Dealing with the Medicare Secondary Payer Rule in the Context of Research Billing

Health Care Compliance Association’s Compliance Institute
April 26-29, 2009

Ramy Fayed, Esq.
Sonnenschein Nath & Rosenthal LLP
1301 K Street N.W.
Suite 600, East Tower
Washington, D.C. 20005
(202) 408-6193
rfayed@sonnenschein.com

William H. Wallace, Jr., JD
Compliance Officer
University of Tennessee
Graduate School of Medicine
1924 Alcoa Hwy., U_94
Knoxville, TN
(865) 305-6192
wwallace@mc.utmck.edu

“There’s really no need for confusion with this Medicare stuff. Page 95, section 33, paragraph L clearly in the instructions quite clearly explains...”
Topics for Discussion

- Overview of Key Elements of MSP Laws as Groundwork for Additional Discussion
- Recent developments (legislative, regulatory and case law)
- Promise to Pay & MSP Liability
- Practical Application

Overview of the MSP Laws
Overview

- Under the MSP laws, Medicare is the secondary payer in specified instances of dual health care coverage.
- The MSP Laws govern coordination of benefits when payment has been made or can reasonably be expected under:
  - A Group Health Plan (“GHP”);  
  - Workers’ Compensation law or plan;  
  - Automobile or Liability Insurance policy or plan (including a self-insured plan); and  
  - No-Fault Insurance.

MSP Authority

- MSP Laws
  - Social Security Act Section 1862(b) (42 U.S.C. § 1395y(b))
    - SCHIP Extension Act of 2007
  - 42 C.F.R. 411, Subparts B through H
    - Final Rule (February 22, 2008)
- MSP Guidance
    - Specific provider billing rules under MSP laws detailed in MSP Manual, Ch. 3
  - Other publications and materials posted on CMS website and disseminated to providers, employers and others.
Overview of MSP Laws: Group Health Plans

- In the GHP context, the rules governing coordination of benefits with Medicare are complex and depend on:
  - Whether an individual’s Medicare entitlement/eligibility is based on:
    - Age;
    - Disability; or
    - ESRD.
  - Employer size
  - Employment status

Overview of MSP Laws: Workers’ Compensation

- Medicare payment may not be made for items and services to the extent that payment has been made or can reasonably be expected to be made under a WC law or plan of the U.S. or a state.
- Applies to WC laws or plans of all states, the District of Columbia, American Samoa, Puerto Rico, Guam, and the Virgin Islands.
- Federal WC plans include (but are not limited to) those provided under:
  - Federal Employees’ Compensation Act;
  - Longshore and Harbor Workers’ Compensation Act; and
  - Federal Black Lung Benefits Program.
Overview of MSP Laws: Liability Insurance

- Medicare is secondary to any liability insurance plan that is required or responsible to pay based on “legal liability for injury or illness or damage to property.” 42 C.F.R. § 411.50.
- Examples include:
  - Homeowners’ insurance;
  - Malpractice insurance; and
  - Product liability insurance.
- An entity that engages in a business, trade, or profession that has not purchased liability insurance may be considered to be self-insured for liability purposes if it “carries its own risk.”

Overview of MSP Laws: No-Fault Insurance

- Medicare is secondary to any no-fault insurance where there is a demonstrated responsibility to pay for the item or service, including under automobile no-fault insurance.
- No-fault insurance provides payment for medical expenses for injuries sustained:
  - on the property or premises of the insured, or
  - in the use, occupancy, or operation of an automobile regardless of who may be responsible for causing the accident.
Helpful Information

The following websites provide general information and resources related to MSP.

