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PHYSICIAN CLINICAL REGISTRY COALITION

November 21, 2022

Submitted Electronically via www.regulations.gov

Attention: Commercial Surveillance ANPR, R111004
The Honorable Lina Khan
Chair
Office of the Secretary
Federal Trade Commission
600 Pennsylvania Avenue NW
Suite CC-5610 (Annex B)
Washington, DC 20580

RE: Physician Clinical Registry Coalition's Comments on the Commercial Surveillance ANPR, R111004

Dear Chair Khan:

The undersigned members of the Physician Clinical Registry Coalition (the "Coalition") appreciate the opportunity to comment on the Federal Trade Commission's ("FTC's") advance notice of proposed rulemaking ("ANPR") entitled "Trade Regulation Rule on Commercial Surveillance and Data Security."[1] The Coalition is a group of medical society-sponsored clinical data registries that collect and analyze clinical outcomes data to identify best practices and improve patient care. We are committed to advocating for policies that encourage and enable the development of clinical data registries and enhance their ability to improve quality of care through the analysis and reporting of clinical outcomes. All of the members of the Coalition are tax-exempt nonprofit organizations.

Clinical data registries collect and aggregate data, including protected health information ("PHI"), from health care providers primarily for purposes of facilitating research and improving the quality of the procedures or treatments covered by the registry. Clinical data registries perform data aggregation and related benchmarking analyses that support one or more predetermined scientific, clinical, or policy purposes, including, but not limited to, describing the natural history of disease, determining the effectiveness (including the comparative effectiveness) of therapeutic modalities, and measuring quality of care to identify best practices. Clinical data registries provide appropriately de-identified real-world evidence to support their members' quality improvement efforts, as well as research projects.

[1] Trade Regulation Rule on Commercial Surveillance and Data Security, 87 Fed. Reg. 51,273 (Aug. 22, 2022).

The federal government, health care products manufacturers, and state and local governments have increasingly come to rely on clinical data registries for a wide variety of purposes. For instance, clinical data registries report medical and clinical data to the Centers for Medicare and Medicaid Services ("CMS") on behalf of their participating health care providers for purposes of the Merit-based Incentive Payment System ("MIPS") program and for more general patient and disease tracking. In addition, the Food and Drug Administration ("FDA") has been encouraging drug and device manufacturers to work with registries to conduct investigational and post-approval surveillance studies to ensure that both unapproved and approved drugs and devices are safe and effective.

Appropriate collection and use of "protected health information" (as defined by the Health Insurance Portability and Accountability Act ("HIPAA") Privacy Rule) is the foundation of any clinical data registry. In collecting data on specified outcomes submitted by physicians, hospitals, and other types of health care providers related to a wide variety of medical procedures, diagnostic tests, and/or clinical conditions, registries typically act as business associates (as defined by HIPAA) of their participant/covered entities. In such cases, clinical data registries are required to comply with the same HIPAA Rules as their health care provider participants. Thus, clinical data registries must enter into HIPAA-compliant business associate agreements with each of their participating hospitals and medical practice groups to ensure that they protect the PHI they collect in accordance with the HIPAA Rules.

Requiring entities covered by the HIPAA Rules to comply with duplicative and redundant privacy or security laws promulgated by the FTC would create unnecessary burdens on the quality improvement and research activities of clinical data registries. **We, therefore, urge the FTC to exempt clinical data registries that are required to comply with HIPAA from any rule on commercial surveillance and data security promulgated by the FTC.** Such exemption would support a strong registry environment that leads to critical insights about quality and patient outcomes.

In addition, the Coalition urges the FTC to adopt an exception to its contemplated privacy rule for tax-exempt, nonprofit organizations. This will ensure the FTC's rule is consistent with the consumer privacy laws adopted by numerous states, including California.

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The Coalition appreciates the opportunity to submit these comments. If you have any questions, please contact Rob Portman or Leela Baggett at Powers Pyles Sutter & Verville, PC (Rob.Portman@PowersLaw.com or Leela.Baggett@PowersLaw.com).

Respectfully submitted,

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American Academy of Otolaryngology – Head and Neck Surgery
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons
American College of Emergency Physicians
American College of Gastroenterology
American College of Rheumatology
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American Society of Plastic Surgeons
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Center for Professionalism and Value in Health Care
College of American Pathologists
Congress of Neurological Surgeons
Society of NeuroInterventional Surgery