KEY IDE DEVICE COVERAGE LAWS/REGULATIONS/POLICIES

Title	Key Provision(s)
42 CFR 405 Subpart B: Medical Services Coverage Decisions That Relate to Health Care Technology	• Key definitions, including Category A (*Experimental*) devices and Category B (*Nonexperimental/investigational*) devices • 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
42 CFR 411.15, Paragraph (o): Particular services excluded from Medicare coverage	• No Medicare coverage for experimental or investigational devices, EXCEPT when provided in a Category B IDE study

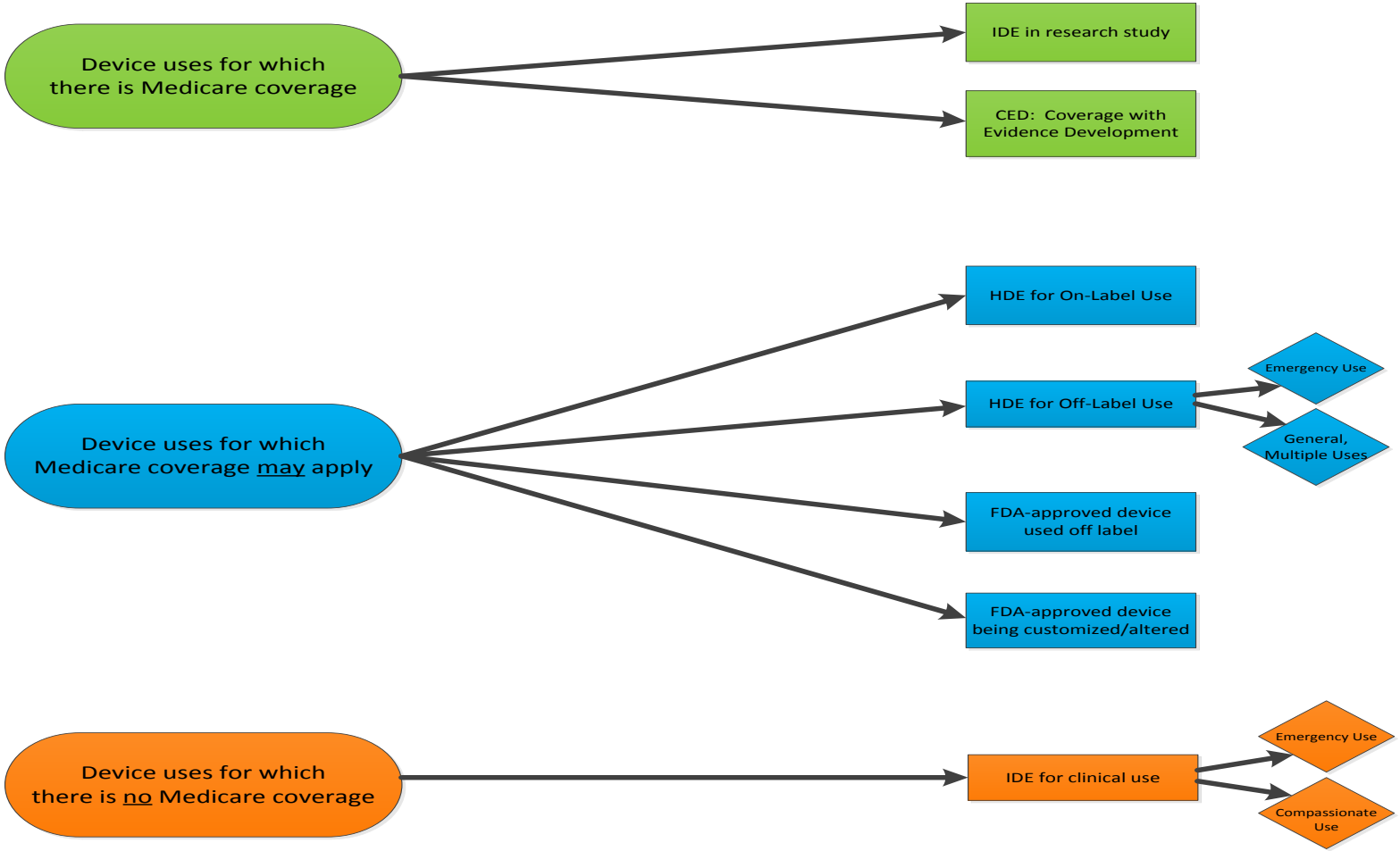
KEY IDE DEVICE COVERAGE LAWS/REGULATIONS/POLICIES

Title	Key Provision(s)
Medicare Benefit Policy Manual Chapter 14 – Medical Devices	• 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	• 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