- Centers for Medicare and Medicaid Services. General information on MSP. www.cms.hhs.gov/COBGeneralInformation/
- Medlearn computer based education and training programs. Includes information on the MSP program. http://www.cms.hhs.gov/MLNProducts/03_WebBasedTraining.asp#TopOfPage

Recent Developments
**Recent Developments**

- **SCHIP Extension Act of 2007**
  - Imposed significant new data collection and reporting requirements on:
    - Insurers, TPAs, and plan administrators or fiduciaries of GHPs that are self-insured or self administered; and
    - Liability insurance plans, no-fault insurance plans and WC laws and plans.
  - Final Rule published February 22, 2008 (similar to Interim Final Rule)
    - Implemented MMA amendments, including:
      - Modification of “self-insured” plan definition;
      - Clarification of reimbursement obligations of primary plans and entities receiving payment from primary plans (e.g., providers); and
      - Modified Section 411.25 notice requirements.

---

**The New Reporting Requirements**

- Summary of new MSP provision on required submission of information (42 U.S.C. § 1395y(b)(8))
  - Applies to liability insurance plans (including self-insured plans), no-fault insurance plans, and WC laws or plans.
  - On or after July 1, 2009, must:
    - Determine whether a “claimant” (including an individual whose claim is unresolved) is entitled to Medicare;
    - If the claimant is a Medicare beneficiary, submit information with respect to claimant in the manner, form and frequency dictated by the Secretary.
    - Required information shall include: (1) identify of the claimant who is a Medicare beneficiary; and (2) such other information as the Secretary may require for COB determination purposes.
The New Reporting Requirements

- Information shall be submitted within a time period specified by the Secretary “after the claim is resolved through settlement, judgment, award or other payment.”
- “Claimant” is (1) a person who files a claim directly against the applicable plan; and (2) a person who files a claim against an individual or entity insured or covered by the applicable plan.
  - Arguably does not apply in the clinical trial context.
- CMPs of $1,000 for each day of non-compliance for each claimant.
- The Secretary may implement this provision “by program instruction or otherwise.” This means no notice and comment rulemaking required.

Promise to Pay & MSP Liability
Does a Voluntary Promise to Pay Trigger MSP Liability?

- 2004 correspondence to CMS requesting confirmation that Medicare is primary payer for costs related to complications arising from a clinical study regarding implantation of an investigational device.
- Hypothetical Sponsor promise to pay in informed consent documentation:
  - Sponsor will “pay for medically necessary services related to injuries received as a result of participation in [the] trial provided that these services are not otherwise covered by another payer.”

CMS Rationale

- Sponsor promise = liability insurance policy or plan
  - CMS asserts the clinical trial sponsor’s agreement with trial participants that it will pay for medical services associated with research related injuries constitutes an “insurance policy or plan.”
- Sponsor’s “agreement to pay for RRI = De facto “demonstration” of Sponsor’s responsibility to pay
  - CMS asserts that the promise to pay in and of itself meets the demonstrated responsibility to pay test.

In April 2004 letter, CMS takes the position that Medicare is NOT the primary payer in this context.
Does a Voluntary Promise to Pay Trigger MSP Liability?

Implications, per CMS

☐ A liability insurance plan must make payment without regard to Medicare (i.e., be primary).

☐ If Medicare is aware of the promise, it will not make conditional payment.

☐ If Sponsor, provider, physician or other supplier becomes aware of any situation where Medicare mistakenly makes payment for research related injuries under such an agreement, it is statutorily required to reimburse Medicare.

☐ Potential new notice requirements – with CMPs – trigger additional Sponsor concerns.
Summary of Rebuttal

- A sponsor is required to pay primary to Medicare if the sponsor has (1) “demonstrated” responsibility to pay for the item or service, (2) under a “primary plan” (i.e., a liability insurance policy or plan (including a self-insurance plan)).
  - Examples:
    - Trial participant successfully sues a self-insured Sponsor under a negligence theory and receives a damages award.
- Both a “liability plan” and “demonstrated responsibility” turn on whether there is liability at issue. A promise to pay for research-related injuries, in and of itself, does not suffice to create “liability” as that term has been defined by courts.
- Indeed, a promise to pay may be made to further ethical principles of research and not to discharge a liability.
- In short, a “promise to pay,” even in an informed consent document, does not create MSP payment obligations.

