Food and Drug Law Institute –
Introduction to Law and Regulation:
Drug and Medical Device Industry

November 17, 2021 | Virtual Course

Introduction to Medical Device Law and Regulation
Coverage, Coding and Payment – Collaboration Between FDA and CMS

Presented by: Michael M. Gaba, Shareholder & Vice Chair, FDA Practice Group

FDLI

Goals

- Distinguish CMS from FDA
- Identify product approval and insurance issues that overlap between FDA and CMS
- Suggest how to coordinate FDA decision-making and data with CMS needs

CMS vs. FDA

CMS	FDA
“reasonable and necessary”	“reasonable assurance of safety and effectiveness”
65 years of age/older	Broad population/not age specific
CMS coverage determination (formal or informal)	FDA-approved labeling
Focus on health benefits	Focus on device function and clinical risk vs. benefits
Economic data are important	Economic data are irrelevant
Superiority endpoint required	Non-inferiority endpoint acceptable
Focus on Medicare beneficiaries	Focus on intended population
Public processes	Generally not public processes
Publishes proposed decisions	Does not publish proposed decisions

FDA Medical Device Framework

- 1976 Medical Device Amendments – FDA risk-based regulation of devices
  - Premarket Approval (“PMA”) for Class III (high risk) devices: “reasonable assurance of safety & efficacy”
  - Premarket Notification for Class II (moderate risk) devices: “Substantial equivalence” to a device already marketed (510 (k))
  - 510(k) exempt – Class I (low risk) devices

