

Presenting a live 90-minute webinar with interactive Q&A

Clinical Trials and Medicare Secondary Payer Rules: Best Practices for Compliance

Navigating Complex MSP Rules and Reporting Requirements
for Research Sponsors and Clinical Sites, and Structuring Agreements

TUESDAY, OCTOBER 29, 2013

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

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Medicare Secondary Payer Rules: Clinical Trials

Strafford Webinar

October 29, 2013

ROPES
& GRAY

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Context

- Sponsor and clinical site generally seek to ensure that subjects receive care for research-related injuries in clinical trials **and** that responsibility for that care is allocated in advance
 - Financial exposure of sponsors, clinical site and subjects is minimized
- Clinical trial agreement and informed consent form are means to allocate responsibility for care
 - No legal obligation for sponsor to pay for care (outside of common law torts)
 - Various legal and ethical standards require that investigator/clinical site provide care and subjects be informed about potential exposure for research-related injury
 - Clinical sites/subjects reluctant to participate in clinical trial if exposure for research-related injury
- Common contractual approach historically was for sponsor to agree to pay for care for research-related injury **to the extent not covered by** subject's health insurance

Context

- Medicare secondary payer (MSP) rules potentially “disrupt” contractual allocation of responsibility for research-related injury
 - MSP rules prevent implementation of common “payer of last resort” or “gap-filling” provisions addressing sponsor coverage for research-related injury as intended by parties
- Sponsors and clinical sites need to understand how MSP rules apply in clinical trial context to adopt effective strategies for allocating coverage responsibility
- Unclear law and guidance create challenges for implementation
- (New MSP reporting obligations discussed separately)

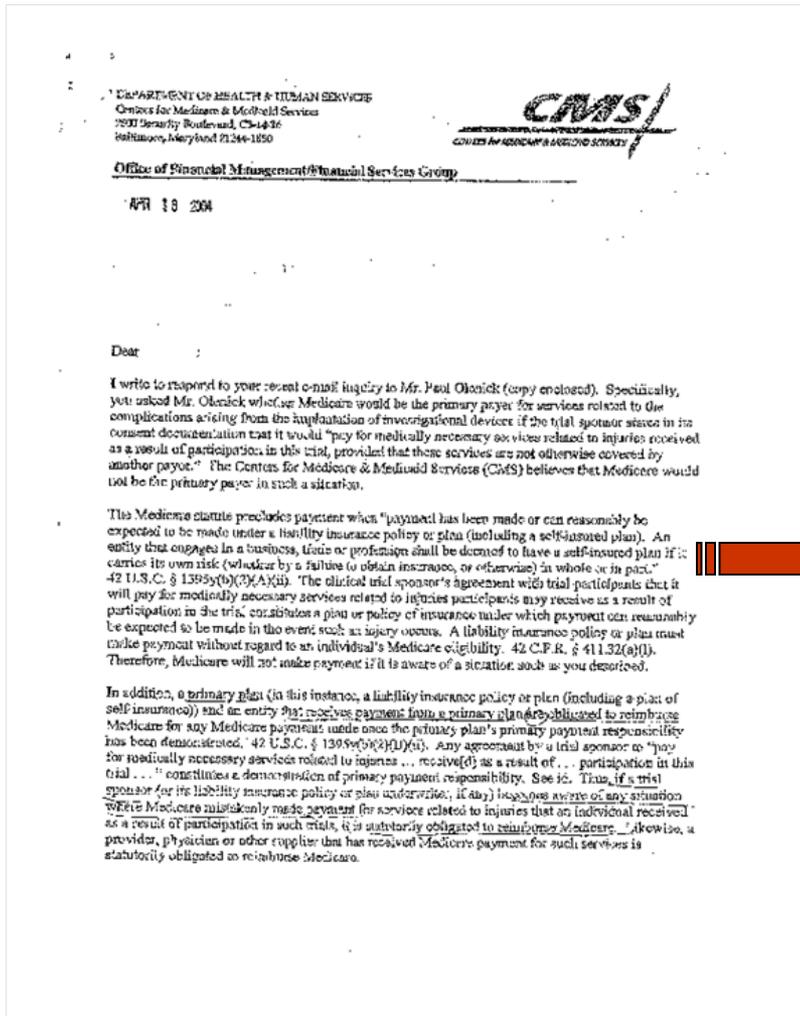
MSP Coordination of Benefit Requirements

