

Analysis of the Proposed Sunshine Rule Implementation Issues

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From 5 States to 50 – Program Management

- **How the overall management approach to HCP reporting may need to be altered due to the amount of data**
 - Dedicated management team/department
 - Moving the responsibility for data quality from the reporting team to the departments initiating the HCP relationship or spend
- **Creating a core team across the company/companies**
 - Steering Committee of top executives from all divisions and companies *[buy-in & the purse strings]*
 - Management Team *[Communications, Training, & Data Accuracy]*
 - Managers from each business unit with spend or affected
 - Internal system owners & IS
 - Operations Team *[Responsible for ongoing program management, the Aggregate Spend system & compiling all reports]*

Data Collection Challenges

- **Reviewing current systems for ability to capture level of detail required**
 - Upgrade may be required for new fields
 - New systems may be necessary for some types of spend
 - Getting on the system owner's radar as they plan regular system upgrades going forward
- **Working with Vendors**
 - Identifying all vendors
 - Structured format for all vendors to provide data
 - Will you require them to 'certify?'
 - Training & Documentation for Meeting Organizers
 - Sign-in Sheets (notification regarding PPACA)
 - Changes to contracts with KOLs & with Vendors

Data Monitoring Challenges

● Identifying Likely Sources of Data Errors

- “Fat finger” errors
 - Create reports to catch outliers
 - Catching errors before they leave the originating system
- Errors due to aggregating system programming
 - Compare number of records that should be transferring from originating system to reporting system
 - Compare a program spend from the originating system to the reporting systems numbers to catch aggregation or allocation issues.
- Customer Master Issues
 - Identifying combined HCPs or duplicate HCP IDs.

Potential Complications – Draft Regs

● What About Meal Allocation?

- If we have to allocate the meal cost for the office to all doctors in that practice, whether or not they were present...
 - Will more entire offices become ‘no-see’ (where there were one or two individual doctors that were no-see previously)?
 - Do you or your customer master have information on all doctors’ affiliations?
 - Where a doctor has multiple practice affiliations, will you report every meal at each office to him/her?

● Indirect Payments & Knowledge of the Recipient

- What will you do when you have given a CME grant to an institution without knowledge of the speaker and later see a flyer with the speaker’s name – are you now obligated to report that payment?