WHAT CLINICAL TRIAL SPONSORS SHOULD KNOW BEFORE PAYING FOR MEDICAL EXPENSES FROM ADVERSE EVENTS

The New Federal Law Reporting Obligations

REGULATORY & CLINICAL RESEARCH INSTITUTE, INC.
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Mandy Klosterman, VP Regulatory Sciences & Legal Services, RCRI

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Why are we here?

A new federal law requires clinical trial Sponsors that pay for Medicare beneficiaries’ medical expenses for adverse events arising out of the trial to REPORT such payments to Medicare.

- Lack of guidance/Complex law => Compliance is challenging
- Hefty Penalties imposed if fail to report

It is of critical importance that Sponsors understand the requirements under this law and develop processes to comply.
Talking points for today

• Overview of the Medicare Secondary Payer rule

• New Section 111 reporting requirements
  – Purpose of Section 111

• How does Section 111 apply to clinical trial Sponsors?
  – What triggers a reportable adverse event?
  – ORM vs. TPOC

• How to be Medicare compliant?
  – The 5 Steps to Compliance

• Challenges faced when reporting

• Resources
Overview of Medicare Secondary Payer Rule

• The Medicare Secondary Payer Rule ("MSPR") mandates certain coordination of benefits
  • Medicare can only be the secondary payer (as opposed to the primary payer) of a medical costs claim if there is another type of coverage available
• Other types of coverage include:
  – Group Health Plans ("GHP"), and
  – Non Group Health Plans ("NGHP"):
    • Automobile insurance,
    • Workers’ Compensation plans, and
    • Liability Insurance (inc. Self-Insurance) plans
      - Clinical Trial Sponsors (considered to be self-insurers)
• This presentation addresses clinical trial Sponsors’ reporting obligations only – not all types of reporting obligations under this Rule
Overview of Medicare Secondary Payer Rule

• If Medicare is not reimbursed, Medicare has a broad statutory right to seek reimbursement from any party to the claim:
  – Beneficiary,
  – Provider,
  – Attorney,
  – Primary payer

• If Medicare is required to take legal action to recover from the primary payer, double damages may be sought
New Section 111 reporting requirements

• Historically enforcement of the secondary payer rule has been compromised as Medicare has not had access to adequate information about payments made to Medicare beneficiaries.

• Hence, Medicare may have paid for medical expenses that should have eventually been covered by the beneficiary or by the primary insurer under MSP rules.

• In order to provide Medicare with greater tools to enforce the MSP Act, Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007 (usually referred to as “Section 111”) imposed new data collection and mandatory reporting requirements on primary payers.
New Section 111 reporting requirements

- New Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007 imposed **new data reporting obligations on insurers which are required to:**
  1. determine whether an injured party is entitled to Medicare benefits; and if yes,
  2. notify Medicare about settlements, judgments, awards, or “other payment” made to Medicare beneficiaries

- No reporting obligations for payments made to Medicaid/SCHIP beneficiaries
Purpose of Section 111

• The data collected through Section 111 reporting will:
  – Enable Medicare to determine who is responsible to pay (primary payer vs. Medicare)
  – Allow Medicare to track (and deny) any future medical bills involving a Medicare beneficiary for which a primary plan has assumed responsibility
  – Facilitate recovery of payments where Medicare is not the primary payer

• Penalties = $1,000 for each day of non-compliance for each injured party
How does Section 111 apply to clinical trial Sponsors?

The policy, in its entirety, states:

- “When payments are made by sponsors of clinical trials for complications or injuries arising out of the trials, such payments are considered to be payments by liability insurance (including self-insurance) and must be reported. The appropriate Responsible Reporting Entity (RRE) should report the date that the injury/complication first arose as the Date of Incident (DOI). The situation should also be reported as one involving Ongoing Responsibility for Medicals (ORM)”

This policy, adopted in 2010, was incorporated in the new MMSEA Section 111 MSP NGHP User Guide v.3.4 (Chapter 3 – Policy Guidance, page 40) (July 3, 2012) on CMS website (http://www.cms.gov/MandatoryInsRep/)
How does Section 111 apply to clinical trial Sponsors?