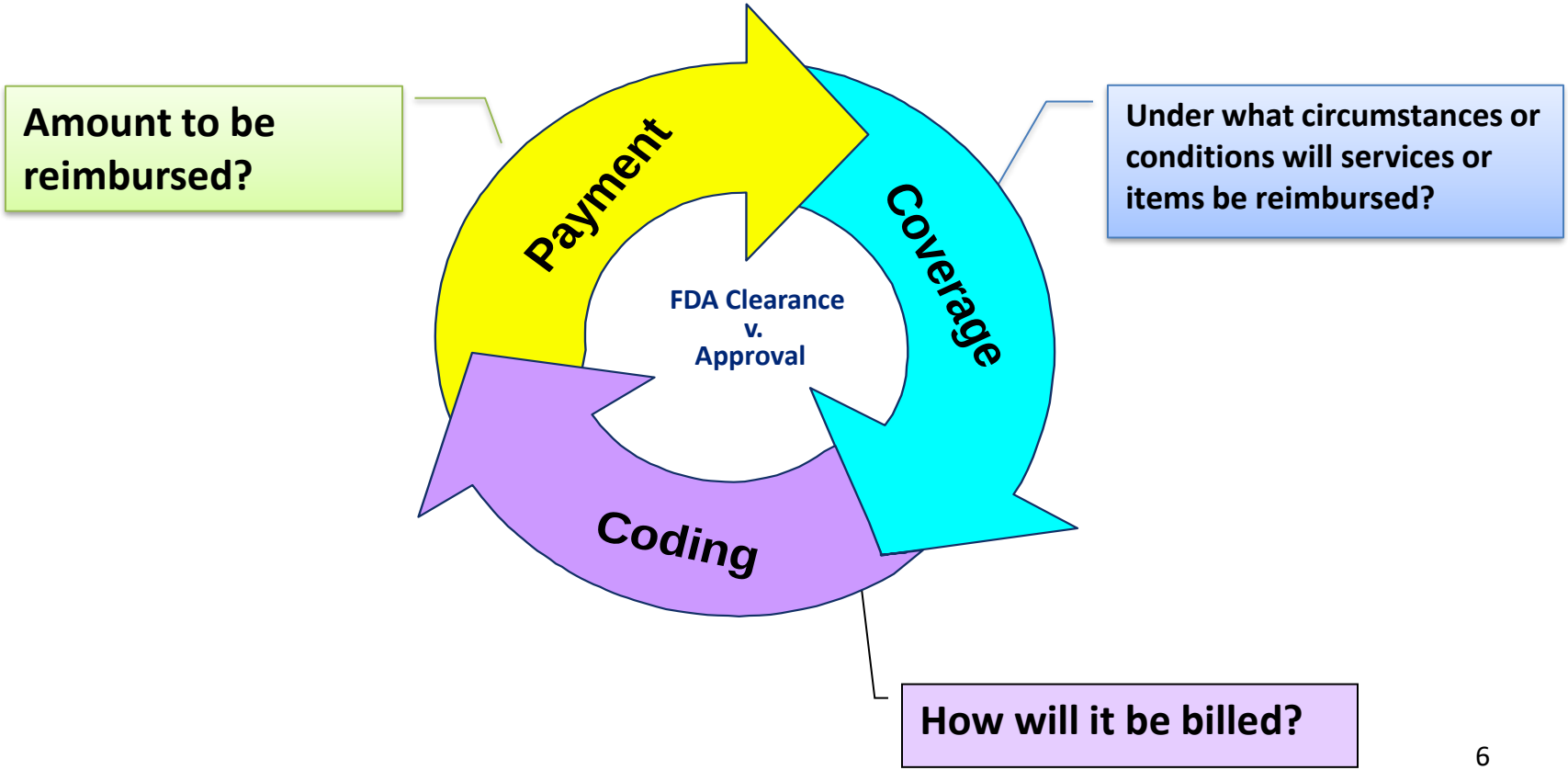
CMS Coverage and Payment Framework

- Coverage question: Will CMS pay?
- Payment question: How much will CMS pay?
  - separate payment?
  - packaged payment?

CMS Coverage Framework

- “Reasonable and Necessary”
- Only definition of “reasonable and necessary” is in statute: “no payment for items . . . which are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member” 42 USC 1395y(a)(1)(A)

