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March 1, 2018

Demetrios Kouzoukas
Principal Deputy Administrator and Director
Center for Medicare

Re: Docket ID: CMS-2017-0163

Dear Mr. Kouzoukas:
At 4am on July 3, 2006 my 80-year-old mother rushed franticly into my bedroom- something was wrong with my father.

My parents, both in their early 80s and still active and independent, had surprised us with a visit over the holiday weekend as they traveled from southern New York back to their home in Vermont. It was my oldest daughter's birthday, and we prepared a nice dinner for them, and Mom and Dad enjoyed catching up with us and playing with their young grandchildren. At about 9pm my father said to us all in his typical joking manner, "I don't know about you cats, but I'm going to bed". They were the last words I ever heard him speak.

Treated with warfarin for atrial fibrillation, he had suffered a massive hemorrhagic stroke in the middle of the night. I held his hand and tried to comfort him as he fixed his terrified eyes upon mine and struggled unsuccessfully to speak. He drifted into unconsciousness before the paramedics arrived, never to recover. He was transported to the local hospital where he was formally diagnosed. With no treatment options available, he was moved to hospice care where he died six days later- on another daughter's birthday. This father of twelve, who had survived service in the Merchant Marine in World War Two and US Army deployment to the Yalu River in the Korean War, had succumbed to a catastrophic adverse event caused by an anticoagulant medication.

The loss of my father moved me to action. As a pharmacist, Senior Program Director for a Quality Improvement Organization (QIO), and Vice President at a managed care plan, I have spent the last twelve years doing everything I can to improve the management of warfarin, as many adverse events (my father's included) can be avoided through the implementation of high-quality anticoagulation management services.

Through my work at the QIO, I analyzed laboratory data from scores of physician practices across the state, and found that most maintained warfarin time in therapeutic range (TTR) well below what is considered acceptable by clinical experts. I led a study that showed that patients prescribed warfarin at long-term care facilities were outside of range more than 50% of the time (and some facilities were out of range more than 70% of the time). I published a paper showing the slow adoption of warfarin home monitoring, published a consensus paper on features of electronic health records that experts consider necessary to support optimal anticoagulant management, and contributed to the development of a quality measure assessing the appropriate monitoring of the INR after initiation of interacting antibiotics for patients prescribed warfarin.

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Despite my efforts and those of organizations such as the National Blood Clot Alliance and the Anticoagulation Forum, warfarin management remains suboptimal in many clinical settings and avoidable adverse drug events associated with the drug are unnecessarily high. Remarkably, during this same time period, there were no major changes to national policy or regulatory standards that required improvement in warfarin management in any meaningful way. No requirements for proper training and certification of prescribers and clinical staff. No requirements for providers to maintain TTR above accepted thresholds. No requirements for pharmacies to have access to current laboratory data prior to dispensing the medication. While such standards (e.g. REMS) have been put in place for less frequently prescribed agents that have newly come to market for the treatment of various conditions, the hundreds of thousands of patients prescribed warfarin could not count on federal standards to assure their safety.

Now, with multiple non-warfarin oral anticoagulants on the market and a valid, claims-based measure of adherence immediately available, CMS is poised to deny yet another generation of anticoagulated patients the protections and assurances of quality and safety already required for other less utilized and less dangerous medications. Strokes and venous thromboembolism continue to be major causes of morbidity and mortality nationally and are largely preventable with appropriate use of anticoagulants- yet a measure assuring even minimum adherence standards for the drug is not going to be implemented? Non-warfarin oral anticoagulants are already among the top ten drugs associated with serious and preventable adverse drug events among seniors- yet programs for the proper use and oversight of these agents are not worthwhile?

Without required quality measure(s) for anticoagulants in place, Medicare Managed Care and Part D plans will have no responsibility for assuring the safe and effective use of these paradoxically effective and dangerous medications. From my experience, the Plans will direct resources towards improving performance on measures to which payment and reporting are tied, and will compel clinicians and health systems in their networks to do likewise. This practice serves to draw plan and provider resources away from care concerns not tied to payment or reporting, and perpetuates the problem of poor anticoagulation management.

Prescribing of non-warfarin oral anticoagulants is increasing, and will continue to do so at an increasing rate. The agents are not only replacing warfarin among chronic outpatient users, but they are suitable alternatives to injectable anticoagulants as well (e.g. treatment of acute DVT). Further, emerging evidence shows their value in DVT prophylaxis in the medically ill, extended secondary prophylaxis against DVT, DVT treatment and prophylaxis in cancer, and in combination with antiplatelet agents in coronary artery disease. The ever-expanding list of clinical indications and the extension of duration of use for prophylaxis will assure that prescriptions for non-warfarin oral anticoagulant prescribing will greatly exceed those of warfarin in the coming years. Being that it takes several years for a measure to progress from a Patient Safety Report to a Star Measure, the time to act is now.

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I urge CMS to take the opportunity to implement the PQA Non-Warfarin Oral Anticoagulant measure as a Patient Safety Report requirement for 2019, as it will be an important first step in driving national improvements in anticoagulation safety. Being a claims-based measure, the level of effort in implementing the measure is miniscule in comparison to the potential positive impact on patient safety.

I greatly appreciate your consideration.

With highest regard,

Darren M. Triller, PharmD
President/CEO

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