From: Greg Segal
To: HRSA Paperwork
Cc: Jennifer Erickson
Subject: [EXTERNAL] OPTN Data Directive Public Comment
Date: Monday, December 30, 2024 11:32:39 AM

December 30, 2024

Carole Johnson
Administrator
Health Services Resources Administration (HRSA)
5600 Fishers Lane
Rockville, MD 20852

Dear Administrator Johnson,

We write today in full support of HRSA's proposed modifications to the Ventilated Patient Form (VPF).

For years, we have joined other patient groups, leading researchers, front-line physicians, equity leaders (e.g., ACLU), pro-reform OPOs, staffers spanning the Clinton-Bush-Obama-Trump administrations, and Congressional leaders (see Senate Finance Committee, and leaders of the House Oversight Committee and the Congressional Black Caucus) in advocating for OPO process data to be available to the government and the public.

For context, the U.S. is the only mature international transplant system that does not require the publication of OPO process data, which is, in part, why our system has been such an unmitigated failure, plagued by conflicts of interest, inequitable care delivery, and what the New York Times editorial board characterized as *"an astounding lack of accountability and oversight in the nation's creaking, monopolistic organ transplant system [which] is allowing hundreds of thousands of potential organ donations to fall through the cracks."*

Process data will also help support smooth enforcement of the OPO rule – which has received broad praise from Congress and patient groups in concept, although has also drawn years of questioning from Congress regarding whether HHS has taken the necessary steps to prepare for rule enforcement.

Such process data will not only serve as a backbone to withstand legal challenges from the OPO industry, which has a history of attempting to obstruct patient-centric reforms; it will also help inform a data-driven criteria for competition so that CMS can best pair high-performing OPOs with the territories they are best positioned to improve.

We understand that entrenched industry interests – both directly, as well as through their well-trod strategy of lying to patients in order to incite them to lobby against their own interests – are fighting against the publication of such process data, given that OPOs feel so clearly threatened by transparency and accountability.

We also understand that such OPO opposition to patient-centric transparency is rooted in a disingenuous invoking of a supposed "reporting burden." In response, we note that – as the House Oversight Committee noted in oversight letters after investigative reporting found that OPOs were intentionally obstructing Congress's requests for such process data – CMS, via CFR § 486.328, already requires OPOs to collect and maintain all of this data, though, inexplicably, has never required OPOs to report it.

Given this, all we are discussing here is whether OPOs should have to transmit this data to the government – a process which, as has been demonstrated as entirely feasible by a collaboration between

the Massachusetts Institute of Technology (MIT) and six pro-transparency OPOs. In fact, the transfer itself took less than an hour, and has already enabled peer-reviewed research that can point to life-saving system improvements.

In summary, the publication of OPO process data:

- Is central to ensuring safe, effective, and equitable care delivery (e.g., OPO process data will allow visibility into the ways in which OPOs deprioritize care delivery for non-white, rural, and veteran patient populations);
- Will help facilitate smooth, data-driven enforcement of the OPO rule;
- Does not actually create any reporting burden (counter to disingenuous lobbying points from industry interests) given existing CMS regulations requiring all OPOs to already collect and maintain all of this data via (CFR § 486.328);
- Is broadly supported by Congress and patient groups; and
- Is a well-established international best practice, including and especially in countries where the transplant system is not plagued by corruption, abuse, inequity, fatal performance failure, Medicare Fraud, and egregiously high kidney discard rates.

We urge HRSA to move urgently to finalize this lifesaving rule, and not to allow corrupt contractors to once again evade accountability.

Yours sincerely,

Greg Segal
Organize, CEO
Patient family member

Jennifer Erickson
Federation of American Scientists, Senior fellow
Patient family member