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# FDA DRAFT GUIDANCE FOR PAYER COMMUNICATIONS: INSIGHTS AND IMPLICATIONS

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# INTRODUCTION

In January 2017, the FDA released draft guidance* "Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities." This guidance explains the FDA's recommendations on communication to payers for 2 types of information:

- **Healthcare Economic Information (HCEI) about approved drugs**

- **Information about unapproved drugs and medical devices**

FDA

*The draft guidance represents significant developments in terms of promoting HCEI and the ability to proactively share certain information with payers prior to FDA-approval.*

*The public comment period on the draft guidance ended on April 19, 2017.

# SECTION 1: HCEI *about* APPROVED DRUGS

## A. Who can receive HCEI?

The FDA defines HCEI as any analysis that identifies, measures, or describes the economic consequences of using a drug. As such, HCEI can only be presented to specific audiences who are involved in coverage and formulary decisions. According to the draft guidance, you CAN promote HCEI to multidisciplinary entities that make drug selection, formulary management, and/or coverage and reimbursement decisions, including:

- **Payers**
- **Formulary committees**
- **Drug information centers**
- **Technology assessment panels**
- **Pharmacy benefit managers**

*HCEI **cannot** be communicated to **health care practitioners, patients**, or **the general public**.*

## B. What information is permissible?

Drug manufacturers are allowed to communicate HCEI that is "truthful, complete and nonmisleading." To ensure that HCEI meets these standards, presentation of HCEI should include the following details:

- **Current FDA-approved indication and labeling**
- **Risk Information**
- **Disclosure of Omitted Studies or Data Sources**
- **Financial/Affiliation Biases**

*Providing HCEI is considered "promotion" by the FDA and **must be fair and balanced.***



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C.

## What about information that is not in the label?

Information that is not explicitly included in the FDA-approved product labeling, but is "related to" the approved labeling, is also permissible. The table below provides examples of HCEI analyses that FDA considers related to an approved indication of a drug.

| Topic | Example |
|---|---|
| **Duration of treatment** | Efficacy and safety of a heart failure product when used for longer than the clinical trials in the label |
| **Practice setting** | Clinical outcomes for an infused product are different in a fee-for-service setting vs managed care setting |
| **Burden of illness** | Data showing the economic consequences of absent work days due to depression |
| **Dosing** | A product for pain is efficacious at a different frequency or total dose |
| **Patient subgroups** | The effect of an anticoagulant is the same regardless of disease severity or comorbidities |
| **Length of stay** | Use of a medical device that results in a shorter duration of time in the hospital |
| **Surrogate endpoints** | A product's effect on blood pressure reduction in patients with stroke or heart attack |
| **Clinical outcome assessments** | An arthritis product demonstrates improved compliance/adherence, work productivity |
| **Health outcome measures** | An oncology product demonstrates improved quality-adjusted life year (QALY) |
| **Persistence** | Drug utilization data shows improved persistence with a product for kidney disease |
| **Comparisons** | Comparative safety or effectiveness (for approved indication) vs another drug or to no treatment |

| HCEI that is NOT considered to be related to the approved indication | Example |
|---|---|
| **Patient populations outside the indicated population** | A discussion of a drug indicated for diabetes cannot include discussion of the effect of the drug on heart failure |
| **Disease course modification for a drug that is only indicated to treat the symptoms of a disease** | An analysis based on reducing the number of asthma attacks (disease course modification) for a drug approved only for the treatment of the signs and symptoms of asthma |

*When communicating HCEI, **a prominent disclaimer** explaining material differences from the FDA-approved label **is required**.*

# SECTION 2: COMMUNICATION *about* UNAPPROVED PRODUCTS

As part of the Draft Guidance, the FDA recognized that payers often request information on investigational products to plan for future coverage and reimbursement scenarios. The document therefore provided insight into what the FDA considers "appropriate" to communicate in regards to unapproved products.

When sharing permissible information, manufacturers must make clear that the product is still under investigation and is not yet approved (safety and efficacy have not been established). The stage of product development should also be included. Should information about the product change, it is important to follow up with payers to communicate the changes.

**The FDA permits the dissemination of information related to unapproved products when presented in a way that is unbiased and nonmisleading:**

- **Product information**
- **Indication sought**
- **Factual results of clinical/ preclinical studies***
- **Anticipated timeline to FDA approval/clearance**
- **Pricing**
- **Targeting/marketing strategies**
- **Product-related programs and services**

*Cannot extrapolate study results to the safety or effectiveness of the product.

*Follow-up with payers if there are **significant changes** to previously communicated information about the product*

# IMPLICATIONS FOR MANUFACTURERS

Previously, a lack of clear insight into the FDA's views about communicating HCEI and information about unapproved products to payers made it difficult for manufacturers to know what is permissible. Although the guidance is not yet finalized, manufacturers now have enough information to evaluate the impact on their current communication strategy by taking the following steps:

- **Consult with the medical/legal/regulatory committee to assess the risk of communicating specific product information**

- **Review current (and previous) materials to determine if there are new opportunities to communicate value to payers**

- **Evaluate how different information resonates with defined formulary decision-makers and adjust the communication strategy accordingly**

How can Entrée Health help your organization evaluate your payer communication strategy? Call us today to find out.

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