

December 21, 2018

Leslie Kux
Associate Commissioner for Policy
Food and Drug Administration (FDA)
5630 Fishers Lan, Rm. 1061
Rockville, MD 20852

RE: Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug Product Labeling; Medication Guide Requirements (Docket No. FDA-2011-N-0902).

Dear Commissioner Kux:

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 248,000 nurse practitioners across the country. We thank you for the opportunity to comment on the FDA's medication guide requirements.

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 86.6% 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.

We look forward to working with the FDA on industry guidance and the best ways to disseminate this necessary information to health care providers and other stakeholders. We continue to encourage the FDA to include nurse practitioners in all advisory panels and activities. Nurse practitioners play a vital role in our health care system and must be included in all initiatives. As we have noted previously, this inclusion extends to all communications, regulations and guidance in order to ensure that nurse practitioners' patients have access to medically necessary drugs and devices.

Provider Neutral Labeling

The FDA requested comment on the medication guide requirements. We continue to encourage the FDA to use provider neutral language in all communications, guidance and regulations. In that vein, we request that the medication guide requirement for drug side effects contained in 21 CFR § 208.20(b)(7)(iii) be updated to replace the term "doctor" with "health professional" to better reflect that other qualified health care providers, such as NPs, can be consulted regarding potential drug side effects. "Health professional"

is used in other sections of the medication guide regulations and using this language in 21 CFR § 208.20(b)(7)(iii) will create consistency throughout the FDA regulations. We believe that this was an oversight given the other language in the current regulations and recent guidance issued by the FDA that has been consistently provider neutral.

The use of the term “physician” or “doctor” on the label confuses patients regarding which qualified 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 appropriate care for patients. The use of provider neutral labeling is necessary to ensure that when payors are drafting prior authorization and other coverage policies, they do not inappropriately create a physician order requirement, which can lead to delays in treatment when the patient is seeing an NP or other qualified health professional. It is important that the FDA updates outdated regulations and guidance, such as those regarding the labeling of over-the-counter (OTC) medications.

In addition to using the phrase “health professional” in other portions of the medication guide regulations, the FDA has also used the phrase “health professional” in labeling a number of products,¹ and “practitioner” in other labeling regulations. This is more consistent with the FDA’s current practice and more accurately reflects the broader scope of clinicians who are licensed and qualified to treat patients. We request that the FDA continue to update outdated regulations with provider neutral language.

We thank the FDA for the opportunity to comment on the medication guide requirements 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

¹ 21 CFR § 201.63, 21 CFR § 201.320, 21 CFR § 201.325, 21 CFR § 801.63.