CMS’ Position and Rebuttal

- CMS: A sponsor’s promise to pay for research related injuries automatically turns the sponsor into a “liability insurance policy or plan.”
- Rebuttal: A simple promise to pay where certain conditions are met (which may or may not encompass situations involving legal liability) is not sufficient to convert a non-insurance entity (such as a sponsor) into an “insurance liability policy or plan.” There must be liability.
  - “Liability insurance” means “insurance (including a self-insured plan) that provides payment based on legal liability for injury or illness or damage to property.”
  - Even though “[a]n entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk… a sponsor does not carry risk by simply making a promise.”
CMS Position and Rebuttal

- **CMS:** Where there is a “research-related injury” in the context of a clinical trial, there is liability. Thus, the sponsor is responsible to pay as a “liability insurance policy or plan” for related health care items or services.

- **Rebuttal:**
  - The “promise to pay” is not the result of legal liability. Rather, it may be offered to further the principles of ethical research.
  - Research is, by definition, investigational/experimental services. As such, injuries can result during the course of a clinical trial not due to any negligence (or failure to exercise reasonable care) by the sponsor but simply because of the nature of the exercise.
  - Subjects are advised of potential injuries/adverse events which may be anticipated during a trial. A valid informed consent process may then create a defense to liability.

Rebuttal continued

- **Cases have held that legal liability in the MSP context must be demonstrated and not assumed.** See, e.g., *Graham v. Farm Bureau Insurance Co.*, No. 1:07-cv-241, 2007 WL 891895.

- The MSP laws do not convert a non-insurance entity (such as a Sponsor) into a self-insured liability insurance plan where there is no evidence of legal liability/responsibility to pay.
CMS Position and Rebuttal

- CMS: A Sponsor’s “promise to pay,” alone, constitutes a “demonstrated” responsibility to pay for items or services under the MSP laws. A demonstrated responsibility may be created through judgment or “by other means” including “settlement, award or contractual obligations.”

- Rebuttal:
  - A “promise to pay” is irrelevant, unless it is associated with the “carrying of risk” for “legal liability,” such that the sponsor is a “liability policy or plan.” Stated otherwise, a contractual obligation alone is not sufficient to trigger the MSP laws.
  - Case law does not support CMS’ interpretation. In Glover v. Philip Morris USA, the court stated that “it cannot be ‘demonstrated’ that an alleged tortfeasor, which has neither been adjudicated as liable nor has agreed to settle a tort claim, ‘has’ an existing ‘responsibility’ to reimburse Medicare or ‘had’ a previous responsibility to do so.”

Rebuttal continued

- Although not expressly stated in the correspondence with CMS (which predated the new MSP regulations), CMS would presumably argue that the Sponsor’s promise to pay is a “contractual obligation” that demonstrates responsibility to pay.

- But, the fact that a contractual obligation exists to pay for health care is not enough. In order for the MSP laws to apply, the Sponsor:
  - Must be a primary plan (but is not the case absent evidence that it has legal liability in the particular case or is carrying risk). This is particularly so since the payment is not made in connection with a settlement, release or waiver. Indeed, waivers and releases cannot be part of the informed consent document.
  - Must have a demonstrated responsibility to pay under the primary plan (but this is not the case, since there is nothing to establish that the arrangement is anything other than a VOLUNTARY promise to pay).
    - This voluntary promise is consistent with ethical principles involving human research (Belmont Report): (1) respect for persons, (b) beneficence, and (3) justice.
    - Numerous cases suggest that responsibility to pay will not be assumed and must be demonstrated by judgment, settlement, or something of like kind (such as payment pursuant to an express agreement to pay for specific claims for which the Sponsor is legally liable to pay).
Rebuttal continued

- The idea that a contractual obligation is not, on its own, sufficient for MSP liability is not novel.
  - GHP is a contractual promise to pay
  - WC plan is a contractual promise to pay
- BUT, in both cases, some other event is needed to transform the contractual obligation into “demonstrated responsibility” See e.g., Fisher v. Clarendon Nat. Ins. Co.
- “Demonstrated Responsibility to Pay” Cases
  - No cause of action unless responsibility to pay has been established.

