

IDE & HDE DEVICE COVERAGE & BILLING: COMPLIANCE INSIGHTS



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1

Any recommendations or opinions shared during this presentation are my own, and do not represent those of my employer, the University of Washington (UW Medicine) in any way, shape, or form.

2

This presentation addresses:

1. The key U.S. Food & Drug Administration (FDA) and Centers for Medicare & Medicaid Services (CMS) regulations affecting Investigational Device Exemption (IDE) and Humanitarian Device Exemption (HDE) device use and coverage
2. IDE and HDE device compliance roles and responsibilities across a health system including: Compliance; the Clinical Trials Office; the IRB; Principal Investigators (PIs), their study teams, and other Providers; Supply Chain; and Billing offices

3

3. Tips for how Compliance departments can promote collaboration and successful partnerships across a health system (such as education and outreach, task forces, and policy review) to reduce regulatory risk and promote system-wide compliance
4. Sample process for analyzing IDE and HDE devices as they enter a health system to help ensure compliant device usage and billing

4



5

Let's get a show of hands – who among us is a...

- Research Coordinator?
- Clinical Trial Offices staff member?
- Revenue Cycle/Chargemaster staff member?
- Institutional Review Board (IRB) member?
- Patient Financial Services staff member?
- Supply Chain staff member?
- Procedure area staff member who works with IDE and/or HDE devices?

6

How Compliance departments can promote collaboration and successful partnerships across a health system:

**Integrate Device topics
(e.g., IDE and HDE Device
Coverage & Billing) into
your Education &
Outreach work!**



7

Investigational Device Exemption (IDE)

- An approved IDE is an investigational device for which an Institutional Review Board (IRB) and the FDA for significant risk devices have approved the sponsor's study application and all the requirements under the FDA's IDE regulations at 21 CFR 812, are met. The FDA assigns a special identifier number to the device once it is granted an IDE. This IDE status permits the device which would otherwise be required to comply with a performance standard or to have premarket approval to be shipped legally for the purpose of conducting human subjects research using that device.
- For purposes of assisting CMS in determining Medicare coverage, the FDA places all approved IDEs in one of two categories – Category A or Category B.

8

Humanitarian Use Device (HUD) & Humanitarian Device Exemption (HDE)

- As defined in 21 CFR 814.3(n), a Humanitarian Use Device (HUD) is a “medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year.”
- Following HUD designation, the FDA may then approve an HDE to allow the manufacturer to market the device without proving efficacy. The HDE indicates that the device is legally approved for specific indications. The FDA assigns a special identifier number that corresponds to each device granted an HDE.

9

Class I devices

- Very low risk devices that are generally exempt from FDA regulations. Class I medical devices are exempt from the requirement of premarket notification (510K) unless the device is intended for a use that is of substantial importance in preventing impairment to human health or presents a potentially unreasonable risk of illness or injury.
- Examples: tongue depressors; stethoscopes; elastic bandages

10

Class II devices

- Moderate risk devices that are generally subject to “510K clearance”. Clinical investigations are not required in most cases. However, if clinical data are necessary to demonstrate “substantial equivalence” to another device, the clinical study must comply with the IDE regulations. Subject to labeling requirements, mandatory performance standards, and post-market surveillance. Typically non-invasive.
- Examples: MRIs; software; powered wheelchairs; surgical needles

11

Class III devices

- Higher risk devices that require Premarket Approval (PMA). Clinical investigations are necessary to establish the safety and efficacy of these devices, as insufficient information exists to assure safety and effectiveness solely through the general or special controls sufficient for Class I or Class II devices; or is of substantial importance in preventing impairment to human health; or presents a potential unreasonable risk of illness or injury.
- IDE and HDE devices predominantly fall under this category.
- Examples: Artificial Hearts, Neurovascular Stents, TAVR and TMVR-related devices

12

US Food and Drug Administration (FDA)

- Determines device safety and approves them for marketing (e.g., for eventual usage in clinical care).

Centers for Medicare & Medicaid Services (CMS)

- Determines device coverage for Medicare billing purposes. Issues National Coverage Determinations (NCDs), which can impact the coverage of devices and device-related procedures.

