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ACRP Investigator Research Interest Group

IISRA FMV Guidance Document

Position Statement

Ensuring Fair Market Value (FMV) Evaluation in Your Investigator Initiated-Sponsored Research (IISR) Review and Decision Process

Disclaimer: This document should not be construed as providing legal advice. Each company has its own unique program goals and level of risk tolerance. Ultimately, each company should consult their management staff and legal counsel when designing their IISR program.

Purpose

This position statement is intended to provide an overall guidance to companies on methodologies for evaluating the Fair Market Value of budgets associated with the Investigator Initiated-Sponsored Research (IISR) Program. It is not intended to provide a specific step-by-step outline as each company will have unique needs and goals.

It is prudent that all payments to healthcare providers (HCPs) associated with the support of clinical research be consistent with Fair Market Value ("FMV") and that the criteria used to establish FMV should be adequately documented and updated regularly (as appropriate per local laws and guidelines). In the US and other countries, anti-kick-back anti-bribery laws and regulations and the federal Physician Payments Sunshine Act highlight the reasons FMV evaluation is critical for most companies. When determining financial support for an IISR, companies should assess the requested budgets for FMV.

Physician Payment Sunshine Act

The recently released Physician Payments Sunshine Act mentions reporting of funds for clinical trials. Specifically, it is proposed that payments and transfer of value should be reported individually under names and National Provider Identifiers (NPIs) of physician covered recipients serving as principal investigators.

On February 8, 2013, CMS issued the final rule regarding the implementation of requirements in section 6002 of the Affordable Care Act, which added section 1128G to the Social Security Act (the Act). Given the detailed reporting requirements outlined in the Act, it is critical for companies to be able to document a thorough FMV evaluation as part of their approval process for IISRs.

This position statement was developed by the IISRA board with the assistance of Polaris Management Partners who interviewed IISRA members and drafted the document. Interviews were conducted to

better understand current trends, issues, and difficulties facing companies implementing an IISR FMV process into their working practices.

Current FMV Environment Within the IISR Community

Historically, there has been minimal explicit regulatory guidance for IISR programs. More recently, IISR programs have come under intense scrutiny by the Office of the Inspector General, similar to other pharmaceutical activities.

FMV assessment is a critical component of any IISR program. IISRs are complex agreements whose FMV cannot be readily determined from a simple price list. Good FMV practice requires consistent review process that provides clear documentation of the analysis and conclusion of the review. FMV evaluations can vary based on company position on risk and perceptions of costs for implementation.

Some companies purchase commercial databases that provide FMV metrics. Other companies maintain internal databases of costs as well as FMV for specific types of physicians and line item costs. It is easier to maintain internal databases if they are adequately integrated with technology used to track the IISR program. In the absence of available technology, companies can use internal spreadsheets to track and document the FMV evaluation process and approved costs.

Irrespective of the FMV process that a company may implement, the following three principles are essential for the development of FMV evaluation processes. In addition, five best practices are identified which are associated with effective IISR FMV review processes.

FMV Evaluation Principles For IISRs

1) The review and decision process should include clear and consistent FMV evaluation of proposed budgets

2) FMV evaluations should be conducted by subject-matter experts

3) Each IISR FMV evaluation should be clearly documented

Principle 1: FMV evaluation process of proposed budgets

A clear and consistent process for assessing FMV is critical to ensure the success of the IISR program. Implementation of a clear and consistent evaluation process will prevent the appearance of capriciousness or favoritism. Within each company, FMV should be assessed using similar analytic, review, and documentation standards. Inconsistency in the processes and standards used to evaluate

FMV may raise questions about why some requestors or study types are subject to more generous or lenient evaluation standards.

Whenever possible, FMV should be reviewed against available external databases including third party databases and possibly Medicare reimbursement values adjusted to reflect usual and customary payments (i.e. FMV).

Principle 2: FMV evaluations should be conducted by subject-matter experts

FMV evaluations of IISR budgets should be reviewed to ensure budgets are consistently evaluated in the context of the proposed IISR program. Some components of the budget can be assessed against external databases. All budgets, however, should be reviewed by company personnel with relevant clinical and/or scientific experience. Clinical or scientific experience is critical for assessing whether the proposed budget and its components reflect the necessary costs to achieve the goals of the IISR as described in the proposal.

Principle 3: Each IISR FMV evaluation should be clearly documented

Documentation of the actual review conducted is critical for proving that the necessary review was completed. The complex nature of IISRs means that the data and issues examined in the FMV evaluation will likely differ from one IISR to the next. Clear documentation demonstrates that all critical steps of the review process were conducted in an appropriate fashion and that the results of the FMV assessment are clear and consistent with other IISRs reviewed

Best Practices:

1) Require detailed line item budgets for IISR grant requests to facilitate review

In order to effectively evaluate FMV of IISR funding requests, a detailed budget showing how the request funding will be used to fulfill the study goals needs to be provided. Whenever possible, budget line items should clearly state unit costs and volumes used in calculating total cost of the line item in the budget (e.g. hourly rate, number of hours, and staff involved, cost per patient and number of patients, etc.).

