Are You Ready For Reporting?

5 Keys to Open Payments Compliance
INTRODUCTION

Medical device manufacturers, pharmaceutical companies and GPOs face two important deadlines: In accordance with the Sunshine Act, participating organizations must register for CMS’ Enterprise Portal and submit aggregate 2013 payment data by March 31st (a fuzzy deadline at this point in time), and register in the Open Payments system as part of Phase 1 of reporting. In May, Phase 2 begins where detailed 2013 payment data, as well as legal attestation to the accuracy of the data, is required.

The Open Payments program was established as a “national resource for beneficiaries, consumers, and providers to know more about the relationships among physicians, teaching hospitals, and industry” as part of the Open Transparency requirements of the Affordable Care Act.

To remain compliant, medical device and pharmaceutical manufacturers, GPOs and other applicable organizations must report: 1) Payments and other transfers of value from applicable manufacturers of covered drugs, devices, biologicals, or medical supplies to physicians and teaching hospitals; 2) Payments and other transfers of value from applicable GPOs to physician owners/ investors; and 3) Ownerships or investments held by physicians or their immediate family in applicable manufacturers and applicable GPOs.

At the heart of Open Payments compliance is data. To be considered in compliance, the data reported by applicable organizations must be timely, accurate and complete. To be sure, Open Payments reporting will test the strengths and weaknesses of organizational processes with regard to collecting, tracking and maintaining data.

This poses considerable challenges to healthcare manufacturers and GPOs, which are dealing with numerous other changes in processes, payments and technologies. However, with financial penalties ranging from $150,000 for failure to report and $1.5 million for knowingly failing to report, civil and criminal charges and public reputation on the line, ignoring the seriousness of reporting is a risk few companies can afford.

Although applicable manufacturers, Physicians, GPOs and other covered recipients are provided a review period to resolve report disputes before they are made public, Healthcare Data Solutions, along with CEO of the Regulatory Law Group, PLLC, Tim Robinson, recommend the following five keys to ensuring that reports are done correctly the first time around.
Don’t underestimate the time it takes to prepare.

The detailed reports of 2013 payments must be accepted by CMS as accurate in order to be considered in compliance.

Three pre-submission safety measures can significantly increase chances of accurate reporting: ensuring that Physician data and specialty designations are up to date, understanding key provisions of the regulations, and allowing Physicians to review reports before they’re submitted to CMS.

These measures require sufficient time, sound processes and accurate data, however. Delays in any of these areas could result in error penalties ranging from $100,000 to $1.15 million annually, time-consuming disputes and future audits.

Physicians, therefore, must ensure that professional identifiers such as NPI numbers are current, including all specialty designations and state licenses. Medical device and pharmaceutical manufacturers and GPOs should also assess the accuracy of their data, particularly for Physicians who hold licenses in multiple states.

Failure to validate such information has consequences. For example, if a manufacturer or GPO reports a payment or transfer to a Physician in Texas and that Physician’s record only lists a Massachusetts license, that entry will be flagged by CMS as an error.

Developing a clear understanding of what qualifies as direct or indirect payments and transfers of value is also vital – including knowing what not to include in reporting. CMS has listed 12 types of transfers and payments that are exempt from reporting and continuously updates its FAQs as interpretations change. Applicable manufacturers should take the time to understand these exemptions and continually read the FAQs for new interpretations of direct/indirect payments and exclusions.

Although not mandatory, CMS has recommended that applicable manufacturers and GPOs voluntarily provide Physicians the opportunity to conduct pre-submission reviews. Scheduling time for this gives both manufacturers and Physicians an advantage: resolving disputes and discrepancies prior to submitting reports could dramatically reduce errors and minimize the potential for audits in the future.
Review processes to reduce errors and disputes.

The statutory framework of Open Payments reporting is flexible enough to provide reduced penalties for unexpected errors, but applicable companies should still aim to reduce the number of *avoidable* errors. Reports with significant errors will be targeted by CMS for audits and future investigations. Since federal and state authorities will target individuals rather than companies for possible kickbacks, false claims and legal violations, it is vital that compliance officers review and strengthen processes to minimize errors and disputes.

**Random Samples**

It is unrealistic for companies to review every single reporting entry, but compliance officers can ensure the integrity of reports by taking random samples of spends and reviewing them for accuracy. Here, the focus should be on areas where discrepancies are most likely to occur: high-profile specialties with large expenditures and expensive travel scenarios. In reviewing these types of entries, compliance officers can identify who entered the data, how the data was gathered and what, if any, gaps or discrepancies in data exist.

