



TPA NETWORK **Research Consortium**

assists with Emergency Surgery that Saves ERISA Plan Sponsors from Further Taxation Without Representation?

It's only fitting that last night, on the 246th anniversary of the Boston Tea Party protest against *taxation without representation*, ERISA Plan Sponsors won a victory that will end a decade of PCORI *fee* payments to the IRS for research that doesn't benefit them: the multi-billion dollar *Patient-Centered Outcomes Research Institute* reauthorization has been finalized and PCORI can now fund research that considers *cost, price and value*...research of critical importance to Plan Sponsors wanting to transition to a value-based model and comply with ERISA's requirements to safeguard plan assets. *Taxation without representation* has ended and finally, funding will be available to conduct research on topics of value to ERISA Plan Sponsors who live in the real world where plan assets are limited, and resource allocation decisions are not an option.

What's a PCORI?

A byproduct of the Affordable Care Act, PCORI helps patients "make informed healthcare decisions...and improve healthcare delivery and outcomes" by sponsoring patient-centered *comparative effectiveness research* (CER) to determine which drugs, treatments and devices work best and which are ineffective. Indeed, PCORI introduced a new way to understanding value in healthcare by showing that group/average-based treatment benefits are inadequate to guide clinical decision making *at the individual level* and that determining treatment effectiveness must necessarily consider a patient's individual characteristics, perspective and preferences. PCORI does good work. So far, so good.

The Challenge for ERISA Plan Sponsors

The regulatory compliance burden imposed by ERISA on Plan Sponsors may be more encompassing, burdensome and onerous than those imposed on health insurers and managed care entities. Further, the transition to value-based healthcare - and the handling of new medical technologies, innovations and treatments in the new setting - creates special concerns for ERISA Plan Sponsors that don't exist for other payors. In a value-based construct not all health care services are treated alike with respect to freedom of access, reimbursement or choice and decisions regarding their use and coverage require TPAs and Plan Sponsors to rely more heavily on rare evidence-based, payor-oriented research to support their decisions on everything from plan design to financing to compliance. Responsible for the prudent, equitable, reasonable and non-discriminatory use of ERISA plan assets, it is incumbent upon Plan Sponsors to consider all measures of efficacy, quality of life, cost, price, value and patient preference in their assessment of almost everything pertaining to their plan. Unlike the ACA/PCORI designers, ERISA Plan Sponsors live in the real world where plan assets are limited, and resource allocation decisions are not an option. The research funded by PCORI does little to help ERISA Plan Sponsors make the difficult decisions that they are forced to make. In our view, making ERISA Plan Sponsors pay for such research amounts to *taxation without representation*.

Changing PCORI's Research Funding Scope

The torrent of new drugs, medical technologies and health innovations being put into clinical use is estimated to account for 30% of the increase in healthcare costs. Providers, patients and payors alike find it difficult to distinguish which treatments are best or most effective, or if a new drug/treatment is actually *better than* available options; few can actually determine if an item is worth the added *cost* or if it represents a *value*...but we must try.

When the ACA was designed the move to a value-based healthcare model had just begun. PCORI was created to fund novel *patient-centric* research. Today, our thinking about healthcare has evolved to focus equally on fair ways to allocate our limited healthcare dollars and measures like *safe* and *effective* are no longer adequate by themselves to assess medical treatment options. On a population level we're fine with *cost-effectiveness* to measure value as it is comparative in nature; assesses the relative impact of expense of various health interventions; and measures incremental differences in quality attributable to the intervention vs. an alternate choice. The difficult challenge for ERISA Plan sponsors is how to employ cost-effectiveness and other such value measures at the patient level.