The Medical Device Wheel of Fortune



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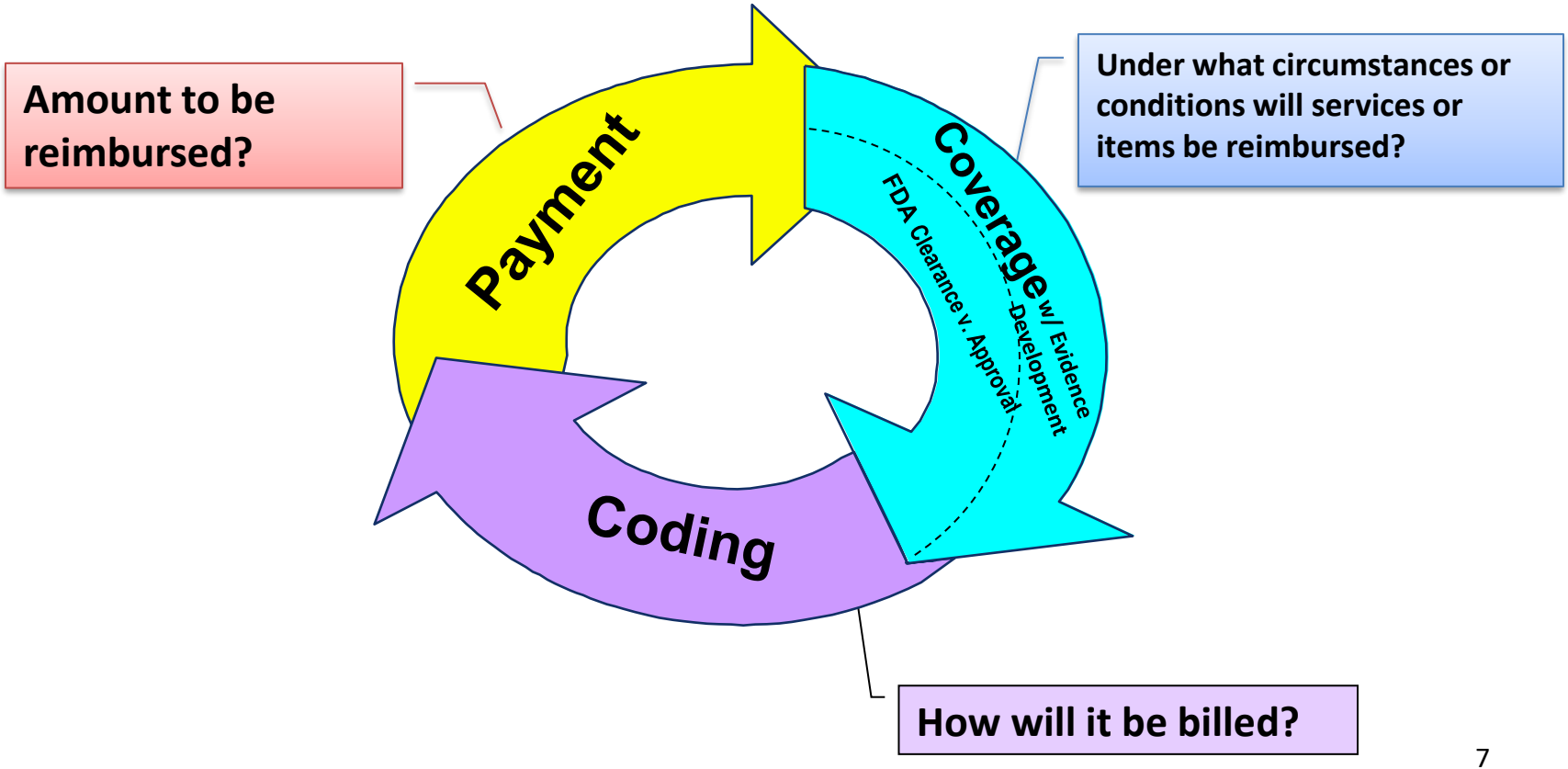
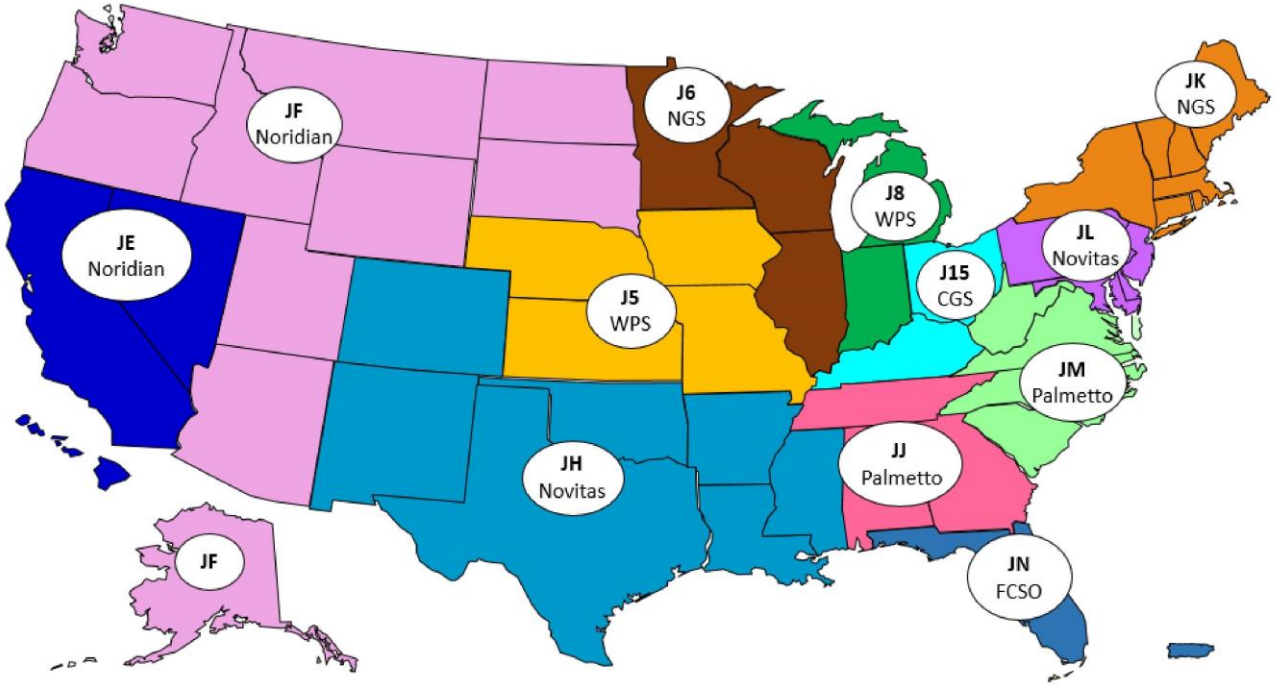