- Medicare considers Clinical Trial Sponsors to be **liability insurers** (i.e. NGHP) for purposes of the MSP reporting requirements when payment is made by the Sponsor for complications or injuries arising out of clinical trials.
- In those circumstances, the Sponsor is considered the primary payer and Medicare is the secondary payer.
What triggers a reportable adverse event?

Reporting obligations are triggered only when:

• Sponsor **pays** for medical expenses to treat an injury or complication or
  – Settles a claim for an injured party for a disputed amount that includes medical expenses

• The payment is made to or **on behalf** of a Medicare beneficiary (if you pay the provider as opposed to a beneficiary you still need to report that payment)

• Sponsors must report the payment made regardless of whether or not there is an admission or determination that the Sponsor is “liable” (at fault)
What triggers a reportable adverse event?

- Section 111 requires the Sponsor to report claim information for Medicare beneficiaries:
  - After it has assumed **Ongoing Responsibility for Medicals** ("ORM")
    - ORM refers to the Sponsor’s responsibility to pay, on an ongoing basis, for the Medicare beneficiary’s medical costs associated with a claim for the rest of the patient’s life
  - After paying the **Total Payment Obligation to the Claimant** ("TPOC") in the form of a settlement, judgment, award, or other payment
    - TPOC refers to the dollar amount of a settlement, judgment, award or other payment in addition to or apart from ORM
ORM vs. TPOC

ORM
• Typically applies to Auto insurance and Workers Compensation
• Although discussed, trigger for reporting is the **date the Sponsor assumed ORM** (the “promise to pay” e.g. in a CTA or ICF does not trigger any reporting obligation)
• If Sponsor pays the bill it may be responsible for all future medical expenses associated with the claim
• Claims information where ORM was assumed on or after Jan. 1, 2010 must be reported. In addition, payments must be reported where ORM existed on or through Jan. 1, 2010
• Sponsor makes the 1st report when it assumes ORM and gets a notification from Medicare that this record was accepted. Sponsor needs not report each time a payment is made for medical services. Sponsor reports again when ORM is terminated

TPOC
• Typically reflects a one-time or lump sum payment intended to resolve or partially resolve a claim
• Trigger for reporting is the date the TPOC obligation was established:
  ▪ Date the obligation is signed (e.g. written agreement) unless Court approval is required
  ▪ If Court approval is required then it is the later of the date the obligation is signed or the date of Court approval
  ▪ If no written agreement, it is the date the payment is issued
• If TPOC is established on or after October 1, 2011 => quarterly reporting started April 1, 2012 for payments >$100,000
• Thresholds: TPOC Date Sliding Scale between $50,000 - $300 (October 1, 2014)
How to be Medicare compliant?

The 5 Steps to Compliance:

1. Identify the Responsible Reporting Entity ("RRE")
2. Register your company with Medicare
3. Develop/implement internal processes to pay for medical expenses
4. Determine if the injured party is a Medicare beneficiary
5. Report
Step 1: Identify the Responsible Reporting Entity

- In general the RRE is the entity that makes payment to the Medicare beneficiary or its representative
  - Typically, the Clinical Trial Sponsor will be the RRE
- RRE can designate a third party administrator or vendor to manage the data exchange with Medicare
- Keep in mind that:
  - Accountability for reporting in the manner and form required by law still rests with the RRE; and
  - RRE is still responsible for the accuracy of the data submitted
Step 1: Identify the Responsible Reporting Entity

- **Corporate structure and RREs**: the general rule is that an entity may only register as an RRE for itself and for any direct subsidiary in its corporate structure
  - A parent entity may register as an RRE for any subsidiary (or the subsidiary of that subsidiary) in its corporate structure regardless of whether or not the parent would otherwise qualify as an RRE
  - An entity may not register as an RRE for a sibling in its corporate structure
  - A subsidiary may not register as an RRE for its parent
Step 1: Identify the Responsible Reporting Entity

- **A Foreign Insurer** (i.e. insurer which does not have a US Tax Identification Number) is required to report under Section 111 if it is “doing business within the United States” or if a court of competent jurisdiction has exercised jurisdiction over the insurer with respect to a particular claim.
  - NB: These rules do not apply to liability or workers' compensation *self-insurance*.
  - Entities “doing business” in the US defined broadly by Medicare to include:
    - Entities registered in one or more of the 50 States, the District of Columbia, American Samoa, Guam, Puerto Rico, or the Virgin Islands.
    - Entities not registered in a U.S. State, district, or territory but that have a “definite presence” in the US, including entities:
      - Issuing or delivering insurance contracts to persons or corporations licensed to do business in the US.
      - Soliciting applications for insurance contracts registered in the US.
      - Collecting premiums and other fees for insurance contracts in the US.
      - Transacting other insurance business functions in the US.
Step 2: Register with Medicare

