

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

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CDRH | US FDA

FDA | NIH: Regulatory Do's and Don'ts: Tips from FDA
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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

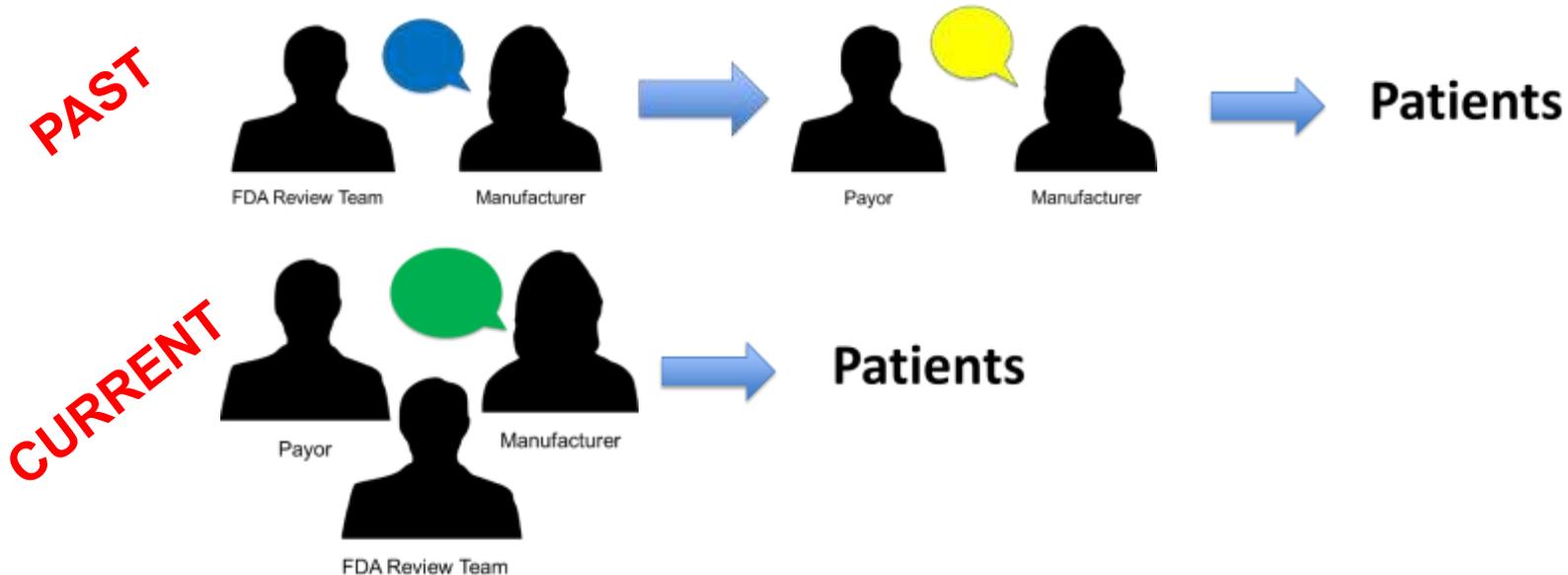
FDA

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 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.



BlueCross BlueShield
Association

**Clover
Health**



Cigna[®]

NICE

National Institute for
Health and Care Excellence

CareFirst[®]



Social Innovation Ventures



UnitedHealth GroupSM



Duke Clinical Research Institute



KAISER
PERMANENTE[®]

PREMIER

aetna[®]

**EXCITE
INTERNATIONAL**

**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>

Sponsor Logistics - Early Payor Feedback Program



1. Contact cdrhearlypayorfeedbackprogram@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

Closing Thought

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

Questions?

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