To Obtain Medicare Coverage

- Must fall within a Medicare benefit category
- Must be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member”
  - Must not be excluded by the statute (hearing aids, eyeglasses, contact lenses)
- Benefit categories
  - Most devices covered as part of an inpatient or outpatient hospital procedure (wound dressings, bandages, syringe, needles)
- Other devices covered as DME, prosthetics, or orthotics

A/B MAC Jurisdictions
as of June 2021



DME MAC Jurisdictions

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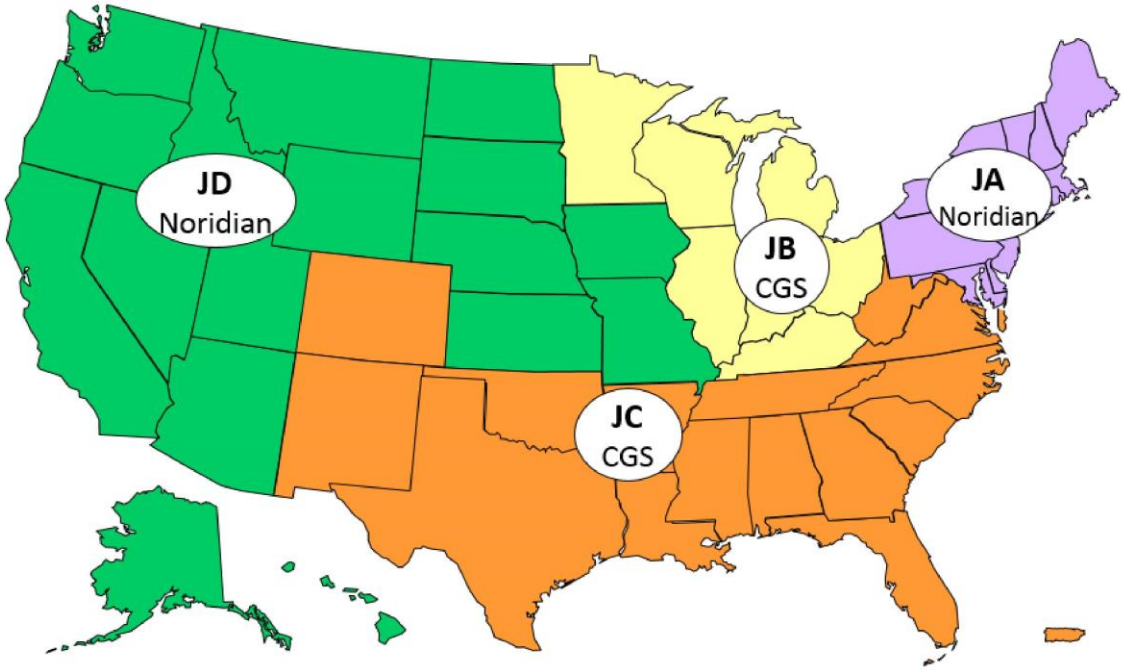

Who Makes Medicare Coverage Decisions?