****NOTE:** FDA permission (safety) does not guarantee Medicare coverage, and Medicare is constrained by law as it cannot pay for IDE devices outside of an IDE trial.

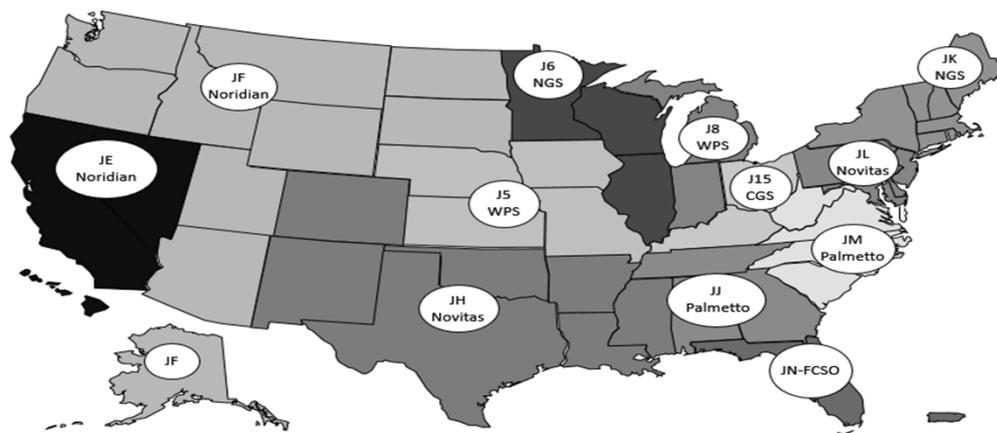
13

Medicare Administrative Contractors (MACs)

- Also determine coverage for devices for Medicare billing purposes, but are subject to NCDs.
- Absent an NCD, a MAC may choose to issue a Local Coverage Determination (LCD), which only applies to institutions/providers in that MAC's region.
- UW Medicine is primarily under Jurisdiction F – Noridian.

14

Medicare Part A/B MAC Jurisdictions as of October 2017



Source: CMS Website

15

Title	Key Provision(s)
<p>42 CFR 405 Subpart B: Medical Services Coverage Decisions That Relate to Health Care Technology</p>	<ul style="list-style-type: none"> • Key definitions, including <u>Category A (Experimental) devices</u> and <u>Category B (Nonexperimental/investigational) devices</u> • CMS Coverage and Study Criteria for IDE studies, using FDA categorization and nomenclature • “New” (effective Jan. 1, 2015) CMS National approval process for IDE device study coverage
<p>42 CFR 411.15, Paragraph (o): Particular services excluded from Medicare coverage</p>	<ul style="list-style-type: none"> • No Medicare coverage for experimental or investigational devices, <u>EXCEPT</u> when provided in a Category B IDE study

16

Title	Key Provision(s)
Medicare Benefit Policy Manual Chapter 14 – Medical Devices	<ul style="list-style-type: none"> • Medicare requirements for coverage of items and services in FDA-approved Category A and B IDE Device Studies, including specific submission information and criteria • This is the “New” (effective Jan. 1, 2015) CMS approval process & criteria for IDE device study coverage, as mentioned on the previous slide
Medicare Claims Processing Manual Chapter 32 – Billing Requirements for Special Services, Section 68	<ul style="list-style-type: none"> • Billing/coding requirements for IDE Studies • IDE studies must follow Qualifying Clinical Trials (Section 69.6) billing/coding requirements for routine costs • National Clinical Trials (NCT) number required as of Jan. 1, 2014

17

IDE Devices:

- When IDE devices are used in a research study and the sponsor is not covering the costs of all items/tests/services (including the IDE device), the sponsor (or study team) applies to CMS for approval to bill the IDE device (Category B IDE devices only) and study-related services (Category A or B IDE devices).
- Medicare must approve the study for the IDE device and/or study-related services for Medicare patients enrolled in the study to be eligible for coverage, **and such approval is required PRIOR to the first study-related claim.**

