**Statement for the Record**
**Special Committee on Aging**
**United States Senate**
**Roundtable on Implementation of the Physician Payments Sunshine Act**
**September 12, 2012**

Chairman Kohl, Ranking Member Corker, members of the Committee, thank you for extending an invitation to the Association of Clinical Research Organizations (ACRO) and providing us an opportunity to share our concerns regarding Section 6002 of the Patient Protection and Affordable Care Act (PPACA), otherwise known as the Physician Payment Sunshine Act.

My name is Doug Peddicord and I serve as Executive Director of the Association of Clinical Research Organizations (ACRO) which represents the world's leading clinical research organizations (CROs). Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices, from pre-clinical, proof of concept and first-in-man studies through post-approval and pharmacovigilance research. With more than 75,000 employees engaged in research activities around the world, ACRO advances clinical outsourcing to improve the quality, efficiency and safety of biomedical research. Each year, ACRO member companies conduct more than 11,000 clinical trials involving nearly two million research participants in 115 countries.

For CROs, nearly all payments made to physicians and teaching hospitals on behalf of applicable manufacturers are "pass-throughs" for research; that is, the conduct of clinical trials. On average, each of our member companies works with more than 500 research sponsors – applicable manufacturers – annually, so we have a broad and unique understanding of how research payments are made.

For today's Roundtable, I will focus my comments on research and the payments made for basic research activities – for screening and recruiting patients, for engaging with the individual in the informed consent process, for administering test articles and monitoring patient reactions, for performing medical procedures, record-keeping and data submission, and the myriad activities involved in following a research protocol that is meant to produce accurate data for the evaluation of the safety and efficacy of a new drug, biologic or medical device by the FDA and other regulators.

Let me begin by saying that ACRO has argued and continues to believe that fair-market payments made for legitimate research activities should have been excluded from the provisions of Section 6002. Quite unlike payments or other transfers of value that might support activities that benefit (and potentially influence) physicians and teaching hospitals without requiring an actual exchange of value between the payor and the payee, payments made to support or purchase clinical research activities from physicians and teaching hospitals are, simply, fair-market payments for goods (e.g., laboratory tests) and services (e.g., physical examinations). Several state statutes regulating "sunshine" already exclude reporting requirements for payments for bona fide research activities and we believe that the inclusion of such payments in sunshine reporting will, inadvertently, create a disincentive for physicians and

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teaching hospitals to participate in the clinical research that produces new drugs and new treatments for the patients who need them. We are not opposed to "sunshine" and greater transparency in how dollars flow from the biopharmaceutical industry to physicians and teaching hospitals – but we are very much concerned that failing to exempt payments for legitimate research activities from the requirements of CMS's proposed rule will have deleterious effects on the research enterprise in the United States.

In fact, survey research conducted in 2010 showed 24 percent of the doctors in the U.S. who conduct clinical research would be less likely to participate in the research if revenues (not revenues in excess of expenses or "profits" but gross revenues which is what CMS's proposed rule requires) were disclosed. We believe the reason for this is because the data has great potential to be misrepresented. And if that is the case, the U.S. faces the potential loss of one-quarter of its clinical investigators, which will slow innovation and delay the delivery of needed treatments for patients.

With our concern for the research enterprise in mind, ACRO looks forward to working with Senators Kohl and Grassley, other stakeholders and, most importantly at this point, CMS to ensure implementation of a rule that achieves the goal of producing a "sunshine" that will illuminate the landscape for patients and other consumers, be fair to physicians and teaching hospitals, AND facilitate desperately needed clinical research.

Direct and Indirect Research Payments

Having reviewed with CMS staff in May 2011 the complexity of the flow of research payments from manufacturers and CROs through a wide variety of vendors and intermediaries to a terminus, typically, at the teaching hospital or physician practice group, (see the attached chart,) ACRO recognizes the December 2011 proposed rule's attempt to capture that complexity by introducing the notion of *direct* and *indirect* research payments. **Regrettably, however, we are entirely confused by the methods the proposed rule suggests for reporting research payments**. Acknowledging that such reporting is likely to be complicated, the rule variously indicates that:

- *direct* research payments would reflect total payments made by manufacturers or CROs to covered recipients, including all items and activities associated with the research project, not only the physician's time and services;
- payments that include both *direct* and *indirect* research payments would report (the same?) total costs paid to teaching hospitals and ultimately to physician covered recipients, regardless of whether a salaried physician actually receives any actual income for the conduct of the research;
- payments made to clinics, hospitals (except for teaching hospitals) and other organizations that facilitate the conduct of research, such as site management organizations (SMOs), that are reported under the rubric of *indirect* research "should also include the name of the entity or individual that received the payment", which presumably means that HHS will have in its data a multitude of non-covered recipients, from physician practice groups to non-teaching hospitals to SMOs; and

- "end users would understand" that total payments made to teaching hospitals would include a wide range of goods and services, but that attributing full research payments to individual physicians "could be misleading" and that HHS will figure out a way to not include such total payments into the aggregated payment amount attributed to an individual physician.

