February 5, 2018

Dr. Scott Gottlieb
Commissioner
Food and Drug Administration (FDA)
5630 Fishers Lan, Rm. 1061
Rockville, MD 20852

RE: Review of Existing Regulatory and Information Collection Requirements (82 FR 57560)

Dear Commissioner Gottlieb:

The American Association of Nurse Practitioners (AANP) is the largest full-service national professional membership organization for nurse practitioners (NPs), which represents the more than 234,000 nurse practitioners across the country. We thank you for the opportunity to comment on existing FDA regulatory requirements and we look forward to working with the FDA to reduce regulatory barriers.

NPs are advanced practice registered nurses who are prepared at the masters or doctoral level to provide primary, acute, chronic and specialty care to patients of all ages and walks of life. Daily practice includes: assessment; ordering, performing, supervising and interpreting diagnostic and laboratory tests; making diagnoses; initiating and managing treatment including prescribing medication and non-pharmacologic treatments; coordinating care; counseling; and educating patients and their families and communities. NPs practice in nearly every health care setting including clinics, hospitals, Veterans Affairs and Indian Health Care facilities, emergency rooms, urgent care sites, private physician or NP practices (both managed and owned by NPs), nursing homes, schools, colleges, retail clinics, public health departments, nurse managed clinics, homeless clinics, and home health. NPs hold prescriptive authority in all 50 states and the District of Columbia. It is important to note that 89.2% of NPs are certified in primary care, the majority of whom see Medicare and Medicaid patients. NPs complete more than one billion patient visits annually.

Our proposals are noted below, and the enclosed attachment has the specific statutes, regulations or guidance that would need to be modified to enact these changes. We encourage the FDA to implement these proposals that will reduce regulatory barriers for nurse practitioners and their patients.

Provider Neutral Labeling

FDA regulations mandate that over-the-counter (OTC) medications and other products containing certain ingredients use warning labels instructing purchasers to consult their "doctor" or "physician" if they have questions about using the product or medication, or in the case of an adverse event.[1] Other healthcare providers including nurse practitioners, often serve as the primary care provider for patients using that medication or product and are licensed and qualified to provide this information.

[1] 21 CFR § 201.66. (Additional examples on attached chart).

During the warning label rulemaking, the FDA acknowledged that other healthcare providers, including nurse practitioners, would be treating patients in these situations but stated that "[T]he agency has decided not to endeavor to list each specific practitioner who is licensed and qualified in the clinical practice of medicine and in disease management. For OTC drug products, the term ''doctor'' in this subheading is sufficiently broad and inclusive."[2]

We respectfully disagree with this determination and request that the FDA amend their regulatory language to reflect the fact that nurse practitioners and other healthcare providers treat patients using these products. We disagree with the FDA's determination that the label "physician" is sufficiently broad and inclusive. We are not asking the FDA to list each specific practitioner who is licensed to treat patients; we are asking the FDA to replace the word "physician" or "doctor" in the regulations with the phrase "health professional." This language, which FDA has used in labeling a number of products[3], is not cumbersome and more accurately reflects the broader scope of clinicians who are licensed and qualified to treat patients.

The use of the term "physician" or "doctor" confuses patients regarding which clinicians are authorized to provide care, and undermines the scope of practice and quality of care provided by nurse practitioners. This can lead to unfair restraints on practice, an unfair competitive advantage in the healthcare marketplace and decreased access to care for patients. It is important that the FDA does not continue to utilize the word "physician" when other qualified health professionals, such as NPs, are licensed and qualified to treat patients using these medications and products.

Use of the Term Mid-Level Provider

In the regulations related to controlled substances, the FDA uses the term "mid-level provider" to refer to NPs and other healthcare providers.[4] NPs are licensed, independent practitioners who work throughout the entire health care spectrum from health promotion and disease prevention to diagnosis and treatment of patients with acute and chronic illnesses. This label originated decades ago; it has been removed from all regulatory language with the exception of outdated regulatory language used by DEA and FDA, and is not compatible with NP licensure.

The term fails to recognize the established national scope of practice for the NP role and the authority of NPs to practice to the full extent of their education and clinical preparation. It term confuses health care consumers due to its vague nature and is not a true reflection of the NP role. The term "mid-level provider" implies an inaccurate hierarchy within clinical practice. Nurse practitioners have a steadfast reputation for safe practice and the provision of high quality care. It is well established that patient outcomes for NPs are comparable or better than that of physicians. The FDA should retire the use of this term as it is outdated language that does not reflect the quality of care provided by NPs and the role that they play in the American health care system.

[2] 64 FR 13254, 13262. March 17, 1999.

[3] 21 CFR § 201.63, 21 CFR § 201.320, 21 CFR § 201.325, 21 CFR § 801.63.

[4] 21 CFR § 1300.01

Risk Evaluation and Mitigation Strategy (REMS)

We note that the FDA has undertaken the REMS Integration Initiative in order to improve the implementation of REMS authorities and streamline the REM process for health care providers. This is an important initiative to reduce provider burden of REMS while still maintaining the risk mitigation and educational benefits. As the FDA continues to work to improve the REMs process, we ask that nurse practitioners be involved in the planning and implementation process, and that they be represented on any advisory panels or in any discussions involving this initiative. We look forward to working with the FDA on the development, implementation and integration of REMS.

Requirements for Blood Donations and Transfusions

Historically, FDA regulations require physicians to determine that a donor is eligible to donate blood and physician supervision of blood transfusions.[5] The FDA's process for determining that a patient is eligible to donate blood involves an assessment of the patient's medical history and a physical exam, which are well within the scope of practice for nurse practitioners. The FDA requires a "responsible physician" to be adequately trained and qualified to determine donor eligibility, immunize a donor, collect blood and blood components and return blood or blood components to the donor during collection by apheresis.[6] NPs are also adequately trained and qualified to perform these functions and should be authorized to perform them without the supervision of a physician. We recommend that the FDA expand the class of clinicians allowed to determine that a donor is eligible for a blood transfusion and allowed to oversee blood transfusions to include nurse practitioners.

We thank the FDA for undertaking this regulatory review and we look forward to working with the FDA on reducing regulatory barriers for nurse practitioners and their patients. Should you have comments or questions, please direct them to MaryAnne Sapio, V.P. Federal Government Affairs, msapio@aanp.org, 703-740-2529.

Sincerely,

David Hebert
Chief Executive Officer

[5] 21 CFR Parts 630 and 640.
[6] 21 CFR 630.3