If a Physician consults for a $50,000 fee, but the company reports an amount that includes travel expenses, the Physician may file a dispute, saying he was only paid $50,000. There should be processes in place to resolve this issue.

Similarly, if a sales person takes a Physician out to dinner but does not mark that payment as made to a Physician, such errors need sound processes to remedy.

Random sampling offers a way to distinguish different types of reporting errors and can also help identify Physician entries with missing NPI numbers and state license information.

As the deadline approaches, applicable organizations planning to notify Physicians prior to submitting their reports should plan to do so ASAP.

Rather than rely on online databases or manual methods to fill data gaps and verify that data is correct and up to date, companies should consider using 3rd-party data services like HDS that specialize in providing the most complete and accurate Physician data.
Make sure data aligns with your assumptions.

Applicable manufacturers and GPOs are not required by CMS to submit an Assumptions document with their report, but developing a comprehensive Assumptions document is essential for both internal and external purposes. Internally, the Assumptions document helps to build an understanding of the assumptions made and methodologies used. To external stakeholders, it explains why your company made certain reporting decisions and why those decisions were important.

Consulting with legal counsel can help clarify important definitions, including which affiliate manufacturers are “applicable manufacturers,” how “value” should be determined, what transactions qualify for exclusions, and how to distinguish direct payments or transfers from indirect payments or transfers.

While documenting your assumptions, it is also important to consider how the information could be used against your company. The following assumption statements provide a good starting point for protecting your organization from disputes:

- “At the time of this document, the following assumptions were valid…”
- “This document assumes the physician did not get another license in a different state.”
- “This document assumes that the NPPES is accurate.”
- “This document assumes that sales reps are following established processes for the collection, maintenance and reporting of data.”

Keep in mind that assumptions may look good on paper but may not be applicable in practice, so sufficient time should be allocated to revisit assumptions and make revisions where necessary. Be sure to keep track of all revisions, as other areas in the report may be affected.

Compliance officers and legal counsel should confirm all final assumptions and advise on the merits of submitting the Assumptions document with the final report. Once final assumptions are confirmed, they should be aligned with data to ensure that the report is complete and accurate. Clear documentation that supports final assumptions should also be kept on file in the event of an audit or investigation.
Understand Physician specialty as it relates to your product.

Section 1128G of the Social Security Act requires healthcare manufacturers to identify a Physician’s specialty when reporting payments and transfers of value. Under federal law, medical device and pharmaceutical companies are prohibited from marketing their products to customers for uses not approved as safe and effective by the FDA.

Violating this restriction can result in major criminal fines and forfeiture for violations in the law, which may cost millions, even billions, to resolve.

Such was the case in November, 2013, when one of the world’s leading healthcare giants and its subsidiaries were ordered to pay more than $2 billion in fraud settlements – one of the largest cases of healthcare fraud settlements in U.S. history.

Thus, in order to understand how designated specialties relate to approved products, it is critical for manufacturers to review and confirm Physician specialty data prior to reporting. Payments and transfers of value that are inconsistent with Physician specialties will arouse suspicion of off-label marketing.

Companies utilizing trusted data that is regularly updated and validated for accuracy have an advantage over those that do not.
Solidify your internal certification process.

All fines and penalties associated with reports are directly associated with your company’s level of due diligence in tracking, confirming and reporting data.

As stated in the Rules and Regulations of the Affordable Care Act, “an authorized representative from the applicable manufacturer or GPO must submit a signed attestation certifying the timeliness, accuracy and completeness of the report.”

Authorized representatives include the chief executive officer, chief financial officer or the chief compliance officer. Only those reports with appropriate attestations at the time of original submission will be considered officially submitted by CMS. Therefore, it is critical that applicable manufacturers and GPOs solidify their certification process ahead of time by designating which C-level personnel will sign all attestations.

Additionally, each time a report is modified or updated a new attestation is required, so it is also important to designate a C-level representative who can review and approve changes during the 45-day period following the deadline.

Conclusion

CMS takes compliance with Open Payments reporting seriously. As part of its own preparation, CMS has attempted to simplify procedures, provide helpful tools and support stakeholders throughout the process. While applicable manufacturers and GPOs will have a 45-day period to review reported data before it becomes available in the public domain and 15 days following to resolve disputes from Physicians and teaching hospitals, participating organizations should take every precautionary step to ensure the integrity of their data prior to submitting reports. Applying the five keys presented in this whitepaper, along with utilizing complete and accurate data, can help applicable organizations avoid costly penalties and future audits.

To learn more about HDS compliance services, call 1-877-472-9066.