Not only are the requirements for the reporting of *direct* and *indirect* research payments inconsistent, misleading and sometimes frankly contradictory, ACRO believes that requiring the reporting of many *indirect* payments would exceed the specific legislative language of the Act relating to payment or other transfers of value. Under the Act, manufacturers are required to report indirect payments and transfers that are made to a third party *at the request of the physician or designated on behalf of the physician.* But many payments related to research, such as travel and food costs, *are not made at the request of a covered recipient or designated on behalf of a covered recipient*, but are entirely incidental and thus, we believe, not reportable under the Act. For instance, if physicians participating in a multi-site clinical trial program travel to an investigator meeting to review and train on the research protocol, as is typical and necessary, any travel or food or other related costs of the meeting occur incidentally to the physician's participation in the research project, and are neither "requested by" nor "designated on behalf of" the physician – typically such costs are not even attributed to individual covered recipients (i.e., to Dr. Jones as opposed to Dr. Johnson, at a meeting that includes 20 physicians) for accounting purposes. Similarly, the proposed rule's intention to capture payment data relating to non-covered recipients, such as non-teaching hospitals and SMOs, exceeds the legislative authority conveyed by Sec. 6002.

Related to the issue of *direct* and *indirect* payments for research, the proposed rule presumes a level of visibility by manufacturers and CROs into medical practices and hospitals involved in the conduct of clinical research programs that simply does not exist today. We believe that CMS should replace the proposed standard for research payments or transfers of value with a regulation that provides that in instances where a manufacturer (or CRO on its behalf) does not know the value of specific payments or imputed benefits that are presumed to flow to individual covered recipients and the payment or transfer is not made at the request of a covered recipient or designated on behalf of a covered recipient, such payments or transfers are not reportable. To illustrate, to the extent that a manufacturer's visibility into payments for research stops at the physician practice group or teaching hospital – and does not continue down to the specific dollar amount (whether gross or net 'payment') that ultimately flows to investigator A or B or C, the report that should be made to the Department by the manufacturer is of the total amount paid to covered recipients and there should not be any further effort required to derive or impute sub-amounts or divisions among physician recipients, to the extent that the manufacturer is not aware of those payments or transfers of value today.

In brief, ACRO believes that CMS would do best to 'go back to the drawing board' in its proposals for the tracking of research-related payments and transfers of value – and that it do so by starting with the principle that payments and transfers of value pertaining to research should be tracked and reported to the level of visibility that exists today. Because of the

confusing and highly complex reporting requirements proposed, and resulting inability for us to comment constructively on an understandable and tangible proposal, we strongly urge CMS to issue a second proposed rule for comment before moving to finalize a regulation to implement the Act.

CMS's misunderstanding regarding manufacturer visibility into the details of payments and transfers of value for research services displayed in the proposed rule would create an enormous compliance burden, not only for manufacturers but on the physicians and hospitals who would be asked to report back to manufacturers the distribution of both *direct* and *indirect* payments to-the-penny, because that is the level of transparency that manufacturers will now believe they must have. Related to this point, we note that in its estimate of compliance costs CMS projects only minimal costs for physicians and hospitals relative to their 'review' of payment amounts reported by manufacturers, a paradigm that we believe misses entirely the very substantial costs that will be incurred by covered recipients in order to put in place new financial tracking systems and to create a level of detail ('transparency') that is considered unnecessary today. In practical terms, the proposed rule would force physicians to function as accountants or auditors to verify financial information that has nothing to do with the delivery of care or conduct of research within a medical practice or hospital.

