Clinical Trial and Medicare Provider Quality Improvement Provisions in House Committee 21st Century Cures Discussion Draft

On January 27, 2015, the House Energy & Commerce Committee ("Committee") released a discussion draft of comprehensive medical innovation reform legislation as part of its 21st Century Cures Initiative. According to supporting materials released by the Committee, the key goals of the far-ranging proposals in the discussion draft are to (1) incorporate patient perspectives into the development and approval processes for drugs and medical devices and help address patients' unmet medical needs; (2) build the foundation for 21st century medicine; (3) streamline clinical trials; (4) support continued innovation at our federal public health agencies; and (5) modernize medical product regulation. Ropes & Gray has recently reported on the key proposals concerning drug and device manufacturers in this draft legislation. In this alert, we highlight provisions that are targeted at clinical research stakeholders, as well as proposals related to Medicare provider quality improvement activities.

Key Proposals Related to Data Sharing

The Committee's section-by-section breakdown of the draft legislation notes that the sections under the subtitle of "Building a 21st Century Data Sharing Framework" would serve to "establish a data sharing framework to enable (1) patients and physicians to better identify ongoing clinical trials, thereby increasing opportunities for patients in need of a treatment; (2) researchers and developers to use Medicare data for the purposes of improving the quality of patient care; and (3) a process for Congress to address other issues identified by the President's Council of Advisors on Science and Technology so that data can continue to fuel all areas of the 21st Century Cures cycle." Significant proposals related to data sharing include the following:

- **Standardization of Data in Clinical Trial Registry Data Bank on Eligibility for Clinical Trials.** The discussion draft requires the Director of the National Institutes of Health ("NIH") to ensure that the clinical trial registry and results databank on ClinicalTrials.gov can be "easily used by the public," and that the information is available in a standardized format that includes criteria for trial inclusion and exclusion, such as International Classification of Diseases ("ICD") or Current Procedural Terminology ("CPT") information.
- **Clinical Trial Data System.** The discussion draft provides for the creation of a system for sharing data from clinical trials "sponsored solely by an agency of the Department of Health and Human Services"—in other words, government-funded trials rather than industry-sponsored or academic-sponsored trials—that involve an approved or investigational drug, device, or biologic. The organizations that may be funded to host or arrange such a data-sharing system or platform—institutions of higher education or tax-exempt 501(c)(3) organizations—must demonstrate a proven track record of "being a neutral third party in working with medical product manufacturers, academic institutions, and the [FDA]." This provision also requires a certification that a participating organization must "not currently and does not plan to be involved in sponsoring, operating, or participating in a clinical trial nor collaborating with another entity for the purposes of" doing so. This would seem to exclude most major research universities, which generally perform industry-sponsored, self-sponsored, and NIH-funded trials. This provision also expressly addresses privacy concerns of research subjects, setting forth that a participating organization hosting or providing such a data-sharing system must have "a description of the methodologies to be used to de-identify clinical

trial data consistent with" current or successor regulations in the Code of Federal Regulations, as well as "a plan in place to allow registered users to access and use de-identified clinical trial data."

- **Expanding Availability of Medicare Data.** The discussion draft permits "qualified entities" to provide (or sell at cost) their Medicare claims data or analyses to certain "authorized users," such as providers of services, suppliers, employers, health insurance issuers, medical societies, or other entities approved by the HHS Secretary. The Medicare information may be used for the purposes of "assisting providers of services and suppliers in developing and participating in quality and patient care improvement activities, including developing new models of care." The provision appears to be designed to enable providers to participate in quality improvement activities, employers to evaluate health insurance options for their employees, and health insurers to compare statistics on their own patients against the Medicare population at large. This proposal also provides for access to Medicare data and, at the HHS Secretary's discretion, Medicaid data by "qualified clinical data registries," which are data registries that allow for reporting of certain data related to the quality of physician services (part of a Centers for Medicare & Medicaid Services ("CMS") initiative that provides reimbursement incentives for physicians that improve quality). Under this proposal, the registries may receive such data "for purposes of linking such data with clinical outcomes data and performing risk-adjusted, scientifically valid analyses and research to support quality improvement or patient safety."
- **Empowering Patient Research and Better Outcomes Through CMS Data.** This provision requires the HHS Secretary to promulgate regulations that would allow government or "qualified researchers" to access de-identified "research-identifiable" CMS data files. For purposes of this provision, "qualified researcher means an individual with the education and experience necessary to design and conduct research properly, as determined by the Secretary, regardless of the individual's commercial or institutional affiliation."
- **Allowing Clinical Data Registries to Comply with HIPAA Privacy and Security Law in Lieu of Analogous Common Rule Provisions.** The draft requires the HHS Secretary to "establish an exception" to the Common Rule in regard to the privacy protections for research subjects. Under this provision, clinical trial data registries may, in lieu of complying with the Common Rule in this area, choose to comply with the Health Insurance Portability and Accountability Act ("HIPAA") privacy and security provisions.
- **Commission on Data Sharing for Research and Development.** This provision provides for the creation of a "Commission on Data Sharing for Research and Development" (the "Commission") by the HHS Secretary, with members to be appointed by the Secretary and congressional leaders. The purpose of the Commission is to provide recommendations to Congress on the following topics: (1) the development of a method by which health information about individuals participating in government health care programs (e.g., Medicare) or exchanges established under the Patient Protection and Affordable Care Act ("PPACA") may be shared with "qualified entities," which are organizations established under the PPACA to receive Medicare claims data from HHS for the purpose of evaluating provider/supplier performance; and (2) the development of a process for establishing a registry of clinical data.
- **Recommendations for Development and Use of Clinical Data Registries.** The discussion draft provides for the HHS Secretary to make recommendations regarding standards for clinical data registries generally (as opposed to the Commission, as defined and discussed above, which appears to concern itself with the creation of a single registry consisting of data on government pay or beneficiaries). This section requires the Secretary to consult with "manufacturers of drugs and medical devices" to seek information regarding how registries may be helpful for diseases treated or

