TRACK III: Fair Market Value Update

Implementing Fair Market Value

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THE TWELFTH Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum TRANSFORMATIONAL LEARNING - EFFECTIVE KNOWLEDGE EXCHANGE

Important

- The content and opinions expressed in this presentation are my own, and not necessarily those of my employer.
- This is not advice.

Agenda

- I. Introduction
- II. The Four Key Phases to a successful FMV implementation
- III. Challenges and FAQs
- IV. Q&A

Four Key Phases

Phase I

Data Gathering

Identify Key Stake holder

 Compliance, Legal, Brand Teams, Sales Training, Functional Areas

Document and Data Gathering:

 Policies & Procedures; Honoraria Schedules; Interviews with relevant personnel

Phase II

Analysis

Analyze Company and 3rd Party Data

 Review data against external benchmarks

> Distill information collected along with third party data to develop FMV payment rates

Phase III

Findings & Recommendations

Develop Final FMV Report

Develop final FMV
 rate schedule
 incorporating segment
 sensitivities: HCP
 type, activity, and level
 of effort.

Phase IV

Implementation

Implementation

- Develop process steps, SOP, and training documentation to support the FMV matrix.
- Assist with roll out to impacted stakeholders.

Task

Question/Challenge: "Who owns FMV?"

- FMV is being owned by the business. E&C, Legal can help to facilitate implementation of methodology but don't own the process
- Business is responsible and liable for accuracy of FMV calculations

Question/Challenge: "Why do we have FMV?"

Because it is the law.

Question/Challenge: "What is the right FMV?"

Do not spend time on this – the right number doesn't exist!

Question/Challenge: "Rate Ranges or Fixed Rates?"

- While ranges offer more flexibility, they may lead to operational challenges
- Fixed rates support consistency
- Fixed rates are easier to operationalize

Questions/Challenge:

"Dr. X said he gets paid more by our competitors and will not work for us for the offered FMV rate"

We do not know our competitor's FMV methodology

Challenge: Travel Compensation

Backed into the hourly rates or additional compensation?

Challenge: Exception Process

- Be careful how you communicate internally
- No all requests are true exception requests
- Define KOL (KOL's don't have to be exceptions)
- Exceptions and Deviations (one time, not permanent vs. permanent
- Criteria:
 - offer the regular honorarium and have HCP decline
 - Business justification, incl. rareness/uniqueness
 - Support from Senior Mgt. Member

Challenge: Who does the Leveling of HCPs?

- In-House
- External Party
- Use consistent leveling criteria
- Preference is to use third party

Question: "Can I pay below FMV Rates?"

- If you do, be aware of the risk
- If you do, have documented as to why

Question:

"FMV Calculator vs. Spreadsheets?"

Question:

"The HCP wants to forgo his honorarium – is that okay?"

Question:

"Can we pay the institution instead of the HCP directly?"

Take Aways:

- 1. Choose your stakeholders and influencers wisely
- 2. Don't waste time on finding the right number
- 3. Offer a calculator and think about synergies
- 4. Document, document, document!

Questions?

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