EFS Site
Best Practices Workshop
Event Materials

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MDIC Offices
1501 Wilson Blvd.
Arlington, VA 22209
Coverage Determinations & Site Budgets

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Trial Reimbursement

▪ **Category A**
  – CMS will pay for standard of care / routine procedures, and the implant procedure, but **NOT** the Device

▪ **Category B**
  – CMS will pay for standard of care / routine procedures, the implant procedure, **and** the Device

▪ **No Reimbursement**
  – Sponsor pays for everything, including the device and does not charge for the Device
Developing EFS Budgets

- Start with the protocol and determine what procedures are required by the protocol and which are standard of care (SOC)
- Establish Fair Market Value (FMV) for study procedure costs, SOC vs non-SOC items
  - FMV calculators – Grant Plan, Grant Manager, etc.
  - Establish FMV range from low to high

<table>
<thead>
<tr>
<th>Code</th>
<th>Procedure</th>
<th>Qty</th>
<th>Low</th>
<th>Med</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>79029</td>
<td>IQ/IA Code: Medical History with Informed Consent (formerly IQ/IA code 99209)</td>
<td>8</td>
<td>191</td>
<td>219</td>
<td>268</td>
</tr>
<tr>
<td>50074</td>
<td>New York Heart Association Functional Classification (NYHA); clinical- or researcher-administered</td>
<td>8</td>
<td>39</td>
<td>44</td>
<td>48</td>
</tr>
<tr>
<td>99214</td>
<td>Detailed office or other outpatient examination: Includes at least two of these three components: a detailed medical history, a detailed physical examination including vital signs, medical decision making of moderate complexity. Typically, 25 minutes are spent performing or supervising these services; visit (formerly code 92120, 92130)</td>
<td>9</td>
<td>188</td>
<td>202</td>
<td>212</td>
</tr>
</tbody>
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Procedure Cost Estimation (non-CMS reimbursed)

- If sponsor *doesn’t* have CMS approval, Sponsor will pay for all procedures required by the protocol & hospitalization
  - To obtain implant procedure estimate, pull hospital data for CMS reimbursement for similar procedure and provides estimate and rationale
  - Fee is a one-time fixed payment which will cover everything during hospitalization
- Budget sent to site includes implant and hospitalization fee plus other FMV data required at study intervals
- Goal: Find middle ground with clinical sites within FMV range
Procedure Cost Estimation (non-CMS reimbursed)

- Find appropriate similar procedure DRG
- Estimate the occurrence of major cardiovascular complications and weighted average between reimbursement with or without MCCs
- Compare national average and local hospital reimbursement
- Add any additional costs
  - Hospital component: inpatient reimbursement
  - Physician component: payment for first/second device placement, TEE, etc.
- Medicare reimbursement assumes payment for device; deduct as applicable
- Resulting fee is basis for negotiation with hospital
Challenges with Negotiating Budgets Before CMS Determination

- Clinical sites want higher fees for the implant & hospitalization than what is considered FMV
  - Sites are unsure of the “unknowns” that may occur & don’t want to be left with a large bill
  - Sponsor can only pay within FMV due to kick-back concerns & the payment has to be fixed vs. open ended

- Budget negotiations without CMS determination can take 2x or 3x longer
Budget Negotiations

"Okay, so what number can we both be happy with?"
Common Challenges with MCTAs & CTAs

- Most disputed issues:
  - Who pays in the event of an injury?
  - Breach of confidentiality and damages – LOL Section
  - Indemnification
    - Will we indemnify both the PI and his or her employer that hasn’t entered into the contract?
  - Publication on clinical trials.gov and other disclosure requirements

IT TAKES TIME & ONE ISSUE
ALONE CAN CAUSE DELAYS THAT LAST MONTHS!
Case Scenario A

- Hospital is a university hospital ultimately governed by state policies and regulations
- Hospital claimed that under their university/state policies they may have to disclose all trials they were working on – no secrets as a public institution
- Some EFS trials can be *highly* confidential & sponsor doesn’t always want to disclose trial information
- Site insisted that it could not keep any information secret due to public disclosure requirement
  - Site refused to take the risk of breaching confidentiality provisions
- Impasse lasted months and several rounds of negotiation calls

- In addition …
  - Required external review of SOW; >1 year delay (MDIC site)
Case Scenario B

- Hospital is a university hospital
- EFS program without CMS reimbursement where sponsor proposed FMV budget
- Hospital initially agreed to proposed FMV budget and signed statement of work, site activated to enroll
- Prior to first patient enrolled, site balked and requested increase in procedure cost reimbursement to 3x FMV rate
- Sponsor could not justify 3x FMV from a compliance perspective
  - It’s not always about the actual money, but about the risk sponsors run if they pay over FMV
- EFS was not able to move forward at this site unless the trial received CMS reimbursement