Background

Industry 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. The Centers for Medicare and Medicaid Services (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 MICHIGAN MEDICINE 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.” CMS states 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.” (See Medicare Secondary Payer overview on CMS website): Medicare-Secondary Payer Guidance.

In order to avoid Medicare Secondary Payer (MSP) regulatory concerns, MICHIGAN MEDICINE 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. Many health plans will not cover the cost of medical care associated with an injury that arises from a research trial so the MICHIGAN MEDICINE position protects MICHIGAN MEDICINE 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 non-Standard of Care 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) requires 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 MICHIGAN MEDICINE may revisit the issue.

As further support for its position, MICHIGAN MEDICINE 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, MICHIGAN MEDICINE 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. MICHIGAN MEDICINE 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 MICHIGAN MEDICINE investigator (sometimes in conjunction with the sponsor) makes the determination regarding causation. MICHIGAN MEDICINE does not expect a sponsor to pay for services resulting from an adverse event if the injuries arise from MICHIGAN MEDICINE’s negligence, willful misconduct or from MICHIGAN MEDICINE’s non-compliance with the study protocol.

MICHIĞAN MEDICINE believes this approach is balanced, reasonable and fair to the study participants, the sponsor, and MICHIGAN MEDICINE.