- MSP rules mandate certain coordination of benefits between Medicare and other health insurers or third party payers
- MSP rules apply when both Medicare and another payer are responsible for payment of diagnosis or treatment
- MSP rules generally prohibit Medicare payment for a health care service if “payment has been made, or can reasonably be expected to be made under a . . . liability insurance policy or plan (including a self-insured plan)” (42 U.S.C. §1395y(2)(a)(ii))
 - If another party has responsibility for the payment, then the other party must generally be billed before Medicare
 - Medicare will only pay as a secondary payor
- Medicare can collect mistaken primary payments from patient, provider or other responsible third party payer

MSP Coordination of Benefit Requirements

- MSP rules apply to promises by a research sponsor to pay for subject injuries because the Centers for Medicare & Medicaid Services (CMS) takes the position that a research sponsor making such a promise is a liability insurer subject to the MSP rules
 - Guidance from 2004 and 2010
- **Bottom-Line:** Research sponsors making a promise to pay for research-related injuries must pay before Medicare for subject injuries ***even if*** sponsor says will pay only to the extent that payment not available from other payers

MSP Coordination of Benefit Requirements



The Medicare statute precludes payment when "payment has been made or can reasonably be expected to be made under a liability insurance policy or plan (including a self-insured plan). An entity that engages in a business, trade or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part." 42 U.S.C. § 1395(b)(2)(A)(ii). The clinical trial sponsor's agreement with trial participants that it will pay for medically necessary services related to injuries participants may receive as a result of participation in the trial constitutes a plan or policy of insurance under which payment can reasonably be expected to be made in the event such an injury occurs. A liability insurance policy or plan must make payment without regard to an individual's Medicare eligibility. 42 C.F.R. § 411.32(a)(1). Therefore, Medicare will not make payment if it is aware of a situation such as you described.

MSP Coordination of Benefit Requirements

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While your e-mail to Mr. Olenick was phrased as a hypothetical question, we urge you to advise any of your clients that may have failed to make primary payments for services related to injuries sustained by Medicare beneficiaries in the course of their participation in clinical trials that CMS is willing to work with them to resolve their repayment obligations with minimal inconvenience to participants and their health care providers.

We appreciate your efforts in bringing this matter to our attention. If you wish to discuss this matter further, you may call Tina Merrill on (410) 786-5232.

Sincerely,



Gerald Walters
Director
Financial Services Group
Office of Financial Management

Enclosure

cc:
All Regional Administrators
All Associate Regional Administrators for
Financial Management
All Regional MSP Coordinators



While your e-mail to Mr. Olenick was phrased as a hypothetical question, we urge you to advise any of your clients that may have failed to make primary payments for services related to injuries sustained by Medicare beneficiaries in the course of their participation in clinical trials that CMS is willing to work with them to resolve their payment obligations with minimal inconvenience to participants and their health care providers.

MSP Coordination of Benefit Requirements

- CMS issued guidance in 2010 confirming the position in 2004 letter in connection with implementation of new MSP reporting requirements (discussed below)
- Centers for Medicare & Medicaid Services (CMS) clinical trials alert (May 26, 2010)

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. . . .