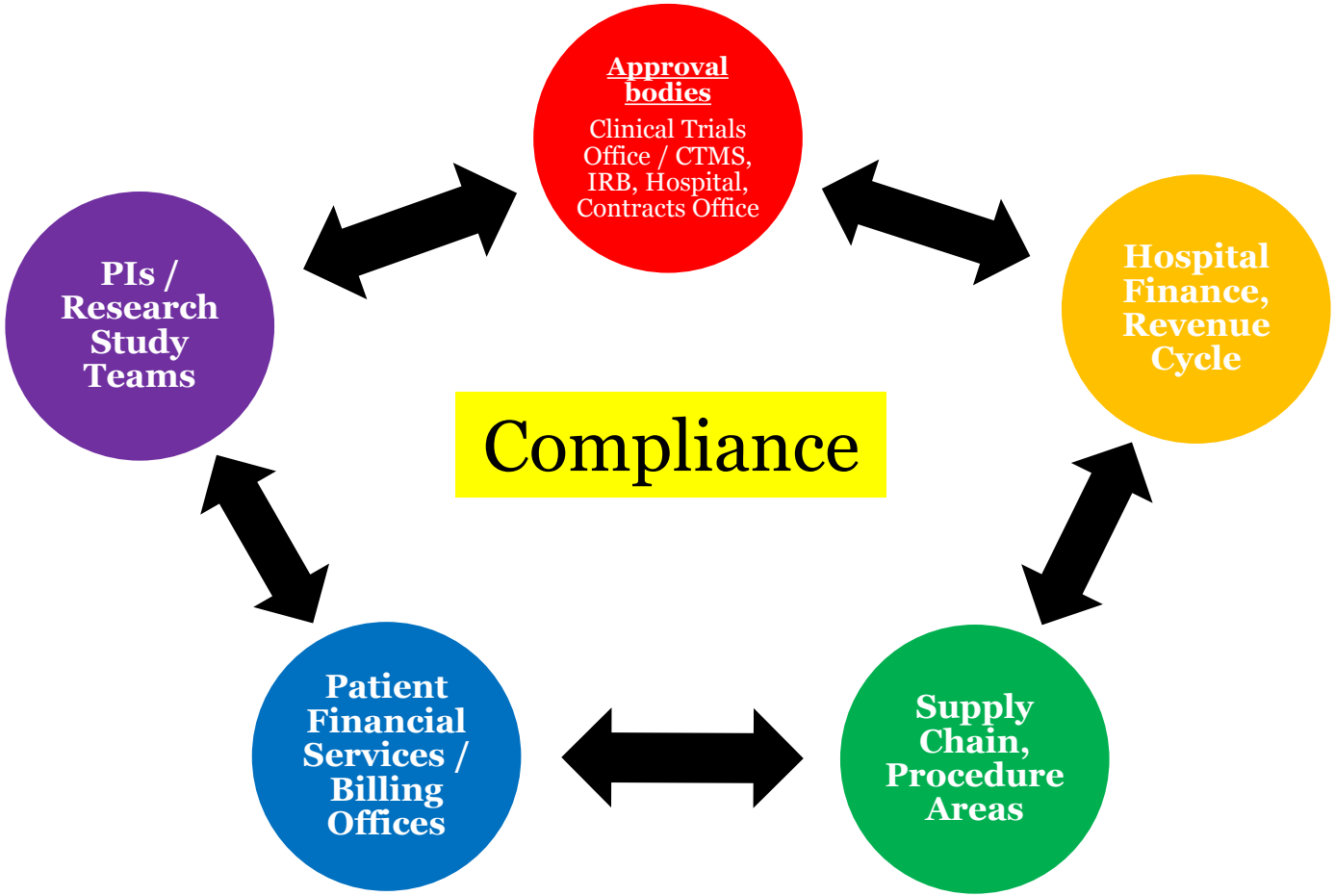
KEY HDE DEVICE COVERAGE LAWS/REGULATIONS/POLICIES

Title	Key Provision(s)
There is NO CMS REGULATION OR POLICY that directly addresses HDE Coverage requirements; however, see NCD 20.7 - Percutaneous Transluminal Angioplasty (PTA)*	*__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
Noridian Jurisdiction F – Medicare Part A: Clinical Trials Coverage and Billing Guide	• 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: ***"HDE claims are not guaranteed payment, and many are denied."***

IDE AND HDE DEVICES: SUMMARY OF USE & MEDICARE COVERAGE SCENARIOS



IDE DEVICE RESEARCH STUDY SAMPLE PROCESS / ROLES & RESPONSIBILITIES



IDE DEVICE RESEARCH STUDY SAMPLE PROCESS / ROLES & RESPONSIBILITIES

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.