managed by their products, thereby providing a potential avenue for industry to participate in the process.

- **Sharing of Data Generated Through NIH-Funded Research.** This provision allows the HHS Secretary to require those receiving a grant or other financial support from the NIH to "share with the public data generated through such research," subject to confidentiality and trade secret protections.
- **Accessing, Sharing, and Using Health Care Data for Research Purposes.** This section of the discussion draft amends the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH Act") to allow for the use and disclosure of protected health information by a covered entity for research purposes in a variety of circumstances. For example, one provision requires the HHS Secretary to authorize the disclosure of protected health information for research activities, including comparative effectiveness studies, similar to the disclosure that is permitted for public health purposes. This section also allows individuals to submit a "one-time valid authorization for the use or disclosure of protected health information of the individual with respect to all future research purposes," if certain informed consent requirements are followed.

Other Proposals Relevant to Clinical Research Stakeholders and Medicare Providers

As noted in Ropes & Gray's prior Alert, the discussion draft also includes a series of proposals to modernize clinical research regulations by clarifying the roles of central and local institutional review boards, minimizing overlap in the regulatory requirements applicable to human subjects research, and establishing a framework for companies to incorporate adaptive trial designs and Bayesian and other statistical methods into an effort to improve the efficiency of clinical trials.

Finally, the discussion draft contains several open-ended proposals relating to "Continuing 21st Century Innovation" at federal public health agencies, including the following proposals:

- **Improve the Medicare Local Coverage Determination Process** by reforming the Medicare local coverage determination process. The discussion draft itself asks the question "are there ways in which the [national and local coverage determination] process can work better for both the administration and those seeking coverage under the Medicare program?" The discussion draft also suggests provisions for seeking public comment in developing the local coverage determination processes that Medicare Administrative Contractors must follow, and the procedures that must be followed if a contractor issues a revised coverage determination.
- **Advance Telehealth Opportunities in Medicare** by requiring the Secretary to implement a methodology to provide for coverage and payment for certain telehealth services (such services to be defined based upon considerations listed in the discussion draft) to the same extent, and in the same amount, as would be provided for services performed in person.
- **Promote Medicare Price Transparency Regarding Site-of-Service** by establishing a searchable public website that provides Medicare beneficiaries with a list of items and services, the providers within a geographic area at which such treatments and services may be provided, and cost information associated with each item or service at each site.
- **Prevent the Implementation of the "Global Surgery Services Rule,"** preventing the Secretary from implementing or enforcing a rule that does away with bundled payments for surgeons.
- **Require CMS to Consider the Effects of Medicare Payment Changes on Provider Consolidation** by requiring the Secretary to seek and evaluate public comment regarding the extent

to which, and how, any proposed change to Medicare payment systems would affect provider consolidation.

Conclusion

The discussion draft represents only an early stage in the legislative process. Supporting materials released by the Committee emphasize the open-ended nature of this early draft legislation, stating that "[t]he release of the 21st Century Cures discussion document marks a new point in the discussion, but it is one that is far from over. Prior to introduction and throughout the legislative process, the committee requests specific feedback from all interested stakeholders about how to improve the legislation." As described in Ropes & Gray's prior Alert, the legislation has not yet been formally introduced in the House; the Senate's efforts are even more preliminary; and it remains to be seen what reforms Congress will be able to enact in the near term.

Ropes & Gray will continue to monitor developments related to this initiative. If you have any questions, please contact any member of our health care group or your usual Ropes & Gray advisor.