18

Title	Key Provision(s)
<p>There is <u>NO CMS REGULATION OR POLICY</u> that directly addresses HDE Coverage requirements; <u>however</u>, see NCD 20.7 - Percutaneous Transluminal Angioplasty (PTA)*</p>	<p>*NOTE: While not explicitly mentioned in NCD 20.7, an HDE device called the Wingspan® Stent System with Gateway® PTA Balloon Catheter (Stryker) is noncovered by Medicare EXCEPT when provided to beneficiaries enrolled in an FDA-approved Category B IDE trial</p>
<p>Noridian Jurisdiction F – Medicare Part A: Clinical Trials Coverage and Billing Guide</p>	<ul style="list-style-type: none"> • Focuses on billing instructions for HDEs when used in a clinical research study • Noridian’s approach to HDEs used clinically (NOT IN RESEARCH) is stated as: <i>“HDE claims are not guaranteed payment, and many are denied.”</i>

19

HDE Devices:

- There is no national Medicare policy related to the coverage of HDE devices; therefore, as a general rule, coverage is at the discretion of the MAC.
- However, an HDE is nationally non-covered if it is associated with a procedure or service that falls under the purview of a Medicare National Coverage Determination (NCD) which nationally non-covers the procedure or service for which the HDE may be used.

20

Emergency Use, Compassionate Use, or Treatment Use of an IDE Device

- The FDA's "Expanded Access" mechanism (a.k.a. "Compassionate Use") allows for drugs, biologics, and devices to be used in expanded populations for treatment outside of research studies/clinical trials when no comparable or satisfactory alternative therapy options are available.
- See 21 CFR 812.35 and 812.36 for FDA requirements.
- Medicare is barred from covering these types of uses of IDE devices – per 42 CFR 411.15, Paragraph (o), as referenced in an earlier slide.

One-time AND General, Multiple Off-label Uses of an HDE Device

- Coverage for HDE use in general is at the discretion of the MAC.

Off-Label use of FDA-approved Devices (non-HDE)

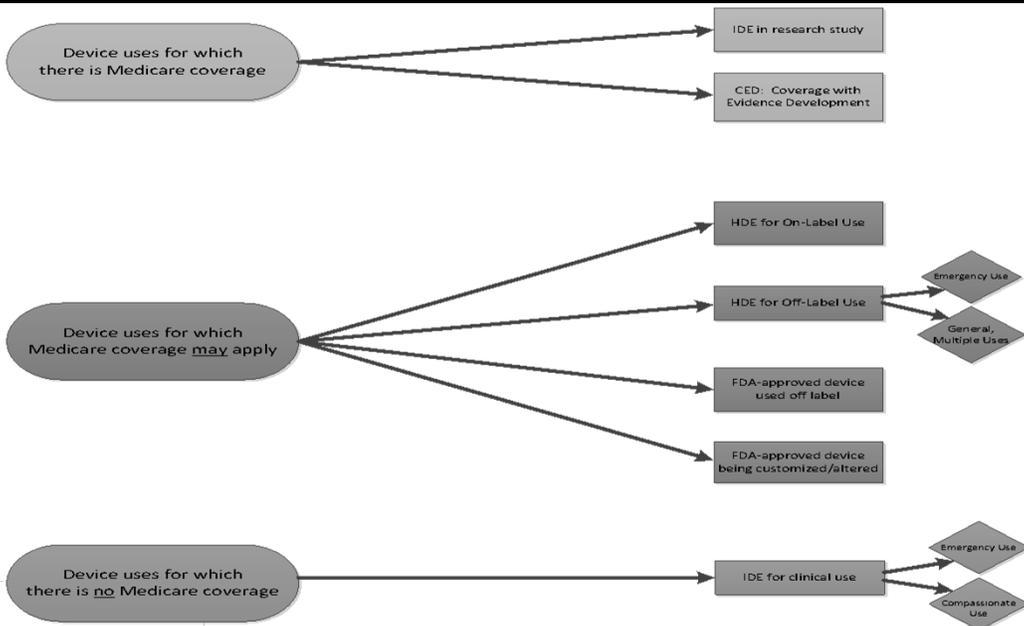
- Does not require new FDA review, BUT Medicare does not have to cover off-label uses.

