# The Buck Stops Here…Or Does It?

## Medicare Secondary Payer and Beneficiary Inducement

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## Introductions

- Diane Austin
  - Aurora Health Care, Research Compliance Officer
- Rachel Delaney
  - Aurora Health Care, Corporate Counsel Research
- Anne Ruff
  - Hall, Render, Killian, Health & Lyman, P.C., Attorney

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## Road Map

- Diane:
  - Background on Medicare Billing for Clinical Trials
- Rachel:
  - Medicare Secondary Payer
  - Waiver of Copays and Deductibles
- Anne:
  - Best Practices and Common MSP Policies

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## Aurora at a Glance


- Private, not-for-profit integrated health care provider
- 30 counties, 90 communities
- 15 hospitals, over 150 clinic sites
- 32,000 caregivers, including 1,800 employed physicians
- 92,000 inpatient discharges
- 2.2 million outpatient visits
- 3.6 million ambulatory care visits
- $4.9 billion in annual revenue
- ~600 active research studies
- ~300 active clinical trials

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# SUMMARY OF MEDICARE CLINICAL TRIAL BILLING REQUIREMENTS

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## Medicare Coverage Rules

| | | |
|---|---|---|
| Device Trial | 42 CFR 405, Subpart B – Medical Services Coverage Decision that Relate to Health Care Technology | All other Medicare rules apply |
| Other Trial | CMS National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1) | All other Medicare rules apply |

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## Device Trial Billing

**FDA Decision**

Device classified as Category A or B

**CMS Decision**

Standard criteria used to determine trial coverage

Approved IDE trials posted to CMS website

**Study Site Decision**

Bill device and items/services on approved studies as allowed by regulation and Ch. 14, Section 20 of Medicare Benefit Policy Manual

References:
https://www.cms.gov/Medicare/Coverage/IDE
Medicare Benefit Policy Manual, Ch. 14

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## Device Trial Billing

**Category A Device**
(novel, first-of-kind technology)

- May bill:
  - Routine care items/services
  - Complications (unless direct result of receipt of device)
- May not bill:
  - Device
  - Services related to use of device

**Category B Device**
(new generation of proven technology)

- May bill:
  - Device
  - Routine care item/services
  - Services related to use of the device
  - Complications

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## Non-Device Trial Billing

Study Site Decision

Medicare coverage analysis (MCA)

- National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)

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## Non-Device Trial Billing

NCD 310.1

- May bill:
  - *Routine costs* of *qualified clinical trials*
  - Complications-all trials


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## Non-Device Trial Billing

**If** Qualified Clinical Trial **Then** Routine Cost

REQUIREMENTS

1) Must evaluate an item or service that falls within a Medicare benefit category, and not be statutorily excluded;

2) must have therapeutic intent; and

3) must enroll patients with a diagnosed disease

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DEEMED CATEGORY

1) Trials funded by NIH, CDC, AHRQ, CMS, DOD and VA;

2) Trials supported by centers or cooperative groups that are funded by NIH, CDC, AHRQ, CMS, DOD and VA;

3) Trials conducted under an investigational new drug application (IND); or

4) Drug trials exempt from having an IND under 21 CFR 312.2(b)(1)

Items/services:

1) typically provided outside a clinical trial; and
2) required solely for:
   - the provision of an investigational item/service
   - the clinical monitoring of effects of the item/service
   - the prevention of complications
3) needed for diagnosis or treatment of complications

Items/services available to Medicare beneficiaries, except:

1) the investigational item/service itself, unless otherwise covered outside the trial;

2) items/services required solely to satisfy data collection and analysis needs; and

**3) items/services customarily provided by the research sponsor**

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## MEDICARE SECONDARY PAYER

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## Medicare Secondary Payer Background

- 42 USC 1395y(b):
  - Legislation passed in 1980
  - Medicare is secondary to all other forms of illness, injury or property damage insurance
  - Medicare is only primary payer for beneficiaries without other types of coverage

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## Medicare Secondary Payer Background

- Common situations where Medicare is secondary:
  - Individual is 65 or older but has group health insurance
  - Individual is disabled but has group health insurance
  - Individual has ESRD and group health insurance – Medicare is secondary for first 30 months
  - Individual is covered by COBRA
  - Individual has a retiree health plan
  - Individual is entitled to Medicare but was in an accident or other situation where no-fault or liability insurance is involved
  - Individual is entitled to Workers' Comp for job related illness/injury

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## MSP and Subject Injury in CTAs

- CMS Clinical Trials MSP Instruction issued 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."

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## MSP Application to Sponsors

- If sponsor takes responsibility for subject injury in the CTA, the sponsor becomes the primary liability insurer and RRE and must do two things:
  (1) report the complication/injury to CMS
  (2) pay for the subject's medical bills resulting from the complication/injury
- See 42 USC 1395y(b)(8)

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## MSP Application to Hospitals

- If a hospital has a situation where the sponsor is the primary payer of an injury or complication, the hospital must:
  - Bill the sponsor instead of Medicare
  - If the hospital has received payment from the sponsor, the hospital must return that payment to Medicare within 60 days
- See 42 CFR 489.20 (f) – (h)

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## CTAs Outside of MSP

- If sponsor does not take responsibility for subject injury in the CTA:
  - Medicare may cover
  - Depends on the status of the trial under the NCD for Routine Costs in Clinical Trials
- Notify subject in informed consent that subject will be financially responsible for research related injury

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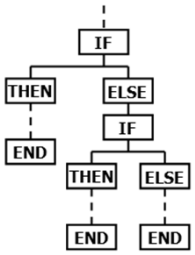
## MSP Outside of Subject Injury: Conditional Insurance

- Often presents in CTAs and informed consents as "conditional insurance" language
  - "If subject's insurance denies coverage for X-procedure, then the sponsor will pay the institution for X-procedure"

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## Conditional Insurance Language

- Medicare and CMS have not specifically commented
  - 2004 private letter from CMS
- Risks of conditional insurance in CTAs:
  - Confusion in billing
  - Risk of submitting a false claim
  - Patients uncertain about costs
  - Potential IRB issues
  - Conflict with NCD

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# WAIVER OF COPAYS AND DEDUCTIBLES

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## Beneficiary Inducement

- HIPAA/OIG Special Advisory Bulletin re Offering Gifts and Other Inducements to Beneficiaries (August 2002)
  - "a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to induce the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services may be liable for civil money penalties (CMPs) of up to $10,000 for each wrongful act"
  - "remuneration" includes waivers of copayments and deductible amounts (or any part thereof) and transfers of items or services for free or for other than FMV
  - Exceptions based on need/indigent status
  - OIG may propose new exception for free goods and services (possibly including waivers of copayments) in connection with NIH or DHHS sponsored clinical trials

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## Application of Beneficiary Inducement Rules to Clinical Trials

- May a research sponsor pay Medicare copays for beneficiaries in a clinical trial?
  - Could be a fraud and abuse problem
  - Only OIG exceptions are for indigent status
- If research sponsor pays for routine costs provided to indigent non-Medicare patient may Medicare payment be made for Medicare beneficiaries?
  - Yes, may waive for indigent status but should bill those who can pay

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## OIG Advisory Opinion 08-11 Issued September 17, 2008

- Clinical trial sponsored by NIH and CMS to study oxygen treatment
- CMS issued an NCD and agreed to pay for items/services for Medicare beneficiaries
- Other research subjects had insurance willing to pay for costs of participation
- Providers waived copays to enhance reliability of study, increase compliance with the protocol and to eliminate financial difference between those who were assigned to the control group and did not receive oxygen therapy versus those who were in the treatment arm and did receive oxygen therapy

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## *…continued…*

- OIG said this study implicates AKS because copays are waived routinely and without regard to financial hardship, however, the OIG would not impose penalties because:
  - Government sponsored study and conflicts of interest will be managed
  - Not a commercial study and not intended to develop a product
  - Subject compliance is essential and waiving copays will enhance compliance and subject retention, will make sure Medicare beneficiaries are not excluded and will eliminate proposed financial differential for treatment vs. non treatment subjects

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## OIG Advisory Opinion 15-07 Issued May 28, 2015

- Medical device clinical trial to test minimally invasive spine surgery instruments
- Control group will receive sham surgery
- Experimental group will receive actual surgery
- Study design includes waiving copayments for both groups
  - Can't charge copayments to those who received sham surgery
  - Charging only those who received actual surgery would compromise study design; it would put sham surgery patients on notice that they did not receive surgery
- CMS said it is okay for sponsor to pay all copays

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## *…continued…*

- OIG said it will not impose penalties because:
  - CMS issued coverage decision for this process and study was designed in conjunction with CMS
  - Waiver of copays is a reasonable means of achieving study goals – allows true impact on health outcomes to be isolated and assessed
  - No one is in a position to refer and all payments will be FMV
  - Patients must satisfy enrollment criteria and sign an informed consent document, physicians must comply with the protocol and all is monitored by the IRB – these factors reduce risk of overutilization

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## MSP and Beneficiary Inducement Re-Cap

- A promise to pay by the sponsor may implicate Medicare Secondary Payer
- A request to waive beneficiary co-pays and deductibles may implicate beneficiary inducement
  - Exceptions for indigent status or study design
- Establish an institutional policy on how to address

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# MSP: What We See, What We'd Like to See, and What's Got to Go

## Triggering Language

- "Conditional insurance"
  - Sponsor agrees to reimburse Institution for reasonable and necessary documented expenses incurred by Study Subjects for injuries caused as a direct result of the use of the Study Drug in accordance with the Protocol and the Informed Consent, provided that such costs are not covered by the Subject's insurance or by a governmental agency providing such coverage
  - In the event of injury due to your participation in this study, the sponsor, will provide reimbursement for the reasonable cost of treatment to the extent that such costs are not covered by your medical or hospital insurance or by a third-party or governmental program and provided you have followed the directions of the study personnel.

## Risk of Conditional Insurance Language

- You have now agreed in the contract not to request Sponsor payment until you receive a denial, so you submit all claims
- Sponsor's promise to pay implicates MSP and they are now primary payer.
- However you have submitted a claim to Medicare that Medicare is not primarily responsible because that is what your contract says

## Risk of Conditional Insurance Language

- False Claims -If Sponsor, provider, physician or other supplier becomes aware of any situation where Medicare mistakenly makes payment for subject injury under such an agreement, it is "statutorily obligated to reimburse Medicare."
- Potential for identified overpayments and 60-day refunds.

## Conditional Language for Routine Costs

In 2008 CMS put out an MLN Matters (Medicare Learning Network) transmittal that had a Q&A on routine costs and MSP

**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.

## Conditional Language for Routine Costs

In 2009 that Q&A on routine costs and MSP was subsequently withdrawn by CMS without any explanation (the other 2 questions in the MLN matters are still available).

How do we interpret that?

## Option #1 – Your Study, Your Problem

**Sponsor agrees to pay for <u>all</u> subject Injury**

- Most preferable for sites
- Under this approach the Sponsor agrees to cover the costs resulting from a subject injury for all subjects.
- No subject injury claims will be submitted, Sponsor must be notified of subject injury
- Watch for limitations
  - definition of subject injury, exclusions, notification requirements

## Option #1 – Your Study, Your Problem

**Sponsor agrees to pay for <u>all</u> subject Injury**

If any illness or injury occurs to a Study Subject as a direct result of the Study Drug or properly performed procedures required by the Protocol ("Subject Injury"), Sponsor agrees to pay all reasonable medical expenses necessary to diagnose and treat such Subject Injury.

## Option #2 – Take it or Leave It

**Sponsor agrees to pay for <u>no</u> subject Injury**

- Least preferable for sites
- Burden for subject injury falls on the study subject
- If the study subject can't pay, hospital may ultimately be responsible for the bad debt
- Consideration given to who you should ask to participate (will you ask those that are not insured or underinsured?)

## Option #2 – Take it or Leave

**Sponsor agrees to pay for <u>no</u> subject Injury**

ICF language and subject injury is missing from CTA

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. Medical treatment will be provided as usual. The study sponsor will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance, you would be billed for any costs."

## Option #3 – The Compromise aka No One is Really Happy

**Sponsor agrees to pay for <u>some</u> subject Injury**

- Not Ideal but Not Illegal
- Sponsor will agree to cover the cost of subject injury for study subjects who are Medicare beneficiaries
- Sponsor will cover the costs of subject injury for other study subjects if such costs are not covered by subject's insurance (copays?)

## Option #3 – The Compromise aka No One is Really Happy

**Sponsor agrees to pay for some subject Injury**

Sponsor shall pay Institution for the costs of diagnosing and treating any injury or illness of a Study Subject that is directly related to the performance of the properly administered Study Drug/Device ("Subject Injury"). Institution shall send claims for Subject Injuries for Study Subjects covered by Medicare directly to Sponsor; otherwise, Sponsor will provide compensation for Subject Injury diagnosis and treatment except to the extent that it is paid for, in whole or in part, by a third party.

## More than MSP – Ethics and Public Policy Considerations

- In 1979, National Commission for the Protection of Human Subjects of Biomedical Behavioral Research produced the Belmont Report.
- The Belmont Report established 3 fundamental ethical principles:
  - Respect for Persons – Individuals have the right to be treated as autonomous agents, and individuals with diminished autonomy (e.g. children, prisoners) are entitled to special protections).
  - Beneficence – Research should maximize the possible benefits while minimizing possible harms to the human subject
  - Justice – focuses on the ethical question of who should receive the benefits of research and who should bear its burdens. (e.g. burden of research should not be unfairly placed on those who do not stand to benefit from it and should be equitably shared).
- These principles remain the basis for the United States Department of Health and Human Services (HHS) human subject protection regulations.

## More than MSP – Ethics and Public Policy Considerations

Policy considerations support:

- Increased participation in clinical trials
- Equitable distribution of risks and benefits
- Participation by financially and medically indigent
  - Particularly for life-saving interventions

## More than MSP – Ethics and Public Policy Considerations

- Option #1
  - If Sponsors must cover all injuries, offers of coverage of subject injury may decrease , which may pose barriers for uninsured patients or increase costs carried by research institutions when injuries occur
  - If your institution insists on it, will you see less innovative research opportunities?

## More than MSP – Ethics and Public Policy Considerations

- Option #2
  - Sponsors get the majority of potential benefits associated with a clinical trial (IP, the revenue if approved), shouldn't they bear the burden associated with a subject's injury?
  - Are we doing a good job informing patients they will be responsible for the costs and what those costs could be?

## More than MSP – Ethics and Public Policy Considerations

- Option #3
  - This can lead to equity concerns, if Medicare patients have coverage for research-related injuries, but uninsured and commercially insured patients do not ( think copays, deductibles, lifetime maximums)
  - Will this impact research recruitment/study results if only Medicare patients participate or participate in high numbers compare to others?

## What about Co-Pays and Deductibles?

- Previously it was not recommended for Sponsors to cover co-pays and deductibles for Medicare beneficiaries.
- 2008/2009 MLN Matters discusses whether a Sponsor may pay Medicare copays for beneficiaries and the response was that this “could” be a fraud and abuse problem.
- June 2015, the OIG posted an advisory opinion that said they would not impose sanctions for a device manufacturer who wanted to pay co-pays for Medicare beneficiaries related to the study.
- Potential change in position?

## What are People Doing?

- Many are taking the position that the Sponsor should provide coverage for all subject injury in investigational drug and device trials, particularly among university-affiliated health systems
  - "This position reflects' [University's] belief that no research participant should bear the financial burden of self-pay, co-payments, deductibles, nor impact on lifetime insurance benefits because they have experienced a research injury while participating in the development of products for companies."

## What are People Doing?

- Many hospitals and health systems are open to all 3 options with the understanding of what is preferred and some process for vetting/approval prior to accepting that Sponsor will provide no subject injury for interventional drug/device studies.
- While not including any subject injury language in CTAs is possible, have not verified any hospitals/health systems that make this a practice

## What are People Doing?

- Do you have a process/policy for handing a subject injury when it occurs?
- How do you define subject injury in your policy? Are we consistently using that definition in the contracts?
- Who identifies a potential subject injury?
- Who gets notified of a potential subject injury and how?
- Who needs to be involved?
  - Finance, Compliance, Risk Management, IRB

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