A \$3+ Billion Research Facility...that Doesn't Benefit its Plan Sponsor Taxpayer Funders

Form 720 (Rev. April 2019) Department of the Treasury Internal Revenue Service		Quarterly Federal Excise Tax Return ▶ See the Instructions for Form 720. ▶ Go to www.irs.gov/Form720 for instructions and the latest information.		OMB No. 1545-0023		
Part II						
Patient-Centered Outcomes Research Fee (see instructions)						
IRS No.	Specified health insurance policies	(a) Avg. number of lives covered (see inst.)	(b) Rate for avg. covered life	(c) Fee (see instructions)	Tax	IRS No.
133	(a) With a policy year ending before October 1, 2018		\$2.39		}	133
	(b) With a policy year ending on or after October 1, 2018, and before October 1, 2019		\$2.45			
	(c) With a plan year ending before October 1, 2018		\$2.39			
	(d) With a plan year ending on or after October 1, 2018, and before October 1, 2019		\$2.45			

Much of PCORI's funding comes from a per capita "fee". For 2019, the tax for a plan with 500 employees/dependents is \$1,225/plan (payable to the IRS from other than plan assets).

Research of use to payors must consider cost-effectiveness, ROI, value vs. the standard of care, etc. At issue is the fact that the PCORI model has significant codified constraints that put it at odds with the type of research needed to perform

value-base healthcare assessment by ERISA payors. Presently, PCORI's research is not useful to Plan Sponsors interested in pursuing value-based healthcare or complying with ERISA's requirements re: the prudent, equitable, reasonable and non-discriminatory use of plan assets. And a lot of money is involved: we estimate that the aggregate PCORI tax paid by the Plan Sponsor clients of a typical mid-size TPA is between 1/3 and \$1 million, annually.

The Sausage-Making Legislative Process

As with anything in health care, PCORI has its supporters and detractors. Some claim that its work amounts to interfering with medical decision-making; that PCORI-based decisions may cause delayed, denied, limited, rationed or sub-optimal coverage/treatment. Others believe its funding must be sourced elsewhere. ERISA Plan Sponsors feel PCORI's inability to fund research that considers *cost, price and value* amounts to *taxation without representation*.

When you give away \$2.5 billion there are lots of folks wanting to protect their interests and overnight, several initiatives emerged on all sides of the issue when PCORI funding was at stake. Everyone was involved in this event. Defund, restructure, repurpose, reauthorize: all were on the table. No less than the Senate Finance, Health, Education, Labor and Pensions Committees and the House Ways & Means, Energy and Commerce Committees took part. Law firms and lobbyists representing ~ 200 medical, healthcare and bureaucratic benefactors weighed in as well as the big benefit firms, biopharma and life science companies, patient and family caregiver organizations, and groups like America's Health Insurance Plans, the Blue Cross Blue Shield Association and the U.S. Chamber of Commerce.

Individual bills that addressed PCORI reauthorization were introduced by various Congressional sponsors as well as "health extender packages" designed to be included in a FY2020 funding package. Some wanted to discontinue PCORI funding from the Medicare Part A and Part B Trust Funds; the Grassley-Wyden bill had provisions to refund the PCOR Trust Fund and Senators Pat Toomey (R-PA) and Mike Crapo (R-ID) introduced S. 3001 that sought to eliminate both the Medicare Trust Fund and the PCORI fee. We examined all available proposals and were most impressed by the stand-alone bi-partisan bill sponsored by Senators Warner (D-VA), Cassidy (R-LA), Van Hollen (D-MD) and Capito (R-WV). It was targeted legislation that included provisions supportive of ERISA Plan Sponsors plus added reporting requirements to support greater accountability/transparency; new governance rules to ensure greater payor representation on the board; and accounting changes to eliminate double counting, etc.

We elected to be as apolitical as we could and to focus our message on support for one singular position: that **PCORI must either expand the scope of the research it funds to include cost, price and value studies of value to ERISA Plan Sponsors...or end the PCORI fee and the *taxation without representation* of ERISA Plan Sponsors.** Nothing is easy or simple within the Beltway and the paperwork needed to reauthorize PCORI is headed to the House floor as a part of a dozen bills and then on to the Senate. The H.R. 1865 FY2020 Appropriations package contains *SEC. 104. Extension of Appropriations to the Patient-Centered Outcomes Research Trust Fund: Extension of Certain Health Insurance Fees* and this language that expands PCORI's research scope. *It's not perfect, but it's a good start.*

Consideration of Full Range of Outcomes Data. Research shall be designed, as appropriate, to take into account and capture the full range of clinical and patient-centered outcomes relevant to, and that meet the needs of, patients, clinicians, purchasers, and policymakers in making informed health decisions. In addition to the relative health outcomes and clinical effectiveness, clinical and patient-centered outcomes shall include the potential burdens and economic impacts of the utilization of medical treatments, items, and services on different stakeholders and decision-makers respectively. These potential burdens and economic impacts include medical out-of-pocket costs, including health plan benefit and formulary design, non-medical costs to the patient and family, including caregiving, effects on future costs of care, workplace productivity and absenteeism, and healthcare utilization.”.