21

- Medicare has special claims preparation rules for billing IDE devices, and MACs may have special claims preparation rules for billing HDE devices.
- There are circumstances (such as a CMS National Coverage Determination – NCD) in which Medicare does not cover certain devices, and the device-related procedures. In those circumstances, everything related to that device and procedure (including the hospital stay **if** the purpose of the admission was for the non-covered device/procedure) is also non-covered.
- Therefore, when Medicare won't pay, or when it's possible that Medicare won't pay, issue an ABN or HINN to the patient.

22

- Commercial payers will look to Medicare standards, and note that many of these payers now offer one or more flavors of Medicare Advantage plans.
- Accordingly, pre-authorization **should be obtained** for any type of use other than FDA approved devices for clinical use.
- It is important to have a documented conversation with the payer. This should include the payer's acknowledgement of the specific device use scenario and what the payer is agreeing to pay for.



(applies to both IDE and HDE usage)

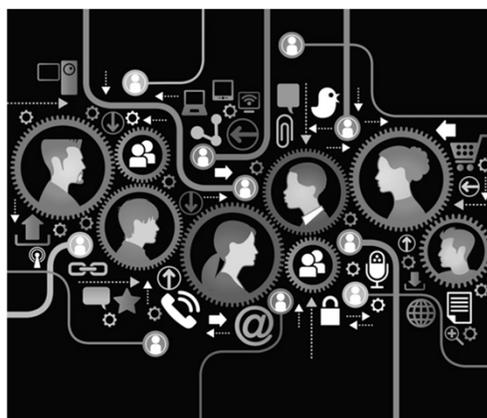
- If required processes are not followed and/or approvals are not obtained in advance of the first date of service, the risks to both hospital and physician claims include:
 - No payment for services rendered
 - Payment denial
 - Improper payment with subsequent repayment
 - This may impact the entire hospital stay and pro fees if the device procedure was the admission reason
- Possible false claims risk



25

How Compliance departments can promote collaboration and successful partnerships across a health system:

Involve Subject Matter Experts across your organization in your Policy Review Process!



26

Applicability: UW Medicine

Policy Title: Budgeting and Billing Requirements for Clinical Research Using UW Medicine Faculty, Facilities or Services

Policy Number: COMP.202

Date Established: April 25, 2005 (**UPDATED IN FY 2019**)

http://depts.washington.edu/comply/docs/comp_202.pdf

27

PURPOSE

The purpose of this policy is to identify when clinical research studies require pre-implementation review by the UW School of Medicine Clinical Research Budget and Billing office (CRBB), and to establish standards for accurate budgeting, billing and documentation related to services that accompany clinical research.

28

POLICY

Complex federal and private payer rules govern the conditions under which services, items and tests associated with a clinical research study can be billed to study sponsors, study subjects and/or their insurers. Accurate clinical research billing depends on planning and collaboration between the study team and a wide variety of individuals and offices before, during and after the clinical research study is initiated...For all clinical research studies covered by this policy as described in the PURPOSE section:

29

6. Clinical research studies involving the use of an Investigational Device Exemption (IDE) device in which any study-related services, items or tests are billed to study subjects and/or study subjects' third party payers (i.e., the study sponsor is not covering 100% of these costs) must be reviewed and approved by the Centers for Medicare and Medicaid Services (CMS) and/or its designated Medicare Administrative Contractor (MAC), with the MAC providing written confirmation that the study has been entered into its Medicare claims processing system. This review and approval process must be completed prior to CRBB activating the study's Epic Research Account and the commencement of study subject enrollment.

30

ROLES AND RESPONSIBILITIES

Each UW Medicine faculty, staff and trainee is responsible for understanding and adhering to UW Medicine's policies and procedures, participating in required training, fulfilling recordkeeping requirements, reporting compliance concerns, seeking clarification when questions arise and responding in a timely manner to requests for information associated with audits or investigations.

- The Principal Investigator (PI) has primary accountability for all aspects of the clinical research projects operating under his/her name. The PI may delegate responsibility for the procedures required by this policy to appropriately qualified members of the study team.
- Clinical Trials Office (CTO) and CRBB provide centralized support for PIs and are responsible for maintaining operations and researcher training programs to support proper budgeting and billing in clinical trials.