- Determinations by CMS and its contractors
  - National Coverage Determinations (NCDs)
  - Local Coverage Determinations (LCDs)
  - Individual Consideration

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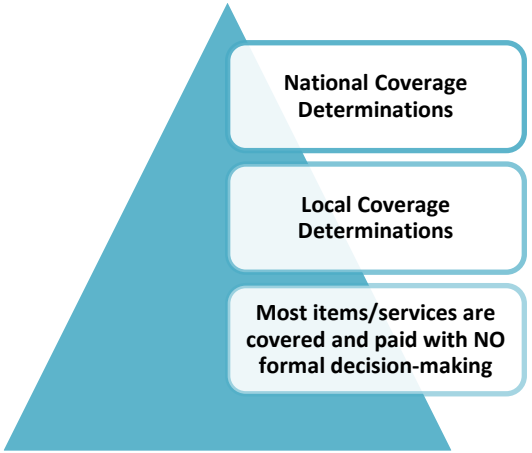


Medicare Coverage of IDE Devices

FDA Categorization of Approved IDEs

Category A devices **are not** eligible for Medicare coverage

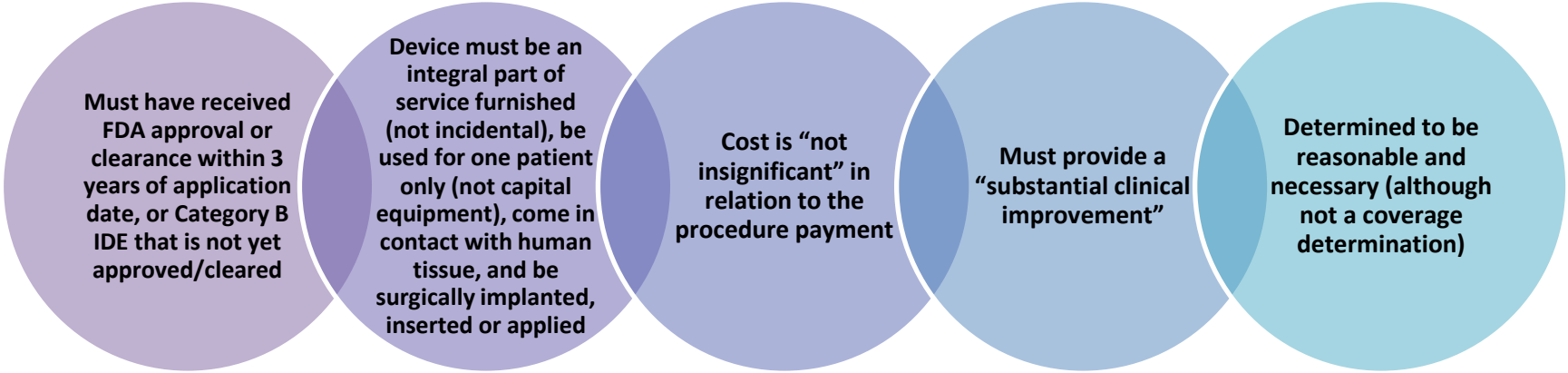
- "experimental" investigational devices where the absolute risk of the device type has not been established and FDA is unsure whether the device type can be safe and effective