Awaiting CMS Guidance

- CMS is acutely aware of this issue, but has not yet provided formal guidance.
- CMS should revisit its position in light of changes in law and significant policy concerns.
  - Recent developments (particularly the new notice requirements) are leading Sponsors to refuse to make these kinds of promises.
  - This will leave Medicare as the primary payer under its Clinical Trial Policy, so there is no ground gained here.
  - If CMS denies payment for some reason, research sites and/or the beneficiaries will be left with the burden of these expenses.
- The better approach is to treat this like any other liability insurance situation, where Medicare makes conditional payments and then seeks recovery when and if there is a judgment, settlement or other payment conditioned upon release.
Thank You

Ramy Fayed, Esq.
Sonnenschein Nath & Rosenthal LLP
1301 K Street N.W.
Suite 600, East Tower
Washington, D.C. 20005
(202) 408-6193
rfayed@sonnenschein.com

---

CMS and Clinical Trials

- Medicare NCD Manual, Chapter 1, Part 4, Sec. 310.1: Routine Costs in Clinical Trials
  - Medicare covers the routine costs of qualifying clinical trials … as well reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials
CMS and Medicare Secondary Payer

Basic Rule: 42 CFR § 411.32 (a)(1)

- Medicare benefits are secondary to benefits payable by a primary payer even if State law or the primary payer states that its benefits are secondary to Medicare benefits or otherwise limits its payments to Medicare beneficiaries.

An Example?

Informed Consent Language:

- If you are injured or become sick as a result of taking part in this study, tell your doctor immediately (phone # xxx-xxx-xxxx). Treatment will be made available to you for such injury or illness. If it is determined by Company X, the study sponsor, that you have become injured or sick as a direct result of the proper administration of the investigational drug, X, as required by the study plan, Company X will pay any reasonable and necessary costs for treating you injury or illness if all the following are true:
An Example?

- You notified your study doctor immediately after you were injured or became sick
- You followed all of the instructions that your study doctor and his/her staff gave you, and you accurately and promptly answered all of their questions
- The study doctor followed all study procedures
- Your injury or illness was not a result of negligence by the study doctor or the hospital/institution at which study was conducted
- The costs are not covered by your insurance or by other third party coverage, such as government programs

An Example?

- Clinical Trial Agreement:
  - If it is determined by Company X that a research subject has suffered an injury or illness as a result of participating in the clinical trial, Company X will pay or provide reimbursement for the reasonable and necessary costs of medical treatment reasonably required to treat such injury or illness in accordance with the terms and conditions of the applicable Informed Consent Form approved by the IRB.
So Who’s Primary or Secondary?

- With these provision in the Informed Consent document and the Clinical Trial Agreement, does CMS remain the primary payer status under the NCD or are they secondary under the MSP?
- That was the question posed to CMS in 2004.
- Much to the disappointment of the letter writer and the rest of us CMS chose the latter position.

The 2004 Letter from CMS

- CMS made two important findings to establish their position:
  1. That such language “constitutes a plan or policy of insurance under which payment can reasonably be expected to be made in the event such an injury occurs; and
  2. That the same language “constitutes a demonstration of primary payment responsibility.”
The Big Questions!

- Do these “Promises to Pay” fall within the “otherwise” category of self-insurance, making the Sponsor a “Primary Payer” with a “Primary Plan”?
- If the Sponsor has a “Primary Plan”, does the provision amount to a “demonstration of responsibility for payment ‘by other means’.”

