

February 20, 2021

Dear President Biden,

On behalf of the American Association of Naturopathic Physicians (AANP) (<u>naturopathic.org</u>), we are writing to congratulate you on your election. The pandemic has revealed deep cracks in the U.S. healthcare system - but brings an opportunity for bold federal solutions to fill those gaps. During this transition period, we want to raise several priorities that are important to our community and offer our services to improve the wellbeing of Americans.

The AANP is the national professional association representing 8,000 licensed and licenseable Naturopathic Doctors (NDs) who are licensed or regulated in 25 states and territories. Licensed naturopathic physicians provide care to over 4 million patients annually, with a focus on primary care, and preventing and managing chronic diseases and pain through strategies that emphasize natural and non-pharmaceutical approaches to restore health.

Naturopathic medicine has been recognized by Congress as safe, effective and affordable healthcare¹. Licensed naturopathic physicians are trained in the art and science of both natural and conventional medicine to provide evidence-based patient-centered care. Naturopathic physicians emphasize early interventions and non-invasive treatments that address underlying causes of diseases, as opposed to focusing solely on treating symptoms. Treatment plans emphasize clinical nutrition, exercise, stress prevention and reduction, toxic load, and other lifestyle measures through advocacy and education.

To be eligible for licensure, NDs must graduate from four-year, full-time, in-residence, doctoral level programs that are accredited by the Council on Naturopathic Medical Education (CNME), an accrediting agency recognized by the U.S. Department of Education. Graduates must then take and pass a standardized board examination to be eligible for licensure. More information about the profession can be found at the <u>US Department of Labor definition of naturopathic physician</u>.

During this critical transition period, AANP wants to communicate its priorities and interests in several key areas: 1) Expanding **patient choice in healthcare** by improving access to and coverage of licensed naturopathic physicians 2) **Lowering healthcare costs** and improving health outcomes by **focusing on disease prevention** 3) Protecting **access to natural and patient-centered medications.**

The current public health emergency (PHE) has exposed major healthcare issues within the United States. However, it has also paved a path towards reforming the current healthcare

¹ Naturopathic Medicine Week, S.Res.221, 113th Congress, (2013).

system to improve our ability to effectively handle not only future epidemics but to also serve the basic health and safety needs of all Americans.

Access to Care

Lack of Primary Care Physicians

Improving quality of care, increasing access to care, and controlling healthcare costs depend on the adequate availability of healthcare providers. Data shows that the United States could see an estimated primary care physician shortage of between 21,400 and 55,200 by 2033.² Additionally, the current utilization patterns show that the demand for primary care physicians is projected to grow more rapidly than physician supply.³ Integrating and utilizing licensed naturopathic physicians, who are trained in primary care and specialize in disease prevention, chronic care management, and whole person wellness, in our health care system could help address the demand for primary care services and supplement the depleting primary physician supply.

In many states, both Medicaid and private insurance provide patient access to the services of licensed NDs. However, any clinic that treats a large Medicare population, which includes most FQHCs and rural clinics who rely on Medicare funding, are unable to hire licensed NDs to fill their primary care workforce shortage, even during this PHE. This is simply because licensed NDs are not Medicare eligible providers and therefore can not treat Medicare patients, creating a massive barrier that prevents clinics from hiring otherwise qualified providers. Lack of Medicare coverage also interrupts patient continuity of care, as elderly patients transition from private insurance or Medicaid to Medicare, often losing access to their preferred and trusted primary care provider.

Our recommendation to resolve the lack of primary care physicians:

- Direct HHS to recognize licensed naturopathic doctors (NDs) as eligible Medicare providers.
- Direct VA to recognize licensed naturopathic doctors (NDs) and integrate them into the VA system.

Healthcare Costs

How Naturopathic Medicine Can Help Lower Health Care Costs

In the U.S., 90% of the nation's \$3.5 trillion in annual health care costs are for people with chronic and mental health conditions. Heart disease, cancer, and diabetes are the leading causes of death in the United States. However, studies have shown that preventing chronic diseases through lifestyle modifications, such as nutrition and exercise, can help lower costs. Licensed NDs use evidence-based clinical tools to effectively promote behaviors in patients which foster health and reduce risk factors for chronic disease. By applying whole-health, whole-person care, licensed NDs address these chronic conditions through a variety of modalities such as clinical nutrition, lifestyle counseling, botanical medicine, nutritional supplementation, acupuncture, exercise, and stress prevention and reduction.