- **Who to report to?**
  - Because of the huge volume of data transmitted, Medicare has engaged the Coordination of Benefits Contractor (COBC) to manage the technical aspects of Section 111 reporting obligations
  - RREs transmit information electronically to Medicare COBC

- **How to register with COBC?**
  - RREs must register on the Section 111 COB secure website ("COBSW") (regardless of whether an agent will be submitting data on the RRE’s behalf)
  - To begin the registration process, go to [http://www.section111.cms.hhs.gov](http://www.section111.cms.hhs.gov). Enter the required data and submit your registration. Once you have registered and completed your account setup you become a RRE
  - For more information please see the “How to get started” document: [http://www.section111.cms.hhs.gov/MRA/help/how to/GetStarted.htm](http://www.section111.cms.hhs.gov/MRA/help/how to/GetStarted.htm)

- **If you anticipate that you may be paying for medical expenses from injuries or complications, we suggest registering now**
  - Coordinate with your legal or finance department (for personal injury lawsuits or other claims)
Step 3: Develop/implement internal processes

- Implement a procedure to review requests to pay for medical expenses for complications or injuries
  - From the study subject, or
  - From the study site
- Collect all information and data to determine if the Sponsor is responsible for payment (review the clinical trial agreement and the informed consent)
- Collect additional information from the site to that is necessary to determine if you need to report:
  - Name, state of residence, gender, DOB, SSN, date of incident, amount of claim
  - Description of complication or injury (including the “codes”)
  - Has the medical bill(s) been submitted to Medicare or paid already?
- Determine whether the injured party is a Medicare beneficiary
  - People age 65 or older
  - People of any age who have certain designated disabilities
  - People of any age who have End-Stage Renal Disease
- If yes, report payments or responsibility payments in a timely manner
- Establish a process for managing the long-term obligations
  - (ORM)
Step 4: Is the injured party a Medicare beneficiary?

- Medicare provides *registered* reporting entities with a *query process* to determine the Medicare status of the injured party prior to reporting
  - All Medicare beneficiaries are assigned an ID which is known as the Medicare “HICN” (and is derived from the individual SSN). It is preferable to submit both to ensure a match in the system
  - The query must indicate the study subject’s SSN (or HICN), name, DOB and gender
- **What about HIPAA?** Exception to the privacy rule when disclosure of protected health information is required by law (45 CFR 164.512(a) of the Rule)
Step 4: Is the injured party a Medicare beneficiary?

• The query process should be used systematically to determine whether any injured study patient is a Medicare beneficiary.

• To avoid lengthy delays, it is advisable to start investigating an injured party’s Medicare status as soon as a questionable claim arises.

• For more information on the query procedure, please refer to Section 13 of the NGHP User Guide.
Step 4: Is the injured party a Medicare beneficiary?

- If the injured party was not a Medicare beneficiary at the time the Sponsor assumed ORM for future medical care, the Sponsor must continue to monitor the injured party’s status when it pays for future medical expenses as the study subject may become a Medicare beneficiary in the future.
- If the injured party becomes a Medicare beneficiary, any ORM or payment of a claim must be reported to Medicare.
Step 5: Report

- **How? Reporting methods:** Information can be exchanged with COBC using any one of 4 methods (the first 3 involve transmission of electronic files):
  - HTTPS (internet) (for RREs sending less than 24,000 claims/year)
  - SFTP (Secure File Transfer Protocol) (for large claims amounts)
  - Connect: Direct (Medicare Extranet Network and Medicare’s private CMSNet) (for very large claims amounts)
  - **Direct Data Entry (“DDE”)** (interactive application) – simplest way to report. RRE manually keys claim information into pages (screens) on the Section 111 website. Recommended if less than 500 claims/year will be reported.