The proposed rule takes the approach that what the Act calls "natures of payment" should be considered and reported in segregable categories. We disagree. ACRO believes that all payments and transfers of value associated with a research project should be aggregated under the category of *research*, even if some of the transfers of value come in the form of food, travel, equipment, and the like. Simply, if a payment or transfer of value occurs incidentally to a research project – again, if physicians participating in a multi-site clinical trial program travel to an investigator meeting to review and train on the research protocol – the transfer of value would not occur at all absent the physician's participation in the research project. Thus, to the extent that such payments or transfers are tracked to specific covered recipients, we believe the travel, food and other costs should be reported as *research* payments. By contrast, the Agency's proposal to allocate such costs across multiple physicians would be arbitrary and expensive, and provide minimal value to an individual trying to understand payments for research from manufacturers to physicians and teaching hospitals.

One specific impact of the proposed rule's contrary approach of segregable categories is that manufacturers would report *research* payments that could be delayed from publication for up to four years, even as the arbitrarily associated payments made for research-related food and travel would be separated and made publicly available in the normal reporting cycle; a distinction that would be misleading and inconsistent with the intent of the law to protect competitive information.

As an alternative, CMS might consider narrowly defining *research* to exclude products which have not yet been approved for any use by the FDA. Likewise, *research* that is mandated by the FDA or another regulatory authority, such as REMS (risk evaluation and mitigation strategies) studies or the maintenance of a registry to which physicians contribute data might also be

exempted. A narrow definition of *research* would significantly reduce the regulatory burden, protect highly-sensitive competitive information and still address the Act's intent to limit a perception of undue influence on physicians.

Finally, ACRO is very much concerned that under the proposed rule the payment and transfer of value data related to *research* to be reported to the Department, and ultimately to the public, is likely to be incomplete at best, terribly inaccurate at worst. We are specifically concerned about the potential for double and even triple counting of research payments that flow "directly" to teaching hospitals and "indirectly" to intermediary organizations such as SMOs and then "indirectly" again down to physician investigators. We agree with the AMA and other physician societies that "CMS's proposal to estimate or impute attribution even when there is no direct transfer or a qualifying indirect transfer is beyond its statutory authority, violates basic principles of due process, and is inconsistent with congressional intent… "

Selected other concerns:

In the proposed rule, *covered recipient* means—"(1) Any physician, except for a physician who is an employee... of an applicable manufacturer...." But CMS makes clear that in regard to *research* CROs make payments on behalf of manufacturers and can be treated interchangeably with manufacturers; for example, payments are made to an institution conducting research "either by an applicable manufacturer or a CRO entity." Just as physicians who are employees of applicable manufacturers are excluded from the definition of "covered recipient," so also physicians who are employees of a CRO or who provide research services on a contract basis to a CRO should be similarly excluded.

For example, CROs employ and contract with physicians as medical directors and medical monitors, and as investigators in Phase I clinical trial units, but none of these physicians are receiving "payments or other transfers of value" consistent with the intended meaning of the Act. CRO physician employees and contractors are certainly not receiving either *direct* or *indirect* payments or transfers of value from manufacturers for research services, but instead are working for the CRO, just as a physician working for a manufacturer is. Thus, we believe that (1) above should read, "Any physician, except for a physician who is an employee... of an applicable manufacturer**, or in the case of payments or transfers of value for research, an employee of or a person who provides research services on a contract basis to a CRO entity**; or".

Reporting and the Costs of Reporting

While the proposed rule contains 'templates' for the reporting of payments/transfers of value and ownership/investment interests, ACRO continues to believe that a template that clearly encourages standardized reporting by manufacturers is required at this point. Today, every applicable manufacturer has its own specific format for how it wants to see payment information. As a result, there is an enormous lack of consistency within the industry, and a great deal of cost being incurred by all, including manufacturers, CROs, hospitals, and

physicians. Consistency in format would not only reduce costs incurred by the affected parties but, as importantly, would likely produce more complete and more accurate data to be made available publicly by the Department.

Timing of Implementation

Finally, the proposed rule appears to presume that the reporting of payments and transfers of value can be easily implemented within 90 days of a final rule being issued. We submit this is not the case and there should be a lag of at least 15 months, as envisioned in the legislation, before reporting is required. Because the financial systems of research and healthcare organizations are designed for calendar year reporting, ACRO strongly believes that reporting of payments and transfers of value related to research should begin at the beginning of a calendar year, with the first reports due in March of the following year. Initiating the system with partial year reporting would not only be impractical and costly, but likely to lead to non-representative, potentially misleading data.

ACRO appreciates this opportunity to participate in today's Roundtable and we look forward to working with CMS and the affected industry toward developing a reporting system that supports transparency without creating undue compliance burdens for those involved in the development of new biomedical products.