

## Healthcare Reform Law May Impact Clinical Trial Billing and Contract Negotiations

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act (the "Act"), into law. Included in the Act's 2400 pages is a provision mandating insurance coverage for certain clinical trial participants (the "Provision"). Since certain items and services will now be paid by the clinical trial subject's insurance, the payment structure for these items and services will change. As a result, clinical trial billing plans, agreements and informed consents may require modification.

Section 10103 of the Act amends the Public Health Service Act to prohibit group health plans and insurance issuers offering group or individual health coverage ("Health Plans") from denying a "qualified individual" participation in an "approved clinical trial". The Provision also prohibits Health Plans from denying or limiting coverage of routine patient costs for items and services furnished in connection with the qualified individual's participation in an approved clinical trial. In addition, the Provision prohibits Health Plans from discriminating against the qualified individual on the basis of the qualified individual's participation in such trial. Exempt from the Provision are Health Plans that were in effect on March 23, 2010, the date of the Act's enactment.

A "qualified individual" is an individual who is a participant or beneficiary in a Health Plan and who meets the trial protocol's eligibility criteria and whose participation is appropriate as determined by the referring health care professional or by medical and scientific literature provided by the Health Plan participant. An "approved clinical trial" is a clinical trial for the prevention, detection, or treatment of cancer or other life-threatening disease or condition and which is either Federally-funded or conducted under an Investigational New Drug (IND) application. Consistent with the Food and Drug Administration's regulations, the term "life-threatening condition" means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

"Routine patient costs" include items and services consistent with the coverage provided in the Health Plan that are typically covered for a qualified individual who is not enrolled in a clinical trial. Routine patient costs do not include the investigational product itself (whether drug, device, or service), or services that are either rendered solely in connection with collecting data about the investigational product or are inconsistent with established standards of care for the condition being studied. A Health Plan is not required to cover services provided outside of the Health Plan's provider network unless out-of-network benefits are covered.

The Provision preempts State laws that require additional coverage. As such, if the Health Plan is located in a State which has enacted laws requiring additional clinical trial coverage, the Health Plan must comply with the more stringent State laws. This has implications for Health Plans in states, like New York, which do not mandate clinical trial coverage. The Provision will take effect in 2014.

The Provision does not address research-related injuries or routine items and services provided to individuals who do not participate in a Health Plan. Under these scenarios, the sponsor generally is expected to pay for such costs.

In addition, under the Medicare Secondary Payer ("MSP") rules, Centers for Medicare & Medicaid Services ("CMS") will not pay for routine items and services when the subject is a "qualified

individual” participating in an “approved clinical trial” because the subject’s Health Plan will be required to cover such costs. As a result, Institutions will need to carefully review their billing procedures to ensure clinical trial costs are billed to the appropriate entity – the subject’s Health Plan, the sponsor or CMS. Clinical trial agreements and informed consents should also be revised to account for the items and services the subject’s Health Plan will cover.

The Provision will likely necessitate issuance of regulations or guidance to clarify how the Provision relates to the MSP rules. We will continue to monitor the Act and keep you informed of changes and updates in the law.

If you have questions or need further information about this Client Alert, please contact **Linda A. Malek**, chair of the [Healthcare Group](#), at 212.554.7814/[lmalek@mosessinger.com](mailto:lmalek@mosessinger.com) or **Jill E. Anderson** at 212.554.7836/[janderson@mosessinger.com](mailto:janderson@mosessinger.com).

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