National Kidney Foundation™

Submission Via Email

February 7, 2017

The Honorable David Wilson
Chairman, Senate Health and Social Services Committee
Alaska State Senate
State Capitol Room 103
Juneau, AK 99801

The Honorable Mia Costello
Chairwoman, Senate Labor and Commerce Committee
Alaska State Senate
State Capitol Room 510
Juneau, AK 99801

Re: **Support SB 32 – Biological products-regulate/pharmacist substitution**

Dear Chairman Wilson, Chairwoman Costello, Members of the Senate Health and Social Services Committee, and Members of the Senate Labor and Commerce Committee:

The National Kidney Foundation (NKF) supports SB 32, which was introduced in the Alaska State legislature to regulate the substitution of biological products for certain biosimilars with prescriber and patient notification.

According to the legislation, Alaska pharmacists will be permitted to substitute a biologic drug for a medication that has been determined by the U.S. Food and Drug Administration (FDA) to be an interchangeable biosimilar. Pharmacists will be required to communicate – to the patient and patient's prescribing physician – any substitution of a biologic medication with an interchangeable biosimilar. NKF supports the expanded access that biosimilars will offer for patients, and as biosimilars enter the market, the substitution of a biosimilar must include communication between the pharmacist and the prescriber to ensure patient safety. NKF also supports patient choice in the decision making and is pleased that this legislation requires patients to be notified of substitutions and informed when an interchangeable biosimilar is available.

The National Kidney Foundation (NKF) is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention and treatment of kidney disease in the US. In addition, NKF has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the NKF Kidney Disease Outcomes Quality Initiative (NKF KDOQI). We also provide professional and patient education, patient support services, and community health programs. We work with volunteers to offer the

scientific, clinical and kidney patient perspective on what needs to be done to prevent kidney disease, delay progression, and better treat kidney disease and kidney failure. NKF has local division and affiliate offices serving our constituents in all 50 states, including Alaska. In Alaska, there are nearly 900 patients with end stage renal disease (ESRD), however, there are an additional estimated 210 individuals on Medicare with CKD stages 1-4 in Alaska.

With biologics, we know that individual patients can respond differently to even seemingly insignificant changes in drug formulation, manufacturing process, packaging, storage, or handling. These unintended consequences could be life threatening. Since biosimilars are produced without access to the innovator's proprietary manufacturing processes, differences in composition compared to the original innovator product are likely to occur.

Over a decade ago the FDA collected information on 82 patients worldwide who had developed pure red-cell aplasia as a result of changes in the manufacture and/or packaging of a reference biological product used by kidney patients. More recently, a synthetic erythropoietin stimulating agent – peginesatide – was approved by FDA in March of 2012 and nearly a year later pulled from the market due to an allergic reaction not seen in patients during the clinical trial. Because of these experiences the kidney community has been especially cautious regarding the possibility of substituting or alternating between reference drugs and biosimilars or between biosimilars. NKF appreciates that the clear labeling of product name and manufacturer required under this legislation will aide in identifying the medication that was dispensed in the unique circumstance that an adverse event occurs.

In conclusion: NKF asks you, in order to protect Alaska's patients, to support SB 32, which includes prescriber and patient communication of substitutions. To monitor for adverse events, it is vital that patients and physicians know, which medication was dispensed.

Please contact me at Tonya.saffer@kidney.org or 202-244-7900 if you have any questions.

Sincerely,

Tonya L. Saffer

Tonya L. Saffer, MPH
Senior Health Policy Director