Category B devices **are** eligible for Medicare coverage

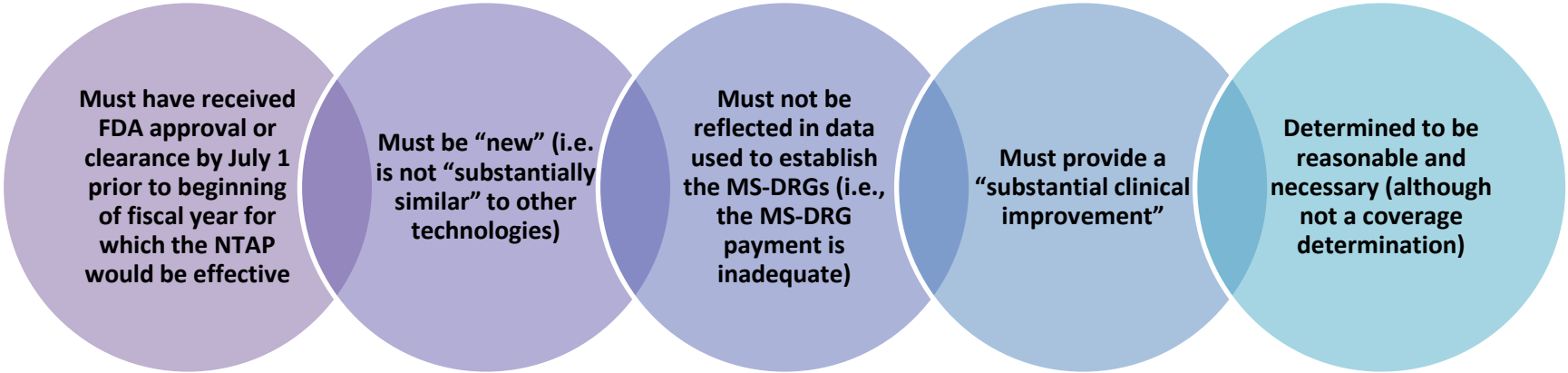
- "non-experimental" investigational devices where the incremental risk is the primary risk in question, i.e., underlying questions of safety and effectiveness of the device type have been resolved

FDA-CMS Memorandum of Understanding effective June 2016 allows for change from Category A to Category B

Outpatient Pass-Through Status: Criteria



Inpatient Add-On Payment (NTAP): Criteria



Memorandum of Understanding

- Signed June 2010
- Formalized the information sharing enterprise
  - had been in the works for several years
  - Natural tension given proprietary data and public process
- Purpose and Goals
  - enhance information sharing through more efficient and robust interagency activities
  - promote efficient utilization of tools and expertise for product analysis, validation and risk identification
  - build infrastructure and processes that meet the common needs for evaluating the safety, efficacy, utilization, coverage, payment and clinical benefit of drugs, biologics and medical devices
- Establishes the framework to launch several collaborative efforts.

FDA-CMS Parallel Review Program

Voluntary pilot program launched in November 2011 (made permanent in October 2016)

Goals:

- **Decrease time between FDA approval and NCD issuance**
- **Quicker patient access to innovative devices**
- **Provide efficiencies in creation and submission of clinical studies**

Program only applicable to devices that meet the following criteria:

- **New device that would require an original or supplemental application for PMA or petition for de novo review**
- **New device that would fall within the scope of a Part A or Part B Medicare benefit category and is not subject to an NCD**