Let’s Try to Answer

- Definitions: 42 CFR § 411.21 & 411.50
  - Primary payer means … any entity that is or was required or responsible to make payment with respect to an item or service under a primary plan.
  - Primary plan means … [a] liability insurance policy or plan (including a self-insured plan).
  - Plan means any arrangement, oral or written … to provide health benefits or medical care….
  - Liability insurance means insurance (including self-insurance) that provides payment based upon legal liability for injury or illness.
Let’s Try to Answer

- What does “by other means” mean?
- CMS decided to define it as such: 42 CFR § 411.22 (b)(3)
  - By other means, including but not limited to a settlement, award, or **contractual obligation**.

Let’s Try to Answer

- So are these promises “contractual obligations?”
- Are they arrangements to provide health benefits?
- If so, then MSP wins out over NCD and the Sponsor pays.
- Unfortunately CMS has taken an all or nothing approach and until it is litigated in the courts we can only guess at the strength of CMS’ argument.
So What Do We Do?

Prior to contractual negotiations for a clinical trial make sure you know who the affected parties will be so that they can be at the table.

If you work at a hospital with employee physicians doing research only one entity is affected; however, if you work at an academic medical center you can have three to four parties involved in the negotiations.

Get them all at the table to discuss the pros and cons of the following approaches.

Don’t bill Medicare until you have reached a conclusion on the provision you will follow.

---

1. The easiest solution is to eliminate these provisions from the contracts and just bill pursuant to the NCD.
   - There is no legal duty imposed upon the sponsor to provide a means by which payment for medical expenses are paid to an injured research subject.
   - Furthermore, there is no ethical obligation imposed on sponsors for such provisions.
   - It removes MSP from the equation but it also leaves uninsured and under-insured study participants out in the cold for injuries that are not caused by negligence. Remember that public perception is very important in the medical world.
So What Do We Do?

2. Keep the provision in place for privately insured/self-pay and explicitly state that the federal government will not be billed for injuries to Medicare Beneficiaries.
   - This does increase the cost to the Sponsor but it also enables them to protect the rest of the study population by having the opportunity to collect from private insurers. It also gives a better public image.
   - I find this to be best of a bad situation.

3. Rewrite the provision to pay for all injuries without regard to insurance or federal/state benefits.
   - This would be most altruistic course to take but it would also be the most expensive.
   - It is not very likely that this a realistic expectation from any sponsor given the current economic climate.
So What Do We Do?

4. Keep the provisions as is and hope that CMS doesn’t come after you.
   - Since the 2004 CMS letter and the new regulations have not been litigated, and since the 2007 NCD did not clarify the issue, there is still a question as to whether CMS is correct in their assumptions.
   - There is no question that these provisions are still out there. So why hasn’t CMS gone after someone? Are they not secure in their position or has no audit turned up the problem.
   - You run the biggest risk with this approach since the amendments to the MSP statute require self-insured plans to disclosed claimants to the Secretary of HHS. Failure to do so costs $1000 a day.

The Erin Brochovich Syndrome

- “Standing to Sue” Cases
  - The MSP allows CMS to sue as well as a beneficiary.
  - Need Article III standing to sue.
    - MSP is not a *qui tam* statute
Other Developments

- Fall 08 – CMS issued 3 FAQs in MLN Matter SE0822
  - First FAQ “clarified” that: (1) if private insurers deny routine costs of services in a clinical trial, and (2) the provider does not pursue non-Medicare patients for payment after the denial, then Medicare payment cannot be made for the same services provided to Medicare beneficiaries and the beneficiary cannot be charged for the routine costs.
  - CMS based its position on the statutory “no legal obligation to pay” doctrine at 42 USC 1395y(a)(2).
- First FAQ withdrawn in January 2009.

Thank You

William H. Wallace, Jr., JD
Compliance Officer
University of Tennessee
Graduate School of Medicine
1924 Alcoa Hwy., U_94
Knoxville, TN
(865) 305-6192
wwallace@mc.utmck.edu