Sidenote: Other Medicare Substantive Principles

- No Legal Obligation to Pay Principle (Medicare Benefit Policy Manual, Ch. 16, §40)
 - Medicare does not cover items or services “for which the individual furnished such items or services has no legal obligation to pay, and which no other person . . . has a legal obligation to provide or pay for”
 - Payment exclusion “applies where items and services are furnished gratuitously without regard to the beneficiary’s ability to pay and without expectation of payment from any source”
 - Not historically considered to apply to research-related injuries subject to sponsor promise to pay because sponsor was another source of payment that assumed the legal obligation to pay
 - CMS guidance even acknowledged situation in which research subjects’ insurance was billed for covered care and other care provided without cost

Sidenote: Other Medicare Substantive Principles

- CMS Medicare Learning Network Matters 2008 transmittal to providers sought to clarify application of the “no legal obligation to pay” principle to clinical trials (MLN Matters SE0822)

Question: *If a research sponsor says in writing that they will pay for routine costs if there is no reimbursement from any insurance company (including Medicare), does that fall into the “free of charge” category?*

Answer: *If the routine costs of the clinical trial are furnished gratuitously (i.e., without regard to the beneficiary’s ability to pay and without expectation of payment from any other source), then Medicare payment cannot be made and the beneficiary cannot be charged. If private insurers deny the routine costs and the provider of services does not pursue the non-Medicare patients for payment after the denials (even though the non-Medicare patient has the ability to pay), Medicare payment cannot be made and the beneficiary cannot be charged for the routine costs.*

- Q&A guidance subsequently withdrawn by CMS without explanation creating uncertainty regarding CMS current position

Responses to MSP Requirements

- No perfect response
 - No alternative ensures full coverage of subject injuries while minimizing financial exposure of sponsor, clinical site and subject
- Unclear guidance creates uncertainty
 - Medicare v. other government payers
- Most appropriate response may depend on facts and circumstances surrounding clinical trial
 - Respective leverage of sponsor and clinical site
 - Likelihood of injury/seriousness of injury
 - Likely subject population

Responses to MSP Requirements

- Full Coverage
 - Sponsor agrees to pay for **all** research-related injury costs
 - MSP coordination of benefit rules not implicated because sponsor is only responsible payer
 - Greatest assurance of coverage for clinical site/subject but greatest financial exposure for sponsor
- No Coverage
 - Sponsor does **not** agree to pay for **any** research-related injury costs
 - MSP coordination of benefit rules not implicated because sponsor is not a potential payer
 - Clinical site/subject rely upon Medicare and other health insurance for coverage
 - No coverage for uninsured

Responses to MSP Requirements

- Full Coverage Hybrid
 - Sponsor agrees to pay for: (1) **all** research-related injury costs for subjects covered under Medicare and other government programs and (2) research-related injury costs for other subjects **only to the extent such costs are not covered by insurance**
 - MSP coordination of benefit rules not implicated because sponsor is only responsible payer for **Medicare** patients
- No Coverage Hybrid
 - Sponsor: (1) does not agree to pay for **any** research-related injury costs for subjects covered under Medicare and other government programs, and (2) does agree to pay for research-related injury costs for other subjects **to the extent the costs are not covered by insurance**
 - MSP coordination of benefit rules not implicated because sponsor is not a potential payer for **Medicare** patients
 - No legal obligation to pay concerns?
 - Medicare non-discrimination concerns?

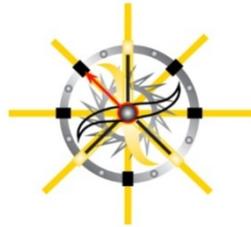
Responses to MSP Requirements

- Case-by-Case Coverage Consideration
 - Sponsor agrees only to **consider** payment of research-related injuries on a case-by-case basis
 - MSP rules arguably not implicated because sponsor does not promise to pay only promises to consider payment
 - Uncertainty for clinical site/subject
- Traditional “Payer of Last Resort” Language
 - Sponsor agrees to pay for research-related injury costs for all subjects to the extent the costs are not covered by insurance
 - Approach that historically raised MSP concerns
 - MSP rules implicated **unless** interpretation is that costs not covered under Medicare because of sponsor promise to pay
 - Parties may agree to language with expectation that open to interpretation
 - Defers coverage dispute until injury occurs

Medicare Secondary Payer Reporting



Medicare, Medicaid, and SCHIP Extension Act of 2007 Medicare Secondary Payer Reporting



