University of Michigan Health System

UMHS Clinical Research Position Statement and Template Language
Effective: September 1, 2010
Approved by Clinical Systems Committee: April 27, 2010

Background

Research sponsors often agree to pay for the costs of items and services that arise from research-related injuries. Sometimes the promise to pay is conditioned upon the receipt of a denial from another payer or stated as a conditional payment if the services are not otherwise covered by other payers. CMS informal guidance from 2004 has resulted in CMS taking a position that such promises to pay trigger Medicare Secondary Payer (MSP) implications for healthcare providers as it relates to services billed to Medicare related to a clinical trial.

CMS's current position is that if a private sponsor of a clinical trial agrees to cover any costs of subject injuries that were denied by third party payers then the sponsor has made a commitment to be the primary payer. MSP laws are clear that Medicare is always the secondary payer. Medicaid laws confirm that Medicaid is always the payer of last resort.

Why UMHS Requires the Study Sponsor to Pay for Research-Related Injuries

CMS views a sponsor's promise to pay for research-related injuries as an action that makes Medicare the "secondary payer" and the sponsor the "primary payer."

The Centers for Medicare and Medicaid Services (CMS) says that a "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 injury occurs….Therefore, Medicare will not make payment." (Letter from CMS, Office of Financial Management, April 13, 2004).
See more recently http://www.cms.gov/MandatoryInsRep/Downloads/AlertClinicalTrailsNGHP.pdf

In order to avoid any Medicare Secondary Payer (MSP) regulatory concerns, the UMHS takes the position that the sponsor should agree to cover research-related injuries in the sponsor agreement regardless of the patient/trial participant's health plan coverage. This avoids not only the MSP issue but also protects patients who have no health plan coverage or whose health plan will not cover research-related injuries. Most health plans will not cover the cost of medical care associated with an injury that arises from a research trial so the UMHS position protects the UMHS from inadvertently billing for services that are either not a covered benefit by many commercial health plans or that would trigger MSP concerns.

The state of Michigan does not currently require insured health plans regulated by the state to cover the costs associated with clinical trials and there is no coverage required for the costs of care associated with injuries that arise from a clinical trial. Similarly, while the Patient Protection and Affordable Care Act (PPACA) will require commercial plan coverage for routine items and services that are part of certain qualified trials, PPACA exempts any plan that is grandfathered from that requirement. More importantly, PPACA, as written, does not require coverage for the monitoring and diagnosis of complications or injuries that arise in a trial for commercial health plans. There is no requirement to pay for medical care arising from research-related injuries. If regulatory guidance appears that alters these requirements, the UMHS may revisit the issue.

As further support for its position, UMHS looks to the American Medical Association Code of Conduct which states "Physicians should ensure that protocols include provisions for the funding of subjects' medical care in the event of

complications associated with the research." *(AMA code of conduct, E-8.0315, paragraph 5, Managing Conflicts of Interest in the Conduct of Clinical Trials)*

While there is the remote possibility that some health plans *may* cover services required as a result of research-related injuries, UMHS believes that its research subjects should not bear the financial burden of participation in the development of products for companies. This is because a patient would bear the financial burden of co-payments and deductibles and because life time coverage limits could be affected.

The Food and Drug Administration (FDA) requires adverse events to be reported to the FDA with the study investigator determining the causality of the adverse event. UMHS relies on the determination of the causality of any injury to the subject to be determined by the investigator (sometimes in conjunction with the sponsor) in order to be consistent with how the adverse event is reported to the sponsor and subsequently the FDA. This position is reflected in the template sponsor contract language that requires sponsors to pay for medical care required as the result of an adverse event and acknowledges that the UMHS investigator (sometimes in conjunction with the sponsor) makes the determination regarding causation. The UMHS does not expect a sponsor to pay for services resulting from an adverse event if the injuries arise from UMHS's negligence, willful misconduct or from UMHS's non-compliance with the study protocol. UMHS believes this approach is balanced, reasonable and fair to the study participants, the sponsor and UMHS.

Preferred Contract Language
Reimbursement of Subject Complication, Injury or illness for Industry Sponsored Projects

The Sponsor shall promptly reimburse Institution (or its subsites)* for reasonable and necessary medical expenses incurred by Subjects for medical care, including hospitalization, in the diagnosis and treatment of complications, injuries or illness caused by research procedures or the Study drug/device following their administration or use in accordance with the Protocol, which are not attributable to the negligence or misconduct of any person in the employment of Institution and that would not be expected from the standard treatment using currently approved therapies. The term "complications, injuries or illness" does not mean the natural progression of an underlying or pre-existing condition or events that would have been expected from the standard treatment using currently approved therapies for the Subject's condition. This section shall survive termination of this Agreement.

*Note: if the reference to subsites is not applicable it may be deleted.

Acceptable Alternative Contract Language Reimbursement for Subject Complication, Injury or illness for Industry Sponsored Projects

I. The Sponsor shall reimburse Institution for the direct, reasonable and necessary medical expenses incurred by Institution for the treatment of any adverse event experienced by, illness of or bodily injury to a study Subject that is caused by treatment of the study Subject in accordance with the Protocol except to the extent that such adverse event, illness or personal injury is caused by (a) failure by Institution, Principal Investigator or any of their respective personnel to comply with this Agreement, the Protocol, any written instructions of Company that have been approved by the Institution's IRB concerning the Study, or any applicable law, regulation or guidance, including good clinical practices, issued by any regulatory authority, or (b) negligence or willful misconduct by Research Institution, Principal Investigator or any of their respective personnel. This section shall survive termination or expiration of this Agreement.

