

June 7, 2016

Dr. Maria Ellis
7500 Security Blvd.
Baltimore MD 21244
Email: Maria.Ellis@cms.hhs.gov

Dear Ms. Ellis,

RE: MEDCAC 2016 Pertaining to Lower Extremity Chronic Venous Disease and Venous Registries.

As an executive officer on the Board of Directors of the American College of Phlebology (ACP), the largest society of physicians and allied health care providers involved in venous disease in North America, I reviewed the questions posed for the MEDCAC meeting slated for July 20, 2016.¹ As part of this review, I performed due diligence by reviewing the transcript from the Peripheral Artery Disease MEDCAC meeting in 2015.² I noted that a presentation on registries was highly valued as an important topic during that session.

In this letter, I would like to describe the ACP Venous registry and make a request to have a dedicated lecture on all of the venous registries presented during the 2016 MEDCAC.

In 2012, the ACP Foundation funded a "Practice Based Evidence (PBE) Research Initiative" that has become the ACP Patient Report Outcome (PRO) Vein registry.³ The ACP PRO Vein registry was developed for scientific purposes. The guiding principles centered around eliminating duplicate entry, and coupling the patient's voice (using generic & disease specific queries) with the routine documentation of clinical vein practice.

ACP PRO Vein registry roll out began after beta-testing in November of 2014. At present, ACP PRO Vein has audited the data of two (2) vein specific EMR vendors who are active participants, and has two additional large multi-practice companies in final steps of compliance that will bring hundreds of additional providers on board in the next twelve months. At the time of this letter, over 10,000 unique patients have been captured. ACP PRO Vein has over 95 NPIs from 29 states in the registry currently and the database is growing at a substantial pace.

A unique feature of the ACP PRO Vein Registry is its coupling patient perceived outcomes with the routine documentation to allow for all of the following:

- Rich epidemiology assessments of a disease process: This allows us to compare burden of disease among different disease patterns, specific patient populations, etc.;
- Best practices may be established based upon patient perceptions and incidence of complications, etc.;

¹ <https://www.cms.gov/medicare-coverage-database/details/medcac-meeting-details.aspx?MEDCACId=72> (last accessed 29-MAY-2016)

² <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/downloads/id70e.pdf> (last accessed 29-MAY-16)

³ https://atlas.liaisonhealthcare.com/domo/dashboards/ACP_PRO_Venous_Registry/main.dashxml#cordaDash=1013 (last accessed 29-MAY-2016)

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- Benchmarking reality as every license comes with a dashboard demonstrating how a provider's patients respond in disease severity with PRO responses over time compared to the aggregate;
- Patient reported outcome (PRO) data allows for complex cost effectiveness & comparative effectiveness calculations to become a reality;
- Automated data uploading from practice sites, which is unique among venous registries currently available.

At the present time, there are three (3) vein specific registries. At a scientific meeting in February, data from each of the two other registries, the Society of Vascular Surgery Vascular Quality Initiative (SVS/VQI registry) and the Heart and Vascular Outcome Research Institute administered Venous Patient Outcome Registry (VPOR) was presented and the data demonstrated substantial differences. As a highlight the SVS/VQI report, mostly thermal ablation was performed a large fraction using general anesthesia in an operating room. In the VPOR, no general anesthesia was employed, and a mix of different techniques of saphenous vein ablation was utilized. These two registries with intentions of reporting vein specific outcomes possess different provider make up, each with their own respective selection bias making interpretation and comparisons difficult.

As background, I will summarize features of the three registries below and offer what might be a clearer picture on how to understand the vein specific registries moving forward:

	ACPPROVEIN Registry	SVS/VQI	VPOR
Society Sponsor	ACP	SVS	HVORI
Disease States	CVI/SVI/Lymph soon to involve Deep Vein Procedures/Pelvic Procedures	CVI/SVI/IVC filters/Stenting	CVI/SVI/Stenting/Pelvic Procedures
Duplicate Entry Avoided	Yes (many vendors 100% cases shared)	Largely manual entry	No
Physician Users	Diverse	Predominately Surgeons	Diverse
Data Focus	Epidemiology & Procedural	Mostly procedural	Mostly procedural
PRO Queries	Yes	No	No
Queries – Vein Specific	SQOR-V & HASTI symptoms	Limited	Limited
Benchmarking	Yes	Yes	Not clear
PSO Affiliation	No	Yes	Not clear
CMS Recognized Scientific Registry	Yes	Not clear	Not Clear

ACP physicians believe that scientific registries will provide robust data to help shape coverage determination policies as the burden of chronic venous disease patterns and treatment outcomes are better characterized. It is my sincere hope that this letter sheds light on how societies, including the ACP, are helping to address concerns with regard to care of patients within the Medicare program by all stakeholders, including patients, providers, payers, and industry.

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The ACP PRO committee of the ACP believes it would be ideal for representatives from both the ACP PRO Vein and the SVS/VQI registries to present to the MEDCAC panel to demonstrate what registries are being used, their relative advantages and disadvantages and what opportunities venous registries in general offer to better understating chronic venous disease and treatment outcomes among Medicare patients.

I welcome any questions you may have upon reviewing this material and thank you in advance for your time and consideration of this request.

Respectfully shared,

Marlin W. Schul, MD, RVT, FACP
Treasurer, American College of Phlebology
On behalf of the ACP PRO Venous Registry

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