David Piatt

Former Medicare Secondary Payer Recovery Contractor
(MSPRC) Program Director

Medicare Secondary Payer Compliance & Services



Medicare Secondary Payer Reporting



Medicare, Medicaid, and SCHIP Extension Act of 2007

– A law with many names: MMSEA, Section 111, Mandatory Insurer Reporting etc

- Section 111 [42 U.S.C. 1395y(b)(7)&(b)(8) - [PL 110-173]
 - Imposes reporting requirements upon Group Health Plans (GHP), liability insurance plans [including self-insurance], no-fault insurance plans and workers' compensation plans or laws:
- 1395y(b)(7) GHP plans
- 1395y(b)(8) Non-GHP plans
 - Liability
 - No-Fault
 - Workers' Compensation
- Provides reporting requirements and civil penalties of \$1000 per day per beneficiary if reporting requirements are not met for each entity for which the information should have been submitted



Medicare Secondary Payer Reporting



Highlights of Reporting

- Who has to Report?
 - Responsible Reporting Entities -- Sponsors of clinical trials
- What do they have to Report?
 - Information identifying the beneficiary
 - When they assume responsibility for the care of the Medicare beneficiary
 - Which injuries they are responsible to cover
 - When they terminate their assumption of care
- When do they have to Report?
 - Once per quarter for situations arising in the previous quarter



Medicare Secondary Payer Reporting

- Key Points

- 42 U.S.C. 1395y(b)(8) mandatory reporting applies to Sponsors of Drug and Device trials
- Sponsor's are required to report research related injuries
- Sponsors are required to report their assumption for medical payments within the quarter in which they are assumed or face significant fines.
 - The trigger for reporting ORM [Ongoing Responsibility for Medicals] is the assumption of ORM by the RRE [Sponsor]. Medical payments do not actually have to be paid for ORM reporting to be required” -- User Guide V4.0
- Sec. 1862. [42 U.S.C. 1395y](b) Medicare as Secondary Payer applies to insurers [sponsors] not providers
 - Reimbursements and Double Damages



Medicare Secondary Payer Reporting

- Definitions

- The Responsible Reporting Entity (RRE) is a plan / entity that is primary to Medicare and the entity required to file quarterly reports
- Non-Group Health Plans (NGHP) -- Workers' Compensation, Liability and No-Fault Plans
- Law establishes an ongoing requirement to report when another plan is responsible for "Ongoing Responsibility for Medicals" (ORM) generally arising from a contract

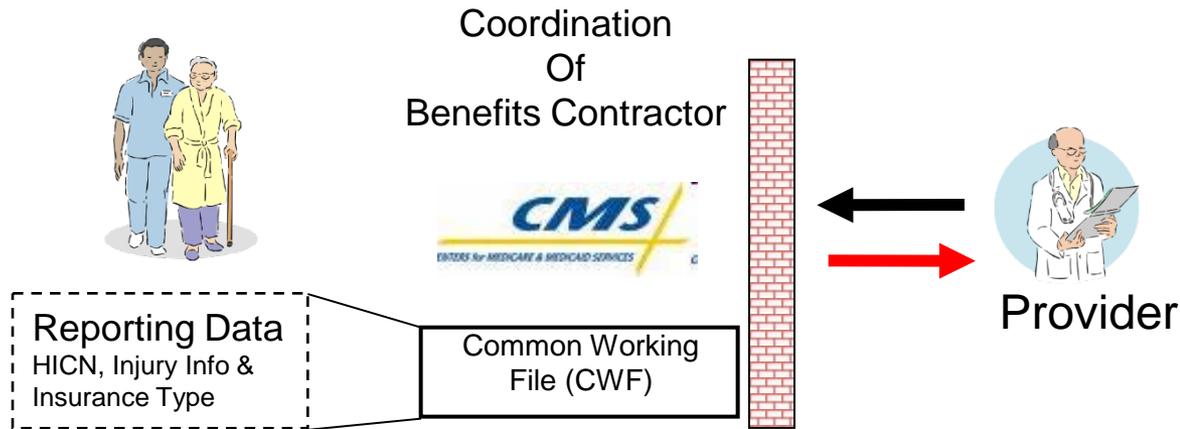
- The Clinical Trial Sites

- Sites are NOT at risk of reporting fines
- In double-blind testing, Sponsors need cooperation from Sites to comply
 - Provide the information required to determine enrollment
 - Gender, Name, DOB and SSN
- Sponsor reporting will improve site Medicare billing compliance
- Sponsors will reimburse Medicare for overpayments