For H.R. 1865's full text: www.researchconsortium.org/files/pcori-reauthorization-bill-text-121719-noon-pst.pdf

TPA NETWORK **Research Consortium**

As a part of our decades-long legacy of supporting TPAs and ERISA Plan Sponsors, we harnessed a group of industry veterans to collaborate and create an independent research facility purpose-built to study topics of value to ERISA Plan Sponsors by focusing on cost-effectiveness, ROI, value vs. the standard of care and patient outcomes/preference.

The founder of the **Research Consortium** helped to power a 35-year-old consultancy that has first-hand experience with the legislative process as it once represented 200 TPAs and five million plan participants at hearings before the U.S. Congress, Committee on Ways & Means on legislation that threatened TPAs. Since then, we've stayed involved with similar initiatives and when we learned that PCORI's funding was soon ending, we suited up. Below is a sample of our message to a few of the key legislators who were involved with this reauthorization effort.

Dear Senator Warner, Senator Cassidy, Senator Van Hollen and Senator Capito,

Thirty years ago, I testified before the U.S. House of Representatives, Committee on Ways & Means on behalf of 200 Third Party Administrators of self-funded benefit plans and their plans' five million participants. The health insurance industry has undergone significant consolidation since 1989 and, while this correspondence represents the consensus of a far fewer number of TPAs, today they manage plans for several million self-funded ERISA plan participants.

Our viewpoint complements those of AHIP, BCBSA, the American Benefits Council and the U.S. Chamber of Commerce. We support the measures in your Patient-Centered Outcomes Research Institute (PCORI) Reauthorization Act however please know that the perspective and interests of ERISA Plan Sponsors is different than those of other commercial payors.

The 10-year multi-billion-dollar reauthorization of an entity that some feel has not "sufficiently demonstrated its value under the limitations with which it has operated" is the rightful concern of every taxpayer. It is of special concern however to ERISA Plan Sponsors as the billions of dollars required to fund PCORI comes in part from fees paid to the IRS by them, health insurers and HMOs. Indeed, ERISA Plan Sponsors make a convincing argument that they are the victim of *taxation without representation* in that they pay for PCORI research but derive no benefit from it. *This is because PCORI-funded research fails to consider cost, price and value metrics and measures.* Unlike health insurers and MCOs, ERISA Plan Sponsors are required *by federal law* to use their limited plan assets in a prudent, fair, reasonable and equitable way. For them, making resource allocation decisions is not an option. In an ERISA ecosystem, the research that PCORI funds is of little value to TPAs or Plan Sponsors, who must *always* consider the financial consequences of their every action.

This correspondence is intended to convey the concern of the thousands of ERISA Plan Sponsors who pay PCORI fees for research that is of little value to them. Much has changed since PCORI's creation and your proposed broadening of the type of research that PCORI will be able to fund is an important first step toward enabling it to continue its good work and fulfill its mission, *for all its constituents.* The language contained in your mark-up is intended to expand the scope of PCORI's research to include studies that involve cost, price and value. This will enable research organizations like ours, the **Research Consortium**, to seek funding to conduct important health plan research of value to ERISA Plan Sponsors.

We appreciate your considering our views on the reauthorization of PCORI and welcome any opportunity to be of further help. We commend you on your bipartisan efforts in support of healthcare research and encourage you to finalize this reauthorization soon so PCORI can begin funding payor-focused, value-oriented research for ERISA Plan Sponsors.

Respectfully,

Richard L. Nicholas
for TPA NETWORK **Research Consortium**
& the TPA/ERISA Plan Sponsor Community