FDA-CMS Parallel Review Program

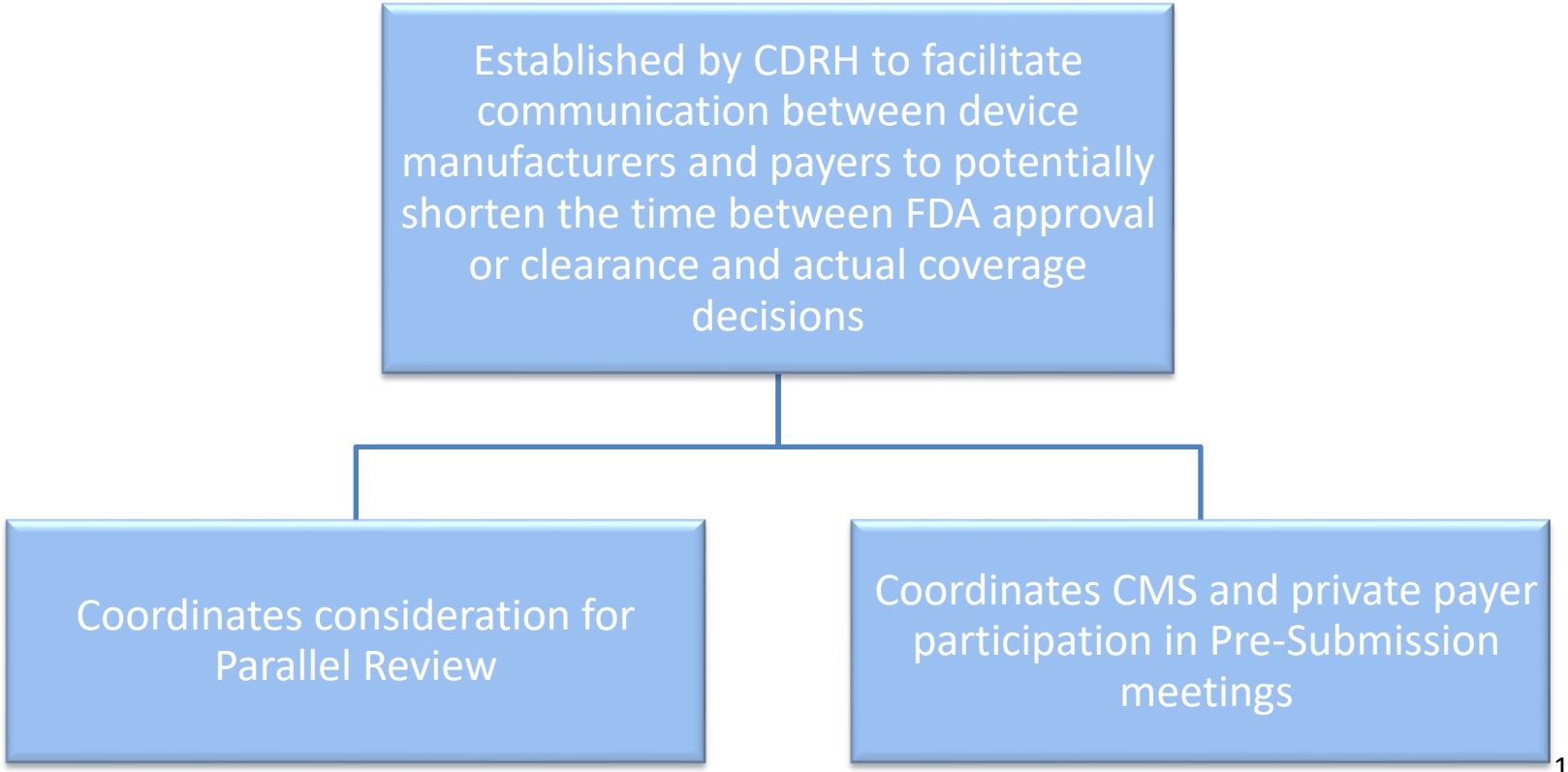
Review Process Is Still a Serial Review

- FDA/CMS consideration – meet within 30 days of receiving a nomination
- Sponsor/Requester notification
- Acceptance meeting
- FDA review
- CMS review – CMS will begin informal NCD review process sometime after submission of the PMA or de novo petition
- Sponsor/requester should file formal request for NCD

Parallel Review

- Exact Sciences
  - Cologuard
- Medtronic
  - Simplicity Renal Denervation System
- Foundation Medicine
  - FoundationOne

FDA Payer Communication Task Force



Coverage with Evidence Development

- Established by CMS in 2006 with Final Guidance Issued Nov 2014
  - What it requires: data collection as a condition of coverage
    - Clinical Study Participation
    - Coverage with Appropriateness Determination (eliminated in 2014)
- CED reflects CMS's embrace of an evidence-based medicine coverage paradigm
  - Coordinated with AHRQ
- CED occurs within the NCD process (with potential for LCD process)
  - Open
  - Transparent
  - Generally expands access to medical technology by beneficiaries