Medicare Secondary Payer Reporting

- The Goal behind Reporting
- Deny payment as soon as possible when another plan is primary
- Coordination of Benefits is cheaper, and saves 3 times as much, as Recovery



- Deny payment to providers not involved in the trial (e.g. Health Clinic, Primary Care Physician etc)
- Deny payments mistakenly billed by site to Medicare (e.g., minimize site's risk of overpayment)



Medicare Secondary Payer Reporting

Implementing Reporting

The MSP Law -- Sec. 1862. [42 U.S.C. 1395y]



42 C.F.R. PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

- 1395y(b)(8)(A)(ii) ... submit the information ... in a form and manner (including frequency) specified by the Secretary.



←
Group Health Plan User Guide

→
Non- GHP User Guide



Medicare Secondary Payer Reporting



Clinical Trials Reporting

- User Guide Requirement

- “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)” -- *NGHP User Guide version 4.0 dated 7 October 2013 COBR-Q4-2013-V4.0*
- First published as an Alert in 2010 and incorporated in version 3.2 (August 2011) and subsequent versions



Medicare Secondary Payer Reporting

- Clinical Trial Agreement & Informed Consent as Liability Insurance
 - ““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.”
 - Contract not Tort
 - Liability arising from legal responsibility, duty or obligation
 - Sponsor’s commitment at the outset of a clinical trial to pay the cost of medical care provided by the site to according to the terms of the contract.
 - Similar contractual agreements
 - Group Health Plans
 - Medicare will not pay for medical claims covered by the plan
 - Workers’ Compensation
 - Medicare will not pay for injuries arising from employment (State Statutes)



Medicare Secondary Payer Reporting



Clinical Trials Reporting

- User Guide Requirement

- “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)**” -- *NGHP User Guide version 4.0 dated 7 October 2013 COBR-Q4-2013-V4.0*



Medicare Secondary Payer Reporting

- Reporting ORM is not when a Payment is made
 - “The situation should also be reported as one involving Ongoing Responsibility for Medicals (ORM)”
 - “Payment” is prima facie evidence of a plan, not the trigger for reporting
 - “The trigger for reporting ORM is the assumption of ORM by the RRE – ... not when (or after) the first payment for medicals under ORM has actually been made. Medical payments do not actually have to be paid for ORM reporting to be required” User Guide V4.0
 - “A physical cash payment is not required to accept ORM in general. What we’ve tried to say is where ORMs has been accepted ... by virtue of the sponsors’ initial agreement and an injury or complication occurs, that should then be reported as ORM.” Barbara Wright, CMS Teleconference -- 22 March 2012



Medicare Secondary Payer Reporting

- Reporting
 - WHO -- Sponsors of Drug and Device Trials
 - WHAT -- Research related injuries
 - WHEN -- Quarterly for injuries arising in the previous quarter
 - HOW
 - Know which test subjects need to be reported to Medicare
 - Monitor the related AEs and SAEs reported by the sites
 - Adjudicate claims to assess your responsibility



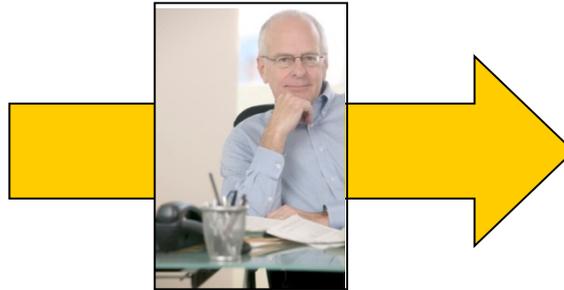
Medicare Secondary Payer Reporting

Mechanics of Reporting

Medicare Secondary Payer Reporting



Responsible Reporting Entities



Medicare

Who is Reported?

