

# Medical Device Coverage Initiatives: Connecting with Payors via the Payor Communication Task Force

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FDA | NIH: Regulatory Do's and Don'ts: Tips from FDA  
September 4, 2024

# Overview

- Understand why you should develop your coverage pathway early
- Describe the process for the Early Payor Feedback Program
- Cover metrics and successes
- Review next steps

# The Journey to Patients



**Medical  
Device**



**Patients**

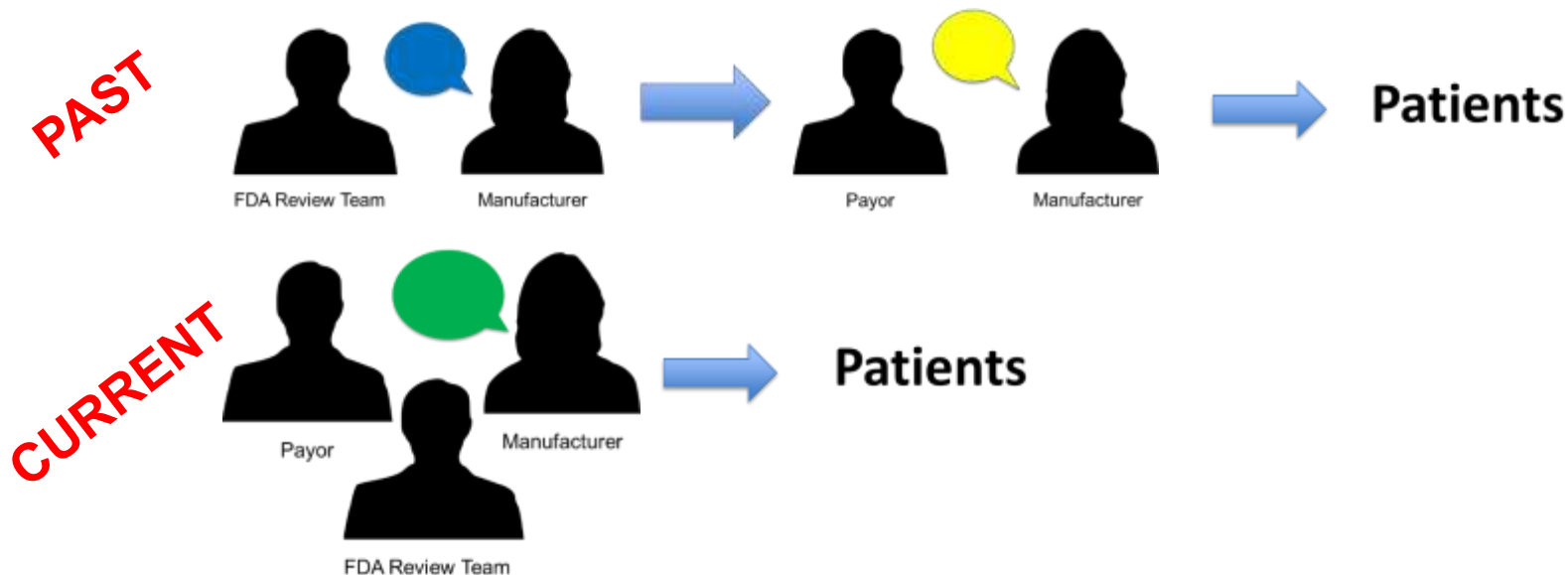
**FDA**

**Payor**

**Facility**

**Physician**

# An Optimized Approach to Coverage



# Early Payor Feedback Program



- Enables sponsors to be voluntarily introduced to payors to learn what evidence the payors may need to make a positive coverage decision
  - Can invite the payor to an upcoming CDRH pre-submission meeting
  - Can meet with the payors independent of CDRH meetings

# Who Would Benefit from this Resource, and When?



- Developing clinical evidence plans for novel devices (first-of-a-kind PMA, De Novo)
- Sharing proposed plans with FDA in preparation for a future marketing submission

# Sponsor Logistics - Early Payor Feedback Program



1. Contact [cdrearlypayorfeedbackprogram@fda.hhs.gov](mailto:cdrearlypayorfeedbackprogram@fda.hhs.gov) for an informational call
2. Complete “Overview Document” & identify payors

# Current Participating Organizations



THE HSC HEALTH CARE SYSTEM  
Health Services for Children  
with Special Needs, Inc.

