The statements and opinions expressed in this presentation are those of the presenters and do not reflect the official policy, position, or views of Medtronic. Any examples provided are illustrative and may not reflect actual events or situations.
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

OVERVIEW OF MEDICAL DEVICE REGULATIONS
MEDICAL DEVICE
UNIQUE RISKS TO MANAGE

 TRANSPARENCY/SUNSHINE
(Reporting of Transfers of Value)

 PRIVACY
(Use and Disclosure of Health Information)

 CONFLICTS OF INTEREST
(Scientific Integrity)

PRODUCT QUALITY & PROMOTION
(FDA approval, GMP/GLP, Claims Substantiation, Off-Label Promotion, etc.)

ANTI-KICKBACK
(Provision of Free or Discounted Services)

MED DEVICE + HEALTHCARE INDUSTRY PARTNERSHIPS

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
NEW WORLD FOR MEDICAL DEVICE

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

- $7.2 TRILLION
  Healthcare costs are skyrocketing

- 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

There’s wide variation in care and delivery of meaningful outcomes

- The need for care is only growing

- Incremental “solutions” have had limited impact

2. Source: ICHOM analysis, Martin Makary, How Health Care’s Successes Became Distractions”, Health Affairs August 2014

Consumer-driven healthcare
Evidence-based medicine
Prior authorization for expensive services

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HEALTHCARE INDUSTRY IS CHANGING FUNDAMENTALLY
REIMBURSEMENT CONTINUES TO EVOLVE

| Fee for Service (e.g. DRGs) | 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 |

VOLUME-BASED SYSTEM ISSUES GLOBALLY

<table>
<thead>
<tr>
<th>Episodic</th>
<th>Disconnected</th>
<th>Inconsistent</th>
<th>Lacking Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare providers are paid for the volume of services, not value</td>
<td>Patient care is not coordinated across the care continuum</td>
<td>Care can vary greatly from patient-to-patient from facility to facility (and sometimes even at the same facility)</td>
<td>Data not shared across the system</td>
</tr>
</tbody>
</table>

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
Products/technologies that by design impact outcomes and cost

EPISODIC CARE BUNDLES
Routine treatment delivered typically includes our product

CHRONIC CARE MANAGEMENT
Impacting care over a more sustained period of time (beyond the product sale)

BUILDING COMPLIANCE PROGRAMS TO KEEP UP WITH INNOVATION
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 chat!
WRITE IT DOWN
KEEP EVERYONE ON THE SAME PAGE

- 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: 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

QUESTIONS?
EACH MODEL PRESENTS UNIQUE RISKS

DEVICE V. SERVICE MODELS

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<td>Product Pull Through</td>
<td>Practice of Medicine</td>
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## DEVELOPING AND LAUNCHING NEW BUSINESS MODELS
### A CROSS-FUNCTIONAL TEAM APPROACH

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