Enrolled Medicare beneficiaries, include citizens 65 years of age or older

End Stage Renal Disease (ESRD) Medicare recipients of any age

People under the age of 65 that are enrolled in Medicare because of certain disabilities

Deceased beneficiary if the individual was deceased at the time of the settlement, judgment, award or other payment



Medicare Secondary Payer Reporting

- Statute applies to enrolled Medicare Beneficiaries
 - First Step -- Which test subjects are beneficiaries?
 - 1395y(b)(8)(A)(i) “determine whether a claimant [test subject] (including an individual whose claim is unresolved) is entitled to benefits under the program under this title on any basis;”
 - Reporting imposes a duty on the RRE to conduct an investigation into enrollment.
 - Medicare provides a tool to determine enrollment, but requires personal information about test subject (e.g., SSN)
 - To maintain double blind, sites provide patient identifying information to Reporting Agent
 - Sponsors do not consider themselves “Health Plans”
 - **No** HIPAA requirements (no names) = **No** Business Agreements
 - Reporting Agents are generally HIPAA Covered Entities (e.g., Health Care Clearinghouses)
 - Reporting Agent gathers PRIVACY DATA not HIPAA from clinical sites to determine enrollment



Medicare Secondary Payer Reporting

- CMS recognizes that requesting an SSN is unusual but required
 - The Medicare Secondary Payer Mandatory Reporting Provisions in Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007 (the MMSEA) (See 42 U.S.C. 1395y(b)(7)&(b)(8)) -- ALERT dated 24 August 2009
 - “Claimants should routinely cooperate in furnishing either their HICN (or SSN if they do not have a HICN available) as requested.”
 - Collection of Medicare Health Insurance Claim Numbers (HICNs), Social Security Numbers (SSNs) and Employer Identification Numbers (EINs) (Tax Identification Numbers) – ALERT dated 06 April 2010
 - “This ALERT is to advise that collection of HICNs, SSNs, or EINs for purposes of compliance with the reporting requirements under Section 111 of Public Law 100-173 is appropriate.”
 - Federal Courts can compel collection of data (Seger v Tank Connection Nebraska District Court)
- *Compliance Officers can find official guidance*
- *Sites should feel comfortable providing SSNs etc*



Medicare Secondary Payer Reporting

What is Reported?



Injured Beneficiary

First Name

Last Name

Gender

DOB

SSN / HICN

- Reporting imposes a duty on the RRE to conduct an investigation into enrollment.
- CMS provides “Query Function” for cases where enrollment is questionable.
 - Requires a Social Security Number
 - Use of the tool does not create a “safe harbor” if information provided by CMS was later proven wrong.
- The claimant can be compelled to provide their SSN or HICN by the RRE
 - In *Seger v Tank Connection* the Nebraska District Court compelled the plaintiff to provide their SSN and HICN to the insurer
- Last Resort -- CMS “model letter” if the claimant refuses requests to provide the information



Medicare Secondary Payer Reporting

What is Reported?



Nature of Injury

Date of Incident

State of venue

ICD 09 Codes

- Injury information
 - Only cases involving medical claims are reported
 - Date of Incident is used as the point in time when Medicare became secondary
 - State of Venue for recovery purposes
 - ICD 09 Codes are used to describe the type of incident, the body parts and the nature of the injury to the body part



Medicare Secondary Payer Reporting

What is Reported?