**Clover  
Health**



**Cigna**

**NICE**

National Institute for  
Health and Care Excellence



**BlueCross BlueShield  
Association**

**CareFirst**



Social Innovation Ventures



UnitedHealth Group



**Duke** Clinical Research Institute

**aetna**

**EXCITE  
INTERNATIONAL**



**KAISER  
PERMANENTE**

**PREMIER**

**MOLINA  
HEALTHCARE**



**ECRI**

**HIGHMARK**

**CMS**  
CENTERS FOR MEDICARE & MEDICAID SERVICES

See our website for current participants: <https://www.fda.gov/about-fda/cdrh-innovation/payor-communication-task-force>

@FDADeviceInfo

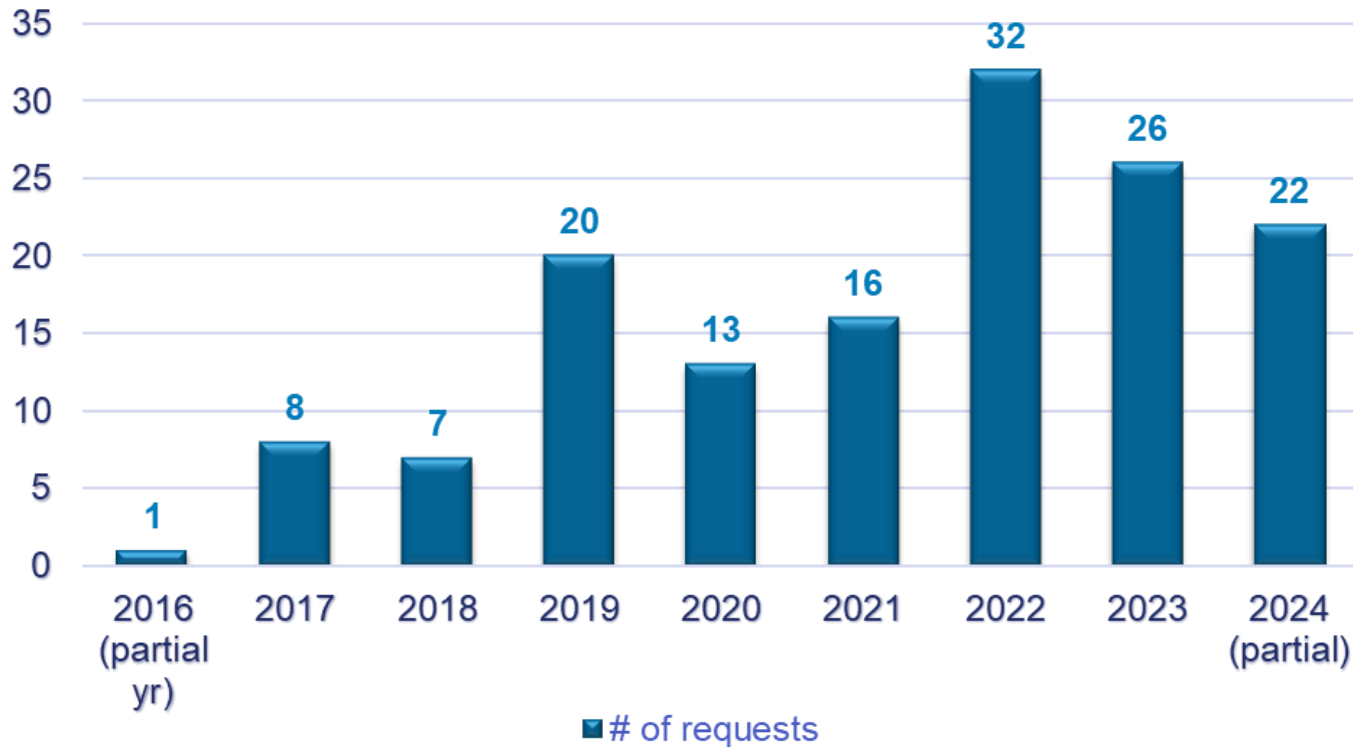


# Sponsor Logistics - Early Payor Feedback Program



1. Contact [cdrearlypayorfeedbackprogram@fda.hhs.gov](mailto:cdrearlypayorfeedbackprogram@fda.hhs.gov) for an informational call
2. Complete “Overview Document” & identify payors
3. CDRH sends requests for feedback to specified payors
4. CDRH facilitates introductions
5. Sponsor submits Pre-submission (if applicable)
6. Sponsor communicates with payors via teleconference and/or in Pre-submission meeting

# EPFP Experience



# EPFP Sponsor Feedback



## Helped sponsors receive:

- Feedback on clinical design
- Input on health economic evidence
- Awareness of evidence needed for coverage
- Learning about payor vs FDA perspective
- Opportunity to discuss future pilots with payors
- Verbal affirmation that devices are reasonable and necessary for given populations

# EPFP Sponsor Feedback



## Sponsors changed their plans based on EPFP Feedback by:

- Using a payor as a clinical trial site
- Ran a health economic study, after previously just considering it
- Modified study design, new subgroup analyses
- Added real-world data to augment randomized controlled trials

# Summary



- CDRH has a voluntary program that introduces sponsors to payors to learn what evidence the payors may need to make a positive coverage
- Can invite the payor to an upcoming CDRH pre-submission meeting or meet with the payors independent of CDRH meetings
- Participating payors and how to apply can be found at <https://www.fda.gov/about-fda/cdrh-innovation/payor-communication-task-force>
- General questions: [CDRHPayorCommunications@fda.hhs.gov](mailto:CDRHPayorCommunications@fda.hhs.gov)

# Closing Thought

Learn what evidence the payors  
may need to make a positive  
coverage decision – EARLY!

# Questions?

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