

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

Danielle R. Fau

Senior Advisor for Technology and Innovation
Division of Health Equity, Office of Strategic Partnerships and
Technology Innovation
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**

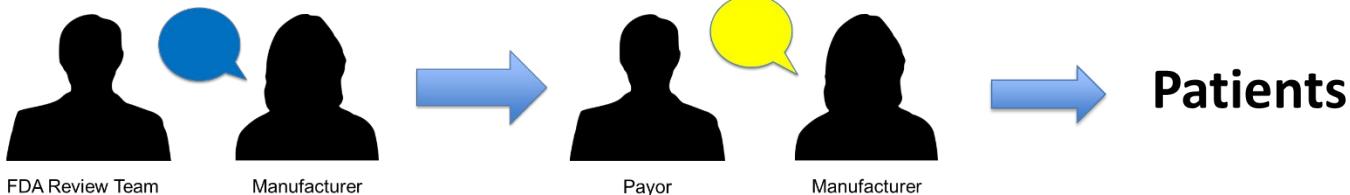
Patients



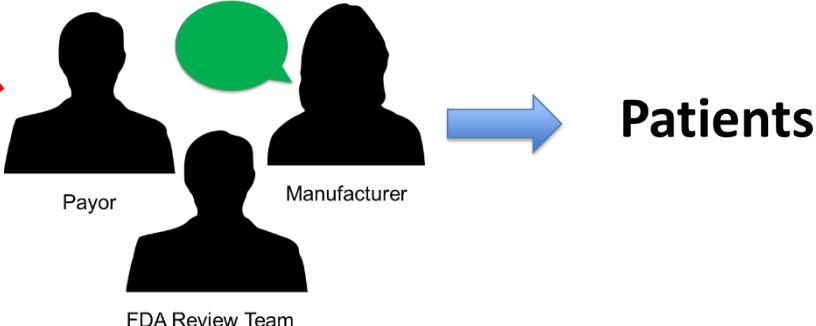
FDA
Payor
Facility
Physician

An Optimized Approach to Coverage

PAST



CURRENT



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 cdrhealypayorfeedbackprogram@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**



 Duke Clinical Research Institute

 aetna®

 MOLINA
HEALTHCARE

 EXCITE
INTERNATIONAL

 ECRI

NICE

National Institute for
Health and Care Excellence



Social Innovation Ventures



**BlueCross BlueShield
Association**

 CareFirst®



UnitedHealth Group™



 PREMIER
KAISER
PERMANENTE®

 CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

 HIGHMARK®

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

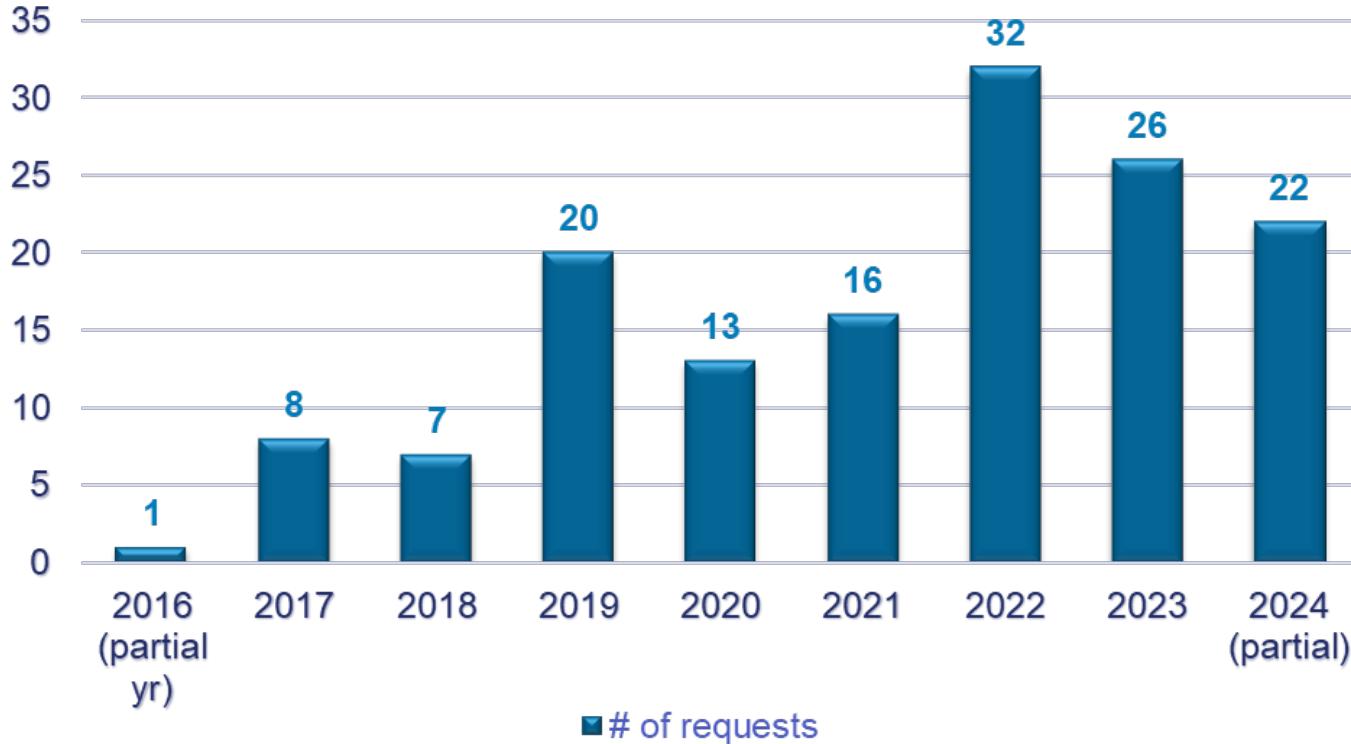
@FDADeviceInfo

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!



**U.S. FOOD & DRUG
ADMINISTRATION**

Questions?

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