Payment

ORM

Termination date

- The assumption (Y or N) and termination of liability for the medical expenses that would otherwise be borne by Medicare (Ongoing Responsibility for Medicals or ORM)



Medicare Secondary Payer Reporting

- Accepting ORM
 - KEY POINT: **The “Date of Incident” and ORM Termination Date mark the periods of acceptance of ORM**
- User Guide Requirement
 - “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)” -- *NGHP User Guide version 4.0 dated 7 October 2013 COBR-Q4-2013-V4.0*



Medicare Secondary Payer Reporting

- Terminating ORM
 - “If the ORM is subject to reopening or otherwise subject to a further request for payment, the record submitted for ORM should remain open.” User Guide 4.0
- Sponsors can change their mind
 - “Reporting for ORM is not a guarantee by the RRE that ongoing medicals will be paid indefinitely or through a particular date; it is simply a report reflecting the responsibility currently assumed.” User Guide 4.0
 - After unblinding
 - Terminate ORM or delete test subject records that took placebo
 - Adjust reporting to match reportable AEs and SAEs



Medicare Secondary Payer Reporting

- Best Practices

- Avoid compliance flags -- reports must be filed within a quarter of assumption
 - Determine which test subjects are enrolled up front because that can take a quarter in itself
 - Waiting on reports of related AEs and SAEs before determining enrollment adds cost and confusion to the process
- Adjudicate claims according to Clinical Trial Agreement,
 - Eliminate
 - Events arising site negligence or violation of protocol
 - Natural progression of existing condition
 - Other unrelated events
 - DO NOT put your site's in a position to adjudicate them for you by awaiting a request for payment
- Monitor your “ongoing responsibility for medicals” by monitoring your clinical trials reports



Medicare Secondary Payer Reporting

MSP & Reporting

Medicare Secondary Payer Reporting



Medicare Secondary Payer

– Accepting Ongoing Responsibility for Medicals (ORM)

- Sec. 1862. [42 U.S.C. 1395y] -- Medicare Secondary Payer
 - Medicare has a direct right of action to recover a payment made by an insurer / self-insured entity
 - A Medicare beneficiary has a direct right of action to recover from a plan that has accepted “ongoing responsibility for medicals”
 - If the plan fails to pay within 120 days, Medicare may pay conditioned upon reimbursement
 - Double damages
 - Medicare may subrogate the beneficiary’s direct right of action
 - Medicare’s right is an independent right
 - Double damages



Medicare Secondary Payer Reporting

- Impact to Sponsors
 - Many test subjects are enrolled in Medicare
 - The Medicare Secondary Payer statute applies to any liability payment or acceptance of ongoing responsibility since December 05 1980.
 - CMS could assert a claim for reimbursement back to 1980
 - If they have to take legal action, the sponsor may pay double damages
 - Stricker et al v Sebelius -- It all began with failing to report
 - Getting a Pass -- Reporting Rules only require that situations that were active 1 January 2010 and those subsequently assumed have to be reported.
 - Sponsors may receive demands for reimbursement from “mistaken” payments made over the period of time they accepted ORM



Medicare Secondary Payer Reporting

- Overall Impact to Sites
 - Downside
 - Modification of test subject intake processes to collect SSN
 - More caution required to avoid overpayments and False Claim Act
 - Upside
 - Reporting will ease the need to deal with overpayments
 - Medicare will deny payments
 - Medicare will send bill for mistaken payments to the sponsor
 - Help your client (sponsor) avoid fines



Medicare Secondary Payer Reporting

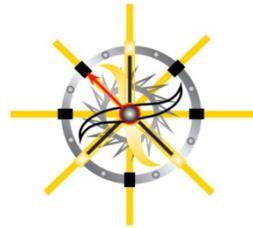
- Key Points

- Deadline has passed -- 1 January 2010
- Sponsors are required to report assumption of Ongoing Responsibility for Medicals -- not when a payment is made.
 - According the terms of their contracts
- Sec. 1862. [42 U.S.C. 1395y](b) Medicare as Secondary Payer applies to sponsors of trials not providers
 - Reporting, Reimbursements and Double Damages
- In double-blind testing, Sponsors need cooperation from Sites to comply
 - Provide information required to determine enrollment
 - Gender, Name, DOB and SSN
- Sponsor reporting will improve Site Medicare compliance
- Sponsors will reimburse Medicare for overpayments



Medicare Secondary Payer Reporting

Thank You



David Piatt

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Medicare Secondary Payer Compliance & Services