February 8, 2017

RE: Senate Bill 32 Opposition

Dear Senator Wilson:

On behalf of the Alaska Rheumatology Alliance, I would like to thank you for taking the time to receive our concerns regarding the newly proposed legislation, Senate Bill 32. As you recall this is the legislation updating pharmacy substitution laws for prescription medications, specifically biological products and substitutability of FDA approved “interchangeable” products.

The concept of the legislation is to define previously undefined biological products (both currently available and future products), establish a way to identify equivalent, interchangeable products, and provide a mechanism for substitution of a prescribed medication at the pharmacy level. The legislation would also mandate communication between the prescribing practitioner and the dispensing pharmacy to document the medication actually provided in the case of a substitution. Though this is a state initiative, there has been significant pressure nationally to accomplish this across the country.

Senate Bill 32, as outlined for Alaska, would define the biologic products, use the FDA approved “interchangeable list”, and allow a pharmacy to substitute a biologic medication without prescriber input, only requiring notification to the prescriber within 3 business days of dispensing the medication to the patient.

The Alaska Rheumatology Alliance strongly opposes the proposed Senate Bill 32 as it is currently written, specifically based on the unrestricted substitution allowance and the 3 days reporting requirement.

Rheumatology as a specialty uses a number of biologic medications to the benefit of our patients and will likely continue to have new agents available in the future. Biologic medications are typically last line agents. They are very specific and often a patient has taken years of unsuccessful treatments to find a medication that works for them. The right medication; however, can be life changing. The medications are also, understandably, very costly and we are sensitive to this in the medications we prescribe. Multiple factors, including patient co-morbidities, other concomitant medications, route of administration, cost, and other factors are taken in to consideration when selecting the right biologic medication.

When there is an unrestricted ability to switch a biologic medication, the patient is placed at a significant risk. As each patient is an individual, some patients will not respond as well to an alternative medication and this is a large concern. Also the practitioner-patient relationship is undermined in this situation. Furthermore with a 3 days post-dispensing reporting requirement, in most cases the medication will
already be administered before the knowledge of the switch becomes known to the provider and the ability to have an informed discussion with the patient is lost.

The Alaska Rheumatology Alliance is in support of cost saving measures for patients and in some cases an interchangeable product could be appropriate, but the determination needs to be made prior to the substitution. Therefore, the Alaska Rheumatology Alliance would be in support of a bill only if notification and authorization was done PRIOR to the dispensing of the interchangeable product. This open communication would be in the best interest of patient and not undermine our work as practitioners.

As a registered pharmacist and actively practicing rheumatologist who uses a significant number of biologic medications, I have been able to reflect on the impact of this proposed change and feel strongly about this legislation.

We have heard the argument for using the “Dispense As Written” or “DAW” code as a way to prevent substitution. While this would definitely stop the interchange of medication, from our perspective as physicians, the “Dispense As Written” code is a nonnegotiable order. At times this is appropriate, but often there are times when a "brand name product" would be preferred but not necessary. Having the legislation with pre-notification and authorization allows the pharmacist an open dialogue with regards to medication with the provider. In many instances, the physician will not have an opposition with the substitution, especially when given additional information, such as cost savings to the patient, which the pharmacist would be able to communicate immediately based on other factors such as insurance preferences and availability of the product.

Previously I worked as a pharmacist and know that the submissions to insurance from the pharmacy is a real time process. It is immediately known whether there would be a cost savings with using a "generic" (or in this case an interchangeable product). This is the valuable information that could be communicated to the provider and then make the best choice for the patient.

I also know that pharmacies are able to electronically submit refill request and notifications of "prior authorizations needed" insurance rejections immediately on a real-time basis to the prescribing provider. There is no reason that this could not be applied to interchangeable product substitutions.

I have personally been involved for months at the national level regarding the impact of such legislation and have worked closely with the Arthritis Foundation, Coalition of State Rheumatology Organizations, and with the American College of Rheumatology. Locally the Alaska Rheumatology Alliance has been working with the community rheumatologists and those at the Alaska Native Hospital. I have also provided feedback and attended a December 13th, meeting in Anchorage which was an informational discussion attended by Dermatologists, Rheumatologists, Pharmacists, Industry representatives, and political activists. I am quite confident that the concerns outlined above echo those of the professionals and practitioners in the community.

The legislation has been touted by its initiators as a way to provide better access to expensive medications and reduce overall pharmacy and healthcare costs while providing accountability and
tracking of the medications. This pressure is spearheaded by pharmaceutical companies, with no doubt, financial incentives in place. While this concept of cost saving to the medical system is a noble one, in other states this has not thus far come to fruition.

Each state has the ability to adopt its own legislation based on its own needs. Alaska has a unique set of challenges because of the remote nature of some pharmacies and clinics, the lack of standard electronic medical records, and the heterogeneity of the population we treat as practitioners. Alaska needs to take the lead in the country in caring for our own patients. What might work for other states is unlikely to work in Alaska and our legislation needs to reflect this difference.

This bill has the support of a number of National Organizations. These same organizations have supported bills in other states. What the initiators of this bill have failed to establish is the support of local Alaskan providers of medical care.

As a take away point, Alaska Rheumatology Alliance would support a bill with a change in language as follows:

22 * Sec. 5. AS 08.80.295 is amended by adding new subsections to read:

23 (c) Except as provided in (d) of this section, if an interchangeable biological

24 product exists for a biological product prescribed to a patient, the dispensing

25 pharmacist or the pharmacist’s designee shall communicate to the prescribing

26 practitioner information regarding the proposed biological product that would be provided to the patient,

27 including the name and manufacturer of the biological product. The communication must be provided and authorization from the prescribing practitioner

28 must be obtained provided within three business days after dispensing the biological product prior to dispensing the interchangeable biological product. The communication may be provided as

29 follows:

Thank you for your attention to this matter and the discussion points above. Please do not hesitate to contact me with any additional questions or concerns.

Sincerely,

John Botson, MD, RPh

President, Alaska Rheumatology Alliance