31

- Study-site personnel (including patient service representatives, billers, coders, clinic administrators and service providers) are responsible for maintaining procedures and working with the PI and study team to ensure that services for patients enrolled in research studies are scheduled, coded, billed and recorded in accordance with instructions from the study team, seeking clarification when questions arise.
- Offices that bill facility and professional fees are responsible for establishing business practices and systems that support compliance with research billing policies and procedures.

32

- Compliance officers in UW Medicine work closely with CRBB, study-sites and operational departments to develop procedural safeguards; receive and investigate allegations of noncompliance; conduct audits; and participate in the development and delivery of compliance training. UW Medicine Compliance also coordinates the required communications with the Medicare Administrative Contractor (MAC) in advance of IDE device clinical research study commencement, as described in #6 under the POLICY section.

33

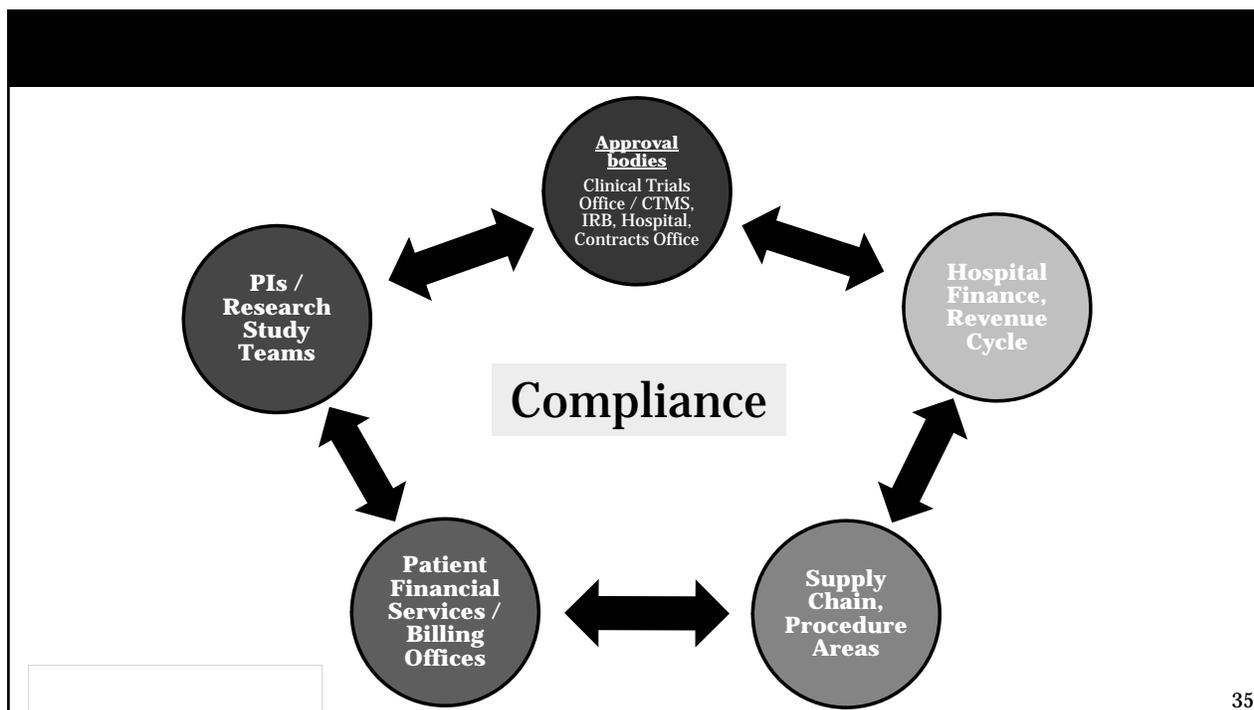
How Compliance departments can promote collaboration and successful partnerships across a health system:

Form a Taskforce to address a specific issue:

- Process improvements to IDE research studies – e.g., to better ensure claims meet Medicare requirements
- Process improvements to HDE device communications - e.g., IRB approval & clinical usage
- New CMS rules or other significant changes to policies/regulations that may impact billing compliance



34



Approval Bodies – A Clinical Trials Office (CTO) helps create a feasible Research Study Budget in conjunction with Medicare Clinical Trials Policy/Coverage Analysis; it is also typically a “Gatekeeper” for activating Research Account in EMR; some of the CTO’s role may be supplemented by a Clinical Trial Management System (CTMS); the IRB helps ensure FDA/Common Rule Human Subjects Compliance. The contracts office ensures that those with the appropriate authority sign Clinical Trial Agreements (CTAs) with industry or nonprofit sponsors.

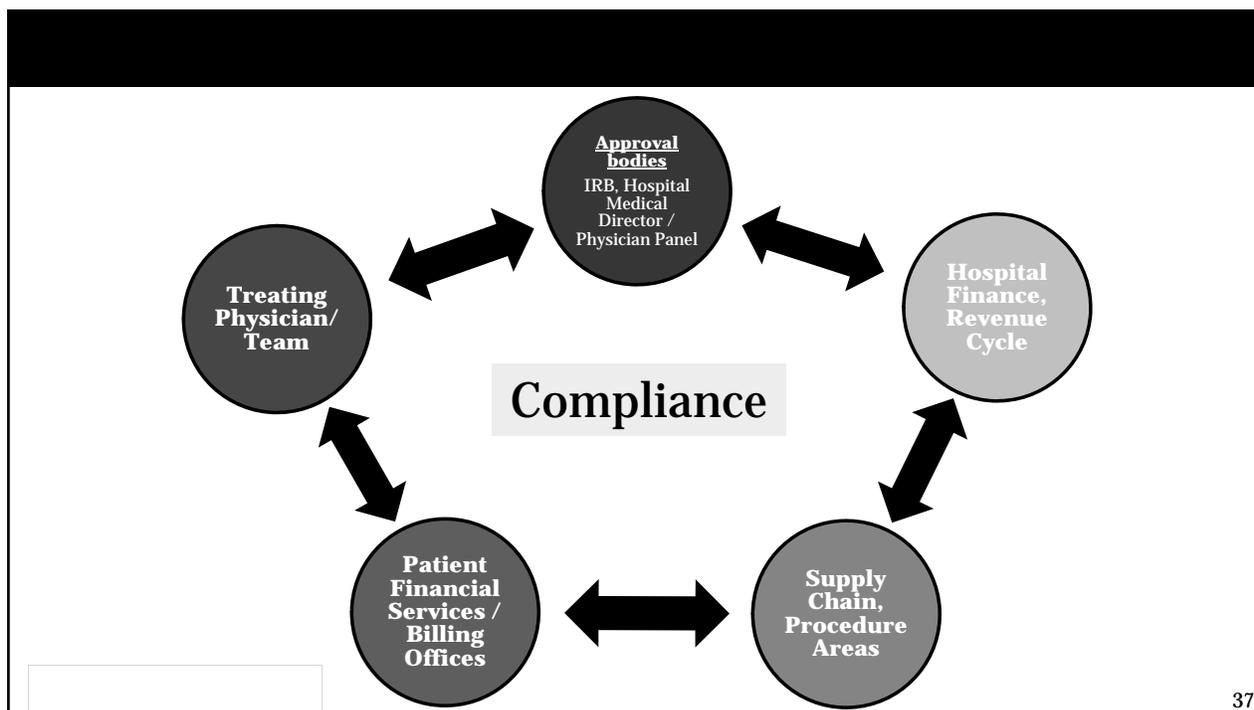
Hospital Finance, Revenue Cycle – Device Pricing and Acquisition, Chargemaster set-up (including Revenue Code 0624 for Category B IDE devices) for the IDE device and the IDE device-related procedure(s).

Supply Chain, Procedure Areas – Device Evaluation/“Value Analysis”; Supply Chain does the inventory set-up and may be responsible for ensuring the FDA approval status for the device is documented; the Procedure Areas work with Supply Chain to manage the device inventory and should have some type of communication protocol (e.g., email list) for when the device is used.

