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

EACH MODEL PRESENTS UNIQUE RISKS
DEVICE V. SERVICE MODELS
NEW WORLD FOR MEDICAL DEVICE

Healthcare costs are skyrocketing

There's wide variation in care meaningful outcomes

The need for care is only growing

Incremental "solutions" have had limited impact

$7.2 TRILLION

HEALTHCARE IS NOT SUSTAINABLE AS IS

HEALTHCARE INDUSTRY IS CHANGING FUNDAMENTALLY

REIMBURSEMENT CONTINUES TO EVOLVE
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></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PATIENT CARE IS NOT COORDINATED ACROSS THE CARE CONTINUUM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CARE CAN VARY GREATLY FROM PATIENT TO PATIENT (AND SOMETIMES EVEN AT THE SAME FACILITY)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DATA NOT SHARED ACROSS THE SYSTEM</td>
<td></td>
<td></td>
<td></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:

<table>
<thead>
<tr>
<th>THERAPEUTIC OPTIMIZATION</th>
<th>EPISODIC CARE BUNDLES</th>
<th>CHRONIC CARE MANAGEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Products/Devices that help manage and care for specific conditions and diseases</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Routine treatment bundles that provide ongoing support, including product and care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improving care over a sustained period of time to manage a patient's condition</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 the type of initiative before, it will take longer to work through the issues
• Look to other parties
  • Partner with hospital compliance/legal teams
  • WRITE IT DOWN
    • 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 PROGRAM: 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?
  - 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?**

---

**BACK UP SLIDES**
**EACH MODEL PRESENTS UNIQUE RISKS**

**DEVICE V. SERVICE MODELS**

<table>
<thead>
<tr>
<th>Device</th>
<th>Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conflict of Interest</td>
<td>Conflict of Interest</td>
</tr>
<tr>
<td>Separation of Data</td>
<td>Separation of Data</td>
</tr>
<tr>
<td>Organizational Structure</td>
<td>Organizational Structure</td>
</tr>
<tr>
<td>Product Pull Through</td>
<td>Practice of Medicine</td>
</tr>
<tr>
<td>Transperancy</td>
<td>Transparency</td>
</tr>
<tr>
<td>Fair Market Value</td>
<td>Fair Market Value</td>
</tr>
<tr>
<td>Clinical Independence</td>
<td>Clinical Independence</td>
</tr>
<tr>
<td>Beneficiary Inducement</td>
<td>Beneficiary Inducement</td>
</tr>
<tr>
<td>AKS</td>
<td>AKS</td>
</tr>
</tbody>
</table>

**DEVELOPING AND LAUNCHING NEW BUSINESS MODELS**

**A CROSS-FUNCTIONAL TEAM APPROACH**

**MARKETING**
- Owns service model strategy and budget.
- Responsible for cross-functional partnerships.
- Develops all promotional or other materials.
- Trains appropriate employees.
- Sells non-product services.

**FINANCE**
- Monitors and tracks service offering financial performance.
- Works with Marketing to develop financial model.
- If rebates/discounts involved, works with Product Sales Force to determine framework.

**LEGAL & COMPLIANCE**
- Provides guidance on permissible arrangements.
- Advises on claims for products or services regulated by the FTC.
- Reviews promotional materials related to products or services regulated by the FDA.
- Reviews any promotional materials related to products or services regulated by the FSA.
- Reviews promotional materials related to products or services regulated by the FTC.
- Advises on available product support offerings currently existing and in development.
- Advises on available product support offerings currently existing and in development.
- Advises on available product support offerings currently existing and in development.

**PRODUCT SALES FORCE**
- Responsible for sale and execution of any product purchase agreements.
- Works with Marketing to develop financial model.
- Monitors and tracks service offering financial performance.
- Develops all promotional or other materials.
- Trains appropriate employees.
- Sells non-product services.

**REGULATORY**
- Advises on claims for products or services regulated by the FTC.
- Reviews promotional materials related to products or services regulated by the FDA.
- Reviews any promotional materials related to products or services regulated by the FSA.
- Advises on available product support offerings currently existing and in development.
- Advises on available product support offerings currently existing and in development.
- Advises on available product support offerings currently existing and in development.

**PRODUCT SUPPORT SERVICES TEAM**
- Advises on available product support offerings currently existing and in development.
- Advises on available product support offerings currently existing and in development.
- Advises on available product support offerings currently existing and in development.
- Advises on available product support offerings currently existing and in development.
- Advises on available product support offerings currently existing and in development.
- Advises on available product support offerings currently existing and in development.

---

Image Access:
1. Page 1: Each model presents unique risks.
2. Page 2: Developing and launching new business models.
3. Page 3: Key issues in medical device compliance: adapting to change and innovation.

---

*The image is reproduced from a presentation slide, and the text may be subject to slight variations.*

---

*The content is for informational purposes only and should not be considered professional advice.*