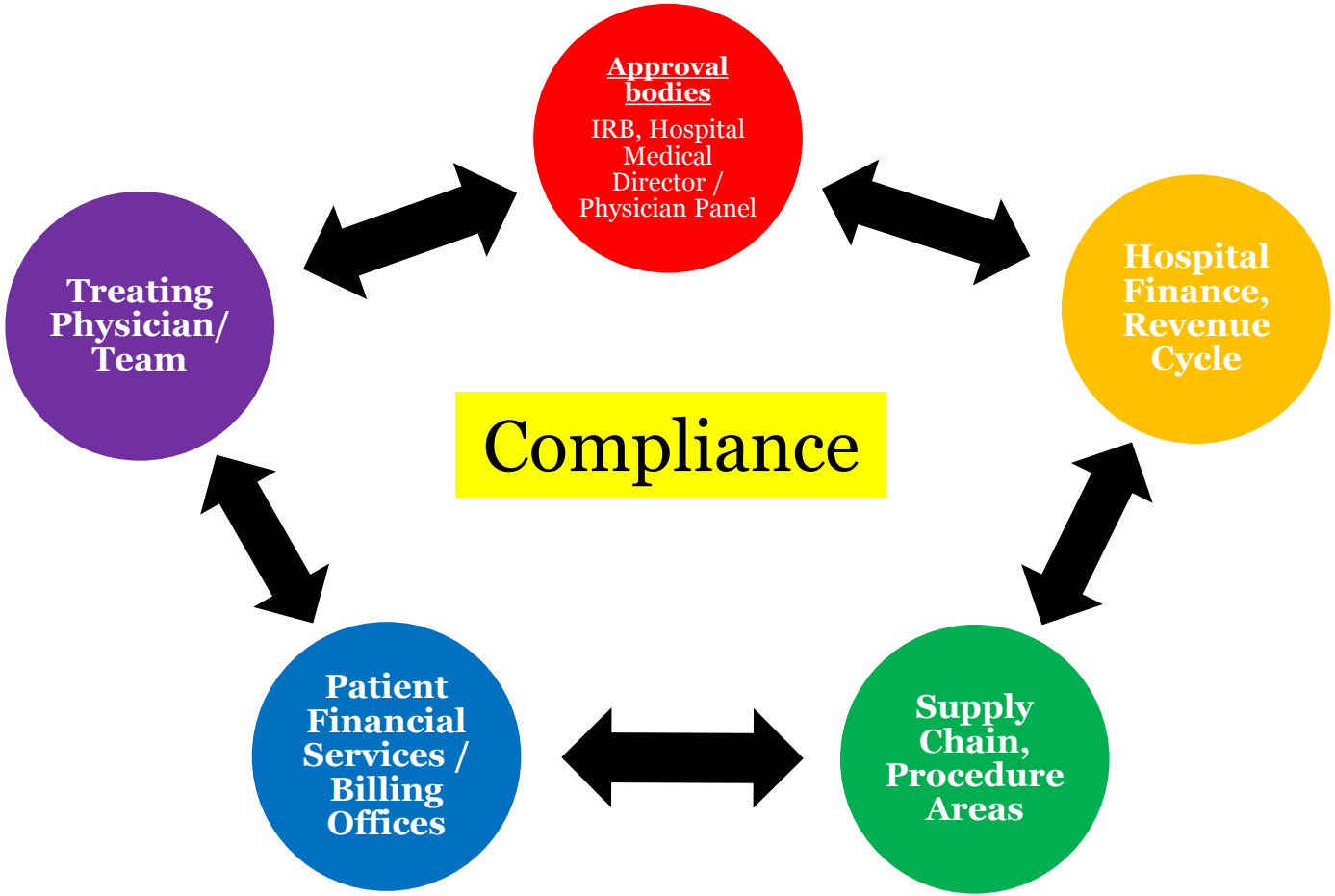
Hospital Finance, Revenue Cycle – Device Pricing and Acquisition, Chargemaster set-up (including Revenue Code 0624 for Category B IDE devices) for the IDE device and the IDE device-related procedure(s).

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.

HDE DEVICE CLINICAL USE SAMPLE PROCESS / ROLES & RESPONSIBILITIES



HDE DEVICE CLINICAL USE SAMPLE PROCESS / ROLES & RESPONSIBILITIES

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.

INTEGRATING REGULATORY & RESOURCE TRACKING INTO YOUR WORK

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

INTEGRATING REGULATORY & RESOURCE TRACKING INTO YOUR WORK

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