- For more information, please refer to Section 15, Electronic Data Exchange in the NGHP User Guide
Step 5: Report

• When did reporting obligations start?
  – ORM date on or after October 1, 2010: quarterly reporting started April 1, 2011
  – TPOC dates made on or after October 1, 2011: quarterly reporting started April 1, 2012 (for payments over $100,000)

• Reporting timeframe:
  – RREs submitting electronic files must submit new or changed information on a *quarterly basis during the RREs assigned 7-day file submission timeframe*
  – RREs using DDE must submit claim information one claim report at a time as soon as the conditions related to the claim require reporting under Section 111 (i.e. within 45 calendar days of the TPOC date)
Step 5: Report

- **Required data includes:**
  - RREs must identify the trigger date:
    - ORM: date on which the responsibility for payment began and the date on which the responsibility for payment ended
    - TPOC date and amount
  - Identity of the injured party (SSN/HICN, first letter of their first name, first six letters of their last name, DOB and gender)
  - RRE TIN
  - RRE address information
  - ICD-9 Diagnosis codes
  - External Cause of Injury Code ("E" Code)

- For more information on data required please see Appendix A and Appendix B in the NGHP User Guide
Step 5: Report (penalties)

- **Penalties = $1,000 for each day of non-compliance for each injured party**
  - For RREs with quarterly reporting schedules, 90 days may pass before the next window is provided to report a missed claim. This would cost the RRE $90,000 per claim
- No directives or guidance have been released as of this time with respect to implementation of the penalty provisions
- Medicare has given verbal assurances that, at this stage, the focus should be on building a proper Section 111 compliance program rather than imposing penalties
- However, the statute states that the penalty *shall* be assessed upon failure to report, not that Medicare *may* impose it upon said failure. In the event of late reporting, Medicare does not seem to have any discretion as to whether to impose the penalty or to waive/compromise the amount due. Further, keep in mind that those penalties will support the Health Insurance trust fund and could make a meaningful difference in the longevity of the Medicare program
Challenges

• Only submit ICD-9 Diagnosis Codes and External Cause of Injury Codes that describe the injury or illness
  • Link the code to the injury/complication not the underlying medical disease/condition
  • E.g. providers may submit claims with ancillary ICD-9 codes like hypertension or depression. If you do not assume ORM for hypertension or depression, do not submit that ICD-9 code on your Section 111 report

• Responsible vs. Goodwill
  • Section 111 will apply without regard to whether a study subject has filed or threatened to file a claim against the Sponsor e.g. even if the Sponsor simply has made a voluntary payment

• Make a thoughtful decision as to when to pay for medical expenses
  • Once the Sponsor pays for an injury, all future expenses may be the Sponsor’s responsibility

• Who to pay if Medicare has already paid the site?

• Seek legal advice when in doubt
Resources

• MMSEA Section 111 Mandatory Insurer Reporting Website: http://www.cms.gov/mandatoryinsrep. The updated User Guide and Alerts can be found on this website under the “NGHP” tab

• Free computer-based training courses
  – To register send an e-mail to Section111CBT@EHMedicare.com and specify that you are requesting the NGHP curriculum and include your company name and the name, phone number and e-mail address for the individuals you would like to register
  – Once COBC has processed the request, a confirmation email containing the URL for the NGHP curriculum will be sent to each individual
Resources

• **Medicare conduct town hall conferences with Q&A**
  – Sporadic, none currently scheduled
  – The transcripts of previous town hall conferences are available on Medicare website

• **EDI representative**
  – All registered RREs are assigned their own EDI representative to assist them in managing all aspects of the Section 111 reporting process

• **Codes are available at:**
  – Both ICD-9 Diagnosis Codes and “E” Codes on same list
    • Alleged cause of injury = External Cause of Injury Code (“E” Code)
    • Diagnosis Code describing the alleged injury/illness = ICD-9 Code (multiple)
Start Reporting!

RCRI can help your organization:

• Develop internal written processes and flow charts to collect information
• Develop decision trees on when to pay for injuries and complications
• Guide you through the process
Your RCRI contacts

Mandy Klosterman, JD
Vice President of Regulatory Sciences and Legal Services
Senior Principal Advisor
(952) 224-2259
mklosterman@rcri-inc.com

Claire Zeiger,
Contracts Manager
(952) 224-3390
czeiger@rcri-inc.com