² Association of American Medical Colleges (AAMC)

³ Health Resources and Services Administration (HRSA)

With a focus on diet and lifestyle interventions, disease prevention, and the natural and integrative treatment of common conditions, **naturopathic medicine can help lower healthcare costs**. Here are a few reasons why:

- 1. Naturopathic medicine decreases prescription drug costs. Many studies have found that naturopathic care results in substantially lower prescription drug costs than conventional care. Naturopathic physicians typically prescribe botanical or nutritional supplements to effectively care for medical problems rather than expensive prescription drugs. Patients who received intensive lifestyle modification and naturopathic therapy in just one year for type II diabetes improved all health scores (lipid levels, body fat percentage, etc.) and decreased medication requirements compared to those on standard therapy.⁴
- 2. Licensed naturopathic physicians offer true disease prevention, thus reducing costs and improving outcomes. By addressing the causes of disease, naturopathic physicians reduce the need for repeated, expensive and often ineffective symptomatic treatment. There is an increasing body of research on naturopathic practice, including how care by licensed NDs can lead to better outcomes in the conditions that predispose individuals to severe cases of COVID-19, including those patients with diabetes, cardiovascular disease, obesity, and more.

Our recommendation to help lower health care costs:

- As noted above, direct HHS to recognize licensed naturopathic doctors (NDs) as eligible Medicare providers.
- Direct HHS to conduct a pilot project to demonstrate the value of naturopathic care for Medicare or Medicaid eligible populations.
- Enforcement of provider non-discrimination provisions for private insurance in the Affordable Care Act (42 U.S. Code § 300gg–5), which have never been enforced by the DOL and HHS.

<u>Protecting Access to Natural and Patient-Centered Medications</u>

Compounded Medications

Compounding medications are customized medications prescribed by physicians based on the specific needs of a patient. For patients who have allergies to common fillers, are unable to swallow pills and need a liquid or topical form, or need a custom dosage, compounding medications can be lifesaving. Compounded medications fill a gap in health care by allowing physicians to practice medicine and creating customized solutions for specific patient needs that cannot be treated with mass-produced, pharmaceutical medications.

Despite a long history of safe use and patient need, the **FDA** is in the process of reviewing and potentially **blocking patient access to more than 300 ingredients used in these compounded medications**. Their current position is that if there is an approved pharmaceutical equivalent that will address the condition, the compounded ingredient is not needed. Yet many

⁴ Hernan WH, Brandle M, Zhang P et al. Costs associated with the primary prevention of type 2 diabetes mellitus in the diabetes prevention program. Diabetes Care. 2003; 26(1):36-47.

of these ingredients have U.S. Pharmacopeia *Dietary Supplement* monographs, which Congress intended to also be available for compounding but which FDA has refused to accept. If these monographs are not accepted, this will have the effect of *restricting patient access to over 300 compounded ingredients*, most of which are natural substances.

Compounded bioidentical hormones (cBHTs), as but one key example, can help men and women to alleviate symptoms associated with age-related hormone changes, such as hot flashes in menopause, or low muscle mass due to decreased testosterone. The FDA recently commissioned a study from the National Academies of Sciences, Engineering, and Medicine (NASEM) on "the safety, effectiveness, and use" of cBHTs. NASEM did not consider evidence that explained why millions of patients rely on these medications but rather supported a ban favoring synthetic, pharmaceutical hormones. If the FDA accepts NASEM's recommendations, as is anticipated, it would limit prescribing guidelines and severely limit the availability of cBHT by placing these hormones on the Agency's Difficult to Compound List.

Our recommendation to help protect access to natural and patient-centered medications:

- Direct the FDA to accept substances with U.S. Pharmacopeia Dietary Supplement monographs in addition to drug monographs for use in compounding patient-specific medications, which are currently used by millions of patients.
- Direct the FDA to not restrict access to cBHTs. If the FDA accepts the NASEM recommendations, it would eliminate patient access to these life saving pharmaceutical alternatives.
- Take administrative action to protect homeopathy. Scientific research shows homeopathy can decrease overuse of antibiotics