At a minimum, budgets should provide all major cost drivers of the project. Specifically, the budget should distinguish costs across three broad cost categories: direct costs, pass-through costs, and indirect costs (e.g., overhead charges). Mixing different cost types in a single line item, significantly limits a company's ability to assess FMV. Within each cost category, key cost items should be detailed separately as line item costs. Budgets should also provide enough detail to support any required reporting under the Federal Physician Payments Sunshine Act including physicians involved in the study, their roles, and anticipated hours.

- **Direct Costs:** These are the main cost items for most IISRs and typically are centered on the cost per patient for executing the specific IISR protocol. Additional staff and equipment costs can also appear under IISR coordination, management, and analysis of results. Specific documentation of unit costs should be encouraged for all major direct cost line items.

- **Pass-Through Costs**: These costs should also be evaluated for FMV and include costs associated with IRB approvals, publications, and supplies. Because these costs are usually associated with non-HCP/HCO third parties, these items can often be evaluated against internal or external data sources. In addition, a strong process for reconciling and recovering unused pass-through costs, can limit companies' exposures.

- **Indirect Costs:** Overhead is one of the largest indirect costs associated with an IISR program and is particularly difficult to evaluate for FMV. Institutional overhead charges can vary significantly by the size, tier, and type of organization. It is common for overhead charges to ranges between 20-30%, but some institutions charge substantially higher rates. Companies working with these institutions will want to have a transparent and robust exception process to address these situations as they arise.

2) Assessment of FMV should be conducted on a line item basis where possible

It is not advisable to approve grants with line item costs that appear to be above FMV (even if the total cost is below the cumulative FMV estimates) as this puts companies at risk. Extenuating circumstances that justify costs above expected FMV should be well documented. Companies should take all appropriate precautions to ensure that IISRs are not perceived as mechanisms for providing inappropriate cash/value to investigators or their organizations.

Effective evaluation of FMV for individual line item costs will typically include an assessment of each of the following three questions:

- Is the cost listed necessary or appropriate for achieving the IISR goals?
- Is the proposed unit cost appropriate given available data on FMV rates?
- Are the budgeted quantities (hours or other units) consistent with the requirements of the IISR?

3) Explore the use of Databases and FMV rate tables

Databases and rate tables can be valuable tools for assessing the FMV of proposed unit costs. Some datasets can also be helpful in evaluating total line item costs, though expertise may be needed to determine if proposed values are realistic estimates for the specific IISR being reviewed.

The most common datasets are built on benchmarking of clinical trials and IISR budgets compiled by third-party vendors. Some companies may already have access to these databases if they are being

used by the company's R&D departments. In using these datasets care must be taken to ensure that the specific data used is an appropriate metric for the particular IISR cost item being evaluated. Databases containing detailed procedure costs or hourly rates for a variety of physician and non-physician skillsets are often effective tools (both IISR sourced databases as well as general clinical trial sourced databases).

Medicare reimbursement values provide another useful reference point particularly for companies that do not have access to the more costly third-party databases. Medicare values, however, may be adjusted to reflect usual and customary payments and offset the price discounts generated by the government's leverage in the price setting process.

Databases for other cost items, particularly activity costs versus product or unit costs, can be more difficult to effectively align with the specifics of the actual IISR being reviewed.

4) Documentation of Communication with Principal Investigators

As companies work to obtain effective budgets to support their FMV evaluations, they are likely to interact more with investigators/requestors in an effort to clarify submissions. This, in turn, creates challenges since actions that may be considered as influencing a principal investigator's study should be discouraged.

All communication should be documented including phone calls. Follow-up emails can be used to document conversations discussed over the phone. A technology solution can be used to effectively track all communications between the requestor and the company. Forms of communication that create an audit trial are necessary in order to document proper communication between the company and requestor.

5) Reconcile and collect unused funds and supplies

Reconciliation can provide companies with valuable data on actual costs rather than proposed costs, which can be built into internal databases to support FMV evaluation.
Reconciliation should include an attestation from principal investigators at the conclusion of a study that all funds were used as described, and if not, any unused funds will be refunded to the company as stated in the contract.

IISR programs should ensure that unused funds are returned and any leftover product, and materials destroyed in line with local regulations. While monetary funds may be easy to identify as kickbacks if not returned, unused products provided for a study may also be construed as items of value and should be treated accordingly. Items not returned or destroyed can be interpreted as gifts, raising possible anti-kickback violations.

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Disclosure: The responses of the interviewees do not reflect the thoughts/opinions of their employers.