Patient Financial Services (PFS) / Billing Offices – Research Coding (NCT#, IDE#, CC 30 for Hospital Claims, Q0/Q1 for Outpatient Claims, etc.) and Charge Segregation (Patient/3rd Party & Research Study Budget/Sponsor Invoicing; edit/“move” charges from one bucket to the other as necessary (e.g., study account to patient account, or vice-versa); PFS may work with Clinical Trials Office to accomplish this.

PIs / Research Study Teams – Work with Study Sponsor to ensure research study documents are submitted to CMS or MAC to obtain approval to bill Medicare – e.g., FDA approval letter for IDE device/study, protocol, IRB approval letter, registering study on ClinicalTrials.gov website to obtain National Clinical Trial (NCT) number, etc.

36



Approval Bodies – the IRB plays a crucial role, as the FDA requires IRB approval **before** a HUD can be used by a hospital (except in Emergency Use situations); additionally the IRB may require some type of consent form to be used (this is an IRB requirement at UW). Also, at UW, our IRB posts a list of all approved HDE devices on its website.

Hospital Finance, Revenue Cycle – Device Pricing and Acquisition, Chargemaster set-up (e.g., Revenue Code 0278; remember that Rev. Code 0624 is only for Category B IDE devices) for the HDE device and the HDE device-related procedure(s)

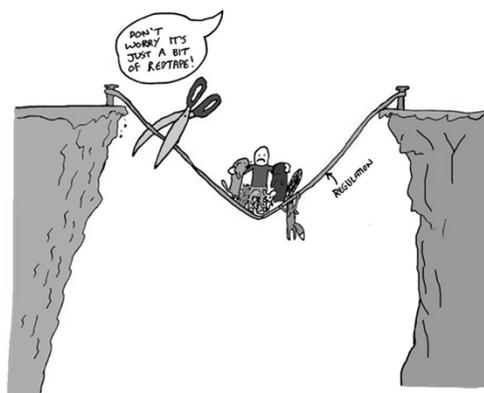
Supply Chain, Procedure Areas – Device Evaluation/“Value Analysis”; Supply Chain also does the inventory set-up and may be responsible for ensuring the FDA approval status for the device is documented; the Procedure Areas work with Supply Chain to manage the device inventory and should have some type of communication protocol (e.g., email list) for when the device is used.

Patient Financial Services (PFS) / Billing Offices – Ensures that coding/additional information, which may be required by the MAC, is added to the claim; for example, some regions’ MACs require the HDE# of the device to be added to the claim.

Treating Physician / Team – Ensures that IRB approval and other approvals (e.g., Hospital Medical Director, etc.) are obtained **before** a device is used; documents medical necessity in the medical record, mindful of the HDE device labeling so that off-label usages are well-supported by medical literature.

How Compliance departments can promote collaboration and successful partnerships across a health system:

Integrate Regulatory Tracking into your work & stay apprised of Resources!



Regulation protects the things we care about - we need to keep it that way

@CARTRONALPH

39

Essential Regulatory Subscriptions (this is just a partial list!):

1. Daily Federal Register Table of Contents

<https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new>

2. Centers for Medicare & Medicaid Services (CMS) Weekly Digest Bulletin

<https://public.govdelivery.com/accounts/USCMS/subscriber/new?preferences=true>

3. Your Local MAC (e.g., Noridian Healthcare Solutions)

<https://naslists.noridian.com/list/subscribe.html?jsessionid=1ED7EA313D3EDF32A15998CF15B2DE51?lui=eZ723q4d&mContainer=2&mOwner=G30392x2n39372t36>

4. HCCA's Compliance Weekly News

<http://hcca-info.informz.net/hcca-info/profile.asp?fid=46>

40

Websites (this is just a partial list!):

1. CMS' Approved IDE Studies
<https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html>
2. CMS' Coverage with Evidence Development (CED) categorical lists
<https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>
3. FDA's Listing of CDRH Humanitarian Device Exemptions
<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm>
4. FDA's PMA Approvals – Publishes monthly PMA lists
<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm630840.htm>

41

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42

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