customer need being addressed, and the fee structure.

II. Scope & Limitation:

The services will be executed within the following parameters:

Customer Identification/Selection	
Who is the target customer?	
How will the target customer be identified?	
Are services available to non-target customers?	
Product Alignment	
What Medtronic products or therapies are specific to the service?	
Duration	
What is the duration of the service?	
Deliverables	
What deliverables will be provided to the customer during or following the provision of services?	

- **Have the business write in words their ideas**
  - Power point leaves the door open to lots of different interpretations
  - Leverage free text fields
  - Consider attaching the form to sharepoint site for reportability purposes
- **Document compliance decisions & control points**
  - What are the risks you are managing and how did you get comfortable?
  - Auditing & monitoring can leverage the same documentation to test?

CONSIDER "PILOTS"
TESTING GROUND FOR NEW BUSINESS MODELS

- Purpose: Learn more about one or more aspects of new business model
  - E.g. fair market value determination, available market, resource needs, validate business model, etc.
- Structure
  - Limited scope, duration, and customer eligibility
  - Should be new to your organization
- Ongoing review and evaluation of pilot performance
- Understand value exchange with customer
  - Transparency reporting may be required
  - AKS Fact and Circumstances Analysis
- Ongoing review of pilot performance
- Solicit Customer feedback

ALIGNING NEW PROGRAMS WITH LEGACY PROGRAMS
WHAT IS THE IMPACT TO YOUR EXISTING COMPLIANCE PROGRAM?

- **Review and revise relevant policies, procedures, conduct standards**
  - Do definitions align with new business model?
  - Can current processes accommodate new business model?
  - Are new policies, procedures, or conduct standards necessary to address new risks?
  - Does current contracting process accommodate needs of new business model?
  - Do new legal or regulatory frameworks apply?
- **Clearly defined roles and responsibilities**
  - Do you need to establish firewalls to segregate data or information?
  - Do program titles or descriptions create confusion with legacy programs?
- **Auditing and monitoring**
  - Do legacy auditing and monitoring techniques accurately evaluate new risks?
  - Are new risks captured in risk assessment process?

POST LAUNCH

- **Consider governance/oversight**
  - How often do you check in with the business about the new offering?
  - Develop the auditing & monitoring plan
- **Role of business to oversee as compared to compliance team**
  - Focus on areas where may perceive risk differently
  - Consider build and then transition
- **Revisit on a periodic basis compliance assumptions**
  - Has the environment changed? New systems or processes or teams?

TIPS AND TRICKS FOR IMPLEMENTING NEW COMPLIANCE PROGRAMS

Pre-Launch

- Educate the business on key risks early and often
- Include compliance on the development core team
- Align on key decision makers and meet with them regularly throughout the project
- Conduct pilot program and incorporate key learnings
- Document guidance provided
- Identify key risk points for future auditing and monitoring

Post-Launch

- Stay involved in any ongoing governance committees and/or business reviews
- Transition ongoing compliance support to appropriate individuals
- Monitor program performance and adjust as necessary
- Develop auditing and monitoring plan

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QUESTIONS?

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BACK UP SLIDES

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EACH MODEL PRESENTS UNIQUE RISKS
DEVICE V. SERVICE MODELS

Device			Services		
Conflict of Interest	Separation of Data	Organizational Structure	Conflict of Interest	Separation of Data	Organizational Structure
Product Pull Through	Transparency	Fair Market Value	Practice of Medicine	Transparency	Fair Market Value
Off-Label/Claims	Clinical Independence	Beneficiary Inducement	Clinical Independence	BCS Applicability	Segregation of Systems
	AKS		Licensure	Debarment	Billing/Coding
			AKS	Beneficiary Inducement	Off-Label/Claims

DEVELOPING AND LAUNCHING NEW BUSINESS MODELS
A CROSS-FUNCTIONAL TEAM APPROACH

MARKETING	FINANCE	LEGAL & COMPLIANCE	PRODUCT SALES FORCE	REGULATORY	PRODUCT SUPPORT SERVICES TEAM(S)
Owns service model strategy and budget. Responsible for execution with input from cross-functional partners. Develops all promotional or other customer facing materials and obtaining necessary approvals. Trains appropriate employees on service model. Sells non-product services	Works with Marketing to develop financial model. Monitors and tracks service offering financial performance. If rebates/discounts involved, works with Product Sales Force to determine framework	Provides guidance/advice on permissible arrangements, structures, activities, etc. Works with business to operationalize legal/compliance guidance Advises on aspects regulated by the FTC Reviews promotional materials that fall outside promotional material review process	Responsible for sale and execution of any product purchase agreements, including rebate and discount agreements. Sells products and product related services only	Advises on claims made related to products or services regulated by the FDA. Reviews any promotional materials related to products or services regulated by the FDA.	Advises on available product support offerings currently existing and in development. Assist in the development of some new product support offerings