Coverage with Evidence Development

- Data submitted by Sponsor to CMS
- CMS reconciles CED coverage decision
- CED balances access to care while gathering data to inform a coverage determination

MCIT – A One Year Arc

- CMS published rule September 1, 2020
- CMS finalized rule January 14, 2021
- Final Rule to go live December 15, 2021
- CMS proposed to repeal MCIT September 15, 2021

MCIT – What Was it Intended to Do?

- Would provide Medicare coverage for up to 4 years upon FDA clearance/approval of medical devices with “breakthrough technology” status
- Eligibility criteria for breakthrough status?
  - The tech is novel or represents a novel application of existing tech
  - Potential to lead to clinical improvement related to life-threatening or irreversibly debilitating human diseases or conditions
  - No approved or cleared alternative exits
  - It offers significant advantages over existing approved or cleared alternatives
  - Device availability in the best interest of the patient

MCIT – What Did it Not Do?

- It did not establish *payment*
- Logic suggests these devices should be eligible for pass-through or NTAP

MCIT – What's Next?

- September 15th proposed rule had a 30-day comment period
- CMS received about 115 comments
- CMS issued Final Rule rescinding MCIT on November 12th – effective December 15th
- Industry is lobbying hard to save it – Members of Congress about to weigh in

FDA Pathway Critical to Reimbursement & Market Success

- 510(k) can put a device into same reimbursement as predicate device – don't expect higher payment
- PMA with IDE can trigger Medicare coverage if FDA Category B device
- Even PMA may not be enough for Medicare coverage
- Outcomes data are crucial to justify enhanced reimbursement
- Include Medicare patients in study design, if need Medicare coverage

FDA v. CMS Data Requirements

- What Medicare Data are Needed
  - Data from patients 65 years of age and older
  - Demonstrated health benefits – not just lack of adverse events
  - Clinically meaningful results: outcomes, outcomes, outcomes

What Medicare Data are Needed

- Reduction in pain
- Increased mobility
- Lowering of narcotic use
- Patient satisfaction and improvement in activities of daily living
- Restoration of overall patient functionality, including return to work
- Durability of benefit over time

The Intersection of FDA & CMS

- 510(k) often leads to SE reimbursement
- IDE/PMA can support early coverage if ask FDA for Category B designation
- Proof of significant clinical improvements needed for new technology DRG add on, new tech APC, new codes
- Coverage with Evidence Development
- MCIT – one day maybe?

Concluding Thoughts: Practical Tips

- Balance
  - Speed to market
  - Volume of market
  - Need for data to be competitive
- Selecting the Predicate
  - SE can apply to coverage, coding and payment – active v. passive wound care
- Claims Made: Intended Use/Labeling
  - What do you want to claim?
  - What can you claim in absence of data?
  - What data do you need to make your claim?
- Clinical Trial Design
  - Data to get to market: PMA
  - Data to stay on market: CED
    - Will FDA use CED data to modify labeling, approval, or take enforcement action?

Questions?

Biography

Michael M. Gaba provides strategic FDA regulatory, Medicare reimbursement, and public policy counsel to medical device and biotech companies. His primary goal is to bring companies to market and then help them remain there in the most efficient, effective manner possible.

Michael draws on more than 25 years of experience to navigate the FDA pre-market regulatory pathways, counsel companies on FDA post-market compliance matters, and resolve Medicare coverage, coding, and reimbursement disputes with the Centers for Medicare and Medicaid Services. By using his FDA and CMS experience during the product development phase, Michael is able to help maximize companies' opportunities to be appropriately compensated in the proper treatment venues, whether a physician's office, hospital outpatient or inpatient departments, ambulatory surgical centers or home care.

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