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Why are so many DLA Piper employees certified in compliance?

See page 16

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The risk of improper billing

» Medicare must not be billed for injuries when a clinical trial agreement (CTA) states the sponsor will pay.
» CTAs that state the sponsor will pay if Medicare will not pay are in violation of the Medicare statutes.
» Sites that improperly bill Medicare risk treble damages under the False Claims Act.
» Sponsors are required to report their obligation to pay or face fines of $1,000 per day per unreported instance.
» Use a coverage analysis to identify funding sources, meet federal requirements to determine if another insurer is the primary payer, and mitigate the risk of improper billing.

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The risk of improper billing in clinical research has many facets that cannot be ignored. For many sites, improper billing is not regarded as a high enough risk to warrant the perceived expense and effort required to guarantee billing compliance. Unfortunately, if the site is audited, the legal defense costs, civil fines, and loss of reputation will greatly exceed the cost of getting it right the first time. What are the risks involved in billing clinical trials improperly?

The Medicare Secondary Payer Statute

Since 1980, Medicare cannot be billed if another insurer has an obligation to pay. Medical providers are generally aware of this fact, because are they required by another law (42 C.F.R. § 489.20) to determine if another insurer is primary; generally through administering a Medicare Secondary Payer (MSP) questionnaire upon admission. Medicare recently stepped up their enforcement of the MSP statute with Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007, often referred to simply as Section 111 or MMSEA. Today, under the new law, insurers as well as providers are required to report to Medicare when there is another insurer that should be paying the bills. These three laws are important to clinical trial sites and sponsors because sponsors have been deemed by Medicare to be "insurers" when they agree to pay for injuries arising from the trial (i.e., subject injury) in their Clinical Trial Agreement (CTA).

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Legal impact to clinical trials

Many sponsors unwittingly add language to their CTA that says they will pay if the subject's own insurance will not pay. According to the MSP statute, Medicare can never by primary when another insurance plan is available. Both the site and the sponsor are at risk of heavy federal fines if they use such clauses to justify billing Medicare before a sponsor. This type of language should not be included in contracts as it puts both the site and the sponsor at risk.

If a research site is working under such a CTA and bills Medicare anyway, then the bill is going to be viewed by Medicare as an "overpayment." Overpayments must be reported by the site and the money must be refunded or the site will be liable for three times the amount of the bill under the False Claims Act.

If the CTA states that the sponsor will pay for injuries arising from the trial, then the trial site should bill the sponsor for treatment of adverse events (AEs) and serious adverse events (SAEs) related to the device or drug being tested—including known AEs and SAEs. Language should be distinct in regard to injury versus adverse events or complications that occur during a trial as a result of the use of a device under an Investigational Device Exemption (IDE).

Sponsors face two risks: (1) Double damages if they fail to pay as the primary insurer when their CTA said they would; and (2) $1,000 per day per unreported instance. The first risk is from the 1980 version of the MSP statute that allows for a test subject, a provider, or Medicare to sue the sponsor for double damages under Title 42 U.S.C. 1395y(b)(3)(a). The second risk is the penalty for not reporting under Section 111.[1]

Reporting to Medicare under Section 111

If the sponsor is obligated to pay for an injury under a contract provision, they are required to report identifying information about the beneficiary (e.g., first name, last name, Social Security Number [SSN] or Health Identification Claim Number [HICN]), information about the injury, and the period of time for which they have accepted responsibility for treating the injury. Importantly, the sponsor must report injuries that occurred in the prior quarter on a quarterly basis to Medicare. The sponsor cannot wait until the trial has been completed and unblinded. Reporting the sponsor's liability for payments is complicated, but the there are ways to limit exposure and add or remove the responsibility for the injuries at the close of the trial.

Sponsors are explicitly required by statute to determine whether a test subject is a beneficiary with no room for negotiation. This is generally accomplished by submitting each test subject to Medicare for verification of

enrollment. Age is not the only discriminator, so research sites are required to collect SSNs from their test subjects.

Collecting SSNs is a contentious subject, mostly due to the confusion by sites about when HIPAA laws must be considered. Without divulging medical information, the collection of SSNs does not invoke HIPPA. The collection of SSNs is a matter of privacy and Medicare has already tackled this problem in response to the same concerns brought up by the insurance community (e.g., group health plans, workers' compensation plans, liability etc.), all of whom are collecting SSNs and have been reporting for years. Medicare's response was published as an Alert[2] officially stating that the "collection of HICNs, SSNs, or EINs for purposes of compliance with the reporting requirements under Section 111 of Public Law 100-173 is appropriate." Clinical trials sites and sponsors should amend their Informed Consent to include the collection of SSNs and modify their patient intake process to meet Medicare's reporting law.

The sponsor is generally alerted to the presence of a beneficiary among the test subjects by a third-party reporting service using only the subject ID to avoid breaking the double blind.

Reporting study subject injury to Medicare

Once the sponsor knows which test subjects are enrolled in Medicare, the sponsor must decide what injuries to report and when to assume and terminate their responsibility for medical payments. This is a difficult step because reporting commits the sponsor to making payments for related AEs and SAEs that may or may not be determined to be related after the study closes. Needless to say, Medicare will not refund the money the sponsor paid for claims that turned out not to be the sponsor's responsibility. The subject injury evaluation process also requires expert analysis to review the related AEs and SAEs to insure they would not imply a responsibility that is too broad or span an unreasonable period of time. Although the FDA is under the same agency as Medicare, the two requirements for reporting AEs and SAEs are for entirely separate reasons. What the sponsor reports under Section 111 does not imply they have accepted this responsibility without recourse (e.g., deny future responsibility when the subject turned out to be on a placebo). However, it might be wise to consider that any related AEs or SAEs reported to the FDA and not Medicare might raise a few red flags.

Once the sponsor has submitted their quarterly report, Medicare will deny medical payments that are related to the reported subject injury. By denying payment, Medicare prohibits uninformed providers (e.g., a local health clinic or personal physician) from billing Medicare when the bill should rightfully be submitted to the sponsor. Test subjects will be forced to seek treatment from the site or its affiliated medical facility.

Not all sites have the capabilities to easily breakout what should be paid by the sponsor and what may be billed to Medicare. Still other sites lack a seamlessly integrated billing system with their affiliated medical facilities, and that might make coordination difficult. Once Medicare begins to deny payments, those issues will come to the forefront, and it would be wise to begin planning how to deal with that now. On a more positive note, the site's risk of improperly billing Medicare will be greatly reduced.

Sponsors face another hurdle all together: They are suddenly going to get bills (or "demands" in Medicare's vernacular) for repayment of claims that Medicare "mistakenly" made on behalf of the sponsor. For instance, when the sponsor's Section 111 quarterly report is processed after Medicare has already paid related medical claims. If the site

bills Medicare before Medicare learns they should have denied the claim, then they are going to send the bill to the sponsor for repayment. Unfortunately, since automated systems are heavily used in creating these demands, it is advisable to employ experts to validate and if necessary, dispute, Medicare's claims.

Developing your action plan

Sponsors can do many things that will facilitate ease in billing compliance for the research sites, such as:

- Register with Medicare as a Responsible Reporting Entity. It can take a couple of months to get through the paperwork, so plan ahead.
- Engage a Section 111 reporting service to collect the personal information of the test subjects from your sites and submit them to Medicare for verification on your behalf.
- Engage your IT department as soon as possible in creating reports that contain the information you are going to need to report. Large firms in particular may find the process of writing requirements, writing software, and then testing it according to company standards is a lengthy process.
- Consider whether you want to adjudicate claims for payment internally or seek help, knowing what you pay is going to be what you report.
- Consider whether or not your firm has the expertise or is willing to develop the expertise to verify and dispute demands from Medicare.
- Do not put, or accept, language in a contract that states the research sites will bill the test subject's insurance for adverse events or injuries, and then once they have a denial, they will bill the sponsor. This is a huge error that puts the sites at high risk.

As a research site, you must do the following to ensure that you are doing due diligence:

- Review your existing clinical trial agreements to determine if they meet MSP statutes (e.g., do not say the sponsor will pay only after a bill has been submitted to the subject's insurance, which explicitly or implicitly includes Medicare).
- Modify your Consent Agreement to be in accord with your CTA and include language that invokes the subject injury language of the CTA while also informing the test subjects that they are required to provide their personal information (including SSN) to verify that they are or are not enrolled in Medicare.
- Modify your clinical trial set up procedures to include a coverage analysis to document how you will be paid and to meet Medicare regulation 42 C.F.R. § 489.20.

- Review your billing systems and procedures and identify any potential roadblocks to proper communication and billing.
- Cooperate with your sponsor and/or your sponsor's vendor when requested to provide privacy information. Remember this is not a request for medical information and does not invoke HIPAA.
- Stay in touch with your sponsor so you are in the loop about which claims have been reported and will subsequently be denied.

Coverage analysis process

Medical facilities and physicians often engage in clinical trials for the prestige it brings to those involved. Unfortunately, trials are costly and many sites have to seek alternative methods of payment just to keep from underwriting the trial themselves, let alone make a profit. Now, add complex state and federal billing regulations and the problem becomes almost unwieldy. This is where a coverage analysis comes into play. A coverage analysis can identify additional sources of funding and tailor the billing to meet the commercial payer's requirements or the government regulations. A coverage analysis process will assist in preventing billing items and services that should not be billed to any payer within the schedule of events. This is a way to systematically review research-related documents to determine the billing status of both the study itself and the items and services provided to the research subjects that are outlined in the research documents over the course of the study. A coverage analysis is based on thorough research, supported by industry guidelines which meet the "generally accepted in the medical community" standard and comply with government regulations. This process assists everyone, including sponsors, clinical research organizations, and sites. It meets Medicare's law that requires providers to determine if another payer is the primary payer. There is nothing better to assist in the budget and contract process.

If a sponsor provides a coverage analysis, use it as a benchmark against your Local Coverage Determinations. This is a tool that can provide dialogue between parties and clearly define what the subject will be responsible for. It should not be taken lightly. If done correctly, you can help identify complications in a qualifying trial that may indeed be billable to a payer and save a tremendous amount of time and effort for all involved.

Summary

Funding for clinical trials has several potential sources. The best way to identify them is with a coverage analysis. A coverage analysis also provides a means for meeting Medicare's requirement to maintain a system that, during the trial's subject admission process, identifies primary payers including but not limited to, Medicare (see 42 C.F.R. § 489.20). The coverage analysis should also include who pays for subject injury. If the sponsor agrees to pay, regardless of their contract language, Medicare will be the secondary payer. Sponsors are required to report these instances to Medicare and the site is obligated to assist them. Ensure that your informed consent, contract, budget, and coverage analysis are convergent, both in language at the sponsor side and at the research site. Both can assist each other with ways to make this process easier and more efficient in billing compliance.

The information provided in this article is for informational purposes and does not constitute legal advice.

1. Title 42 U.S.C. 1395y(b)(8)(E)(i)
2. Collection of Medicare Health Insurance Claim Numbers (HICNs), Social Security Numbers (SSNs) and Employer Identification Numbers (EINs) (Tax Identification Numbers) – ALERT" the revised April 2010 version of which can be found under down loads on Medicare's web site at https://www.cms.gov/MandatoryInsRep