-OR-

II. The Sponsor agrees that it, and not the Institution, is responsible for the costs of diagnosis, care and treatment of any undesirable side effects, adverse reactions, illness or injury to a participant in the Clinical Trial which in the reasonable

judgment of the Principal Investigator or Institution are determined to result from participation in the Clinical Trial, except for such costs that arise directly from (i) the negligent activities, reckless misconduct or intentional misconduct of the Institution, the Principal Investigator or his/her staff or (ii) their failure to adhere to the terms of the Protocol. This section is not intended to create any third-party contractual benefit for any participants in the Clinical Trial.

Approved Informed Consent Language for Reimbursement of Subject Complication, Injury or Illness for Industry Sponsored Projects

The study team has given you instructions about this research study. It is important that you follow these instructions carefully. If you get sick, have a medical complication, or are injured as a result of your being in the study, call Dr. [XXX] immediately, at [XXX-XXX-XXXX]. The doctor will either treat you or send you to another doctor for treatment.

You will get free medical care for any complication, injury, or illness caused by the study drug, device, or procedure. The study sponsor and the study doctor are responsible for determining whether your condition was the result of your participation in the study.

The study sponsor will pay for your treatment only if the need for treatment has been caused by the study drug, device or procedure. This means that you or your health plan must pay for any treatment that is part of your usual medical care or that is related to a medical condition you had before participating in the study.

Approved Informed Consent Language for Federally Funded Projects

The study team has given you instructions about this research study. It is important that you follow these instructions carefully. If you get sick, have a medical complication, or are injured as a result of your being in the study, call Dr. [XXX] immediately, at [XXX-XXX-XXXX]. The doctor will either treat you or send you to another doctor for treatment.

You will get free medical care at the UMHS for any complication, injury, or illness caused by the study drug, device, or procedure. The UMHS and the study doctor are responsible for determining whether your condition was the result of your participation in the study.

The UMHS will pay for your treatment only if the need for treatment has been caused by the study drug, device or procedure. This means that you or your health plan must pay for any treatment that is part of your usual medical care or that is related to a medical condition you had before participating in the study.

It is not the policy of the federal funding agencies to compensate or provide medical treatment for human subjects in federally funded studies.

Instructions for Informed Consent Language for Primary Investigator Initiated Internally Funded Projects

Direct your questions to your CRAO analyst for guidance on section 5.2 and/or section 8.1 of the informed consent in regards to injury language and potential business risk.

Once the risk assessment has been performed, the study team may be instructed to either add the Approved Informed Consent Language for Federally Funded Projects (minus the last sentence), or to add the following:

The study team has given you instructions about this research study. It is important that you follow these instructions carefully. If you get sick, have a medical complication, or are injured as a result of your being in the study, call Dr. [XXX] immediately, at [XXX-XXX-XXXX]. The doctor will either treat you or send you to another

doctor for treatment.

You will get free medical care at the UMHS for any hospitalization directly caused by the study drug, device, or procedure. The UMHS and the study doctor are responsible for determining whether your condition was the result of your participation in the study.

The UMHS will pay for your treatment only if it has been caused by the study drug, device or procedure. This means that you or your health plan must pay for any treatment that is part of your usual medical care or that is related to a medical condition you had before participating in the study.

Medicare Secondary Payer (MSP) Language in Consents and Contracts

Medicare Secondary Payer (MSP) trigger language is never allowed in the Informed Consent Form or the Contract regardless of the type of sponsor (Industry, Federally Funded, or PI Initiated).

The UMHS considers the following proposed consent language to trigger an MSP concern and, therefore, it is unacceptable:

> *The reasonable costs of such treatment beyond that covered by your insurance will be covered by the study sponsor*.

Approved: The UMHS would amend the proposed consent language as follows:

> *The reasonable costs of such treatment ~~beyond that will be provided by your insurance~~ will be covered by the study sponsor.*

The UMHS considers the following proposed contract language to trigger an MSP concern and, therefore, it is unacceptable:

> *Sponsor further agrees that if a patient enrolled in the Study according to the Protocol suffers an injury, provided such injury is not caused in any way by an Indemnified Party's negligence or willful misconduct, breach of the Agreement or failure to adhere to the Protocol, , Sponsor will provide payment for the patient's medical expenses for treatment of injuries to the extent that such expenses are not covered by the patient's health insurance policy: (a) if the patient received reasonable medical care; (b) the patient followed instructions and the schedule visit; (c) if the injury is related to the Study drug or to properly performed Study procedures that are not part of the patient's usual medical care; and (d) that are not the result of the natural course of any underlying disease and/or pre-existing disease process present prior to the proper administration of the Study Drug. Any payment shall not be an admission of wrongdoing on the part of the Sponsor.*

Approved: The UMHS would amend the proposed contract language as follows:

> *Sponsor further agrees that if a patient enrolled in the Study according to the Protocol suffers an injury, provided such injury is not caused in any way by an Indemnified Party's negligence or willful misconduct, breach of the Agreement or failure to adhere to the Protocol, ~~to the extent that such expenses are not covered by the patient's health insurance policy~~, Sponsor will provide payment for the patient's medical*

expenses for treatment of injuries: (a) if the patient received reasonable medical care; (b) the patient followed instructions and the schedule visit; (c) if the injury is related to the Study drug or to properly performed Study procedures that are not part of the patient's usual medical care; and (d) that are not the result of the natural course of any underlying disease and/or pre-existing disease process present prior to the proper administration of the Study Drug. Any payment shall not be an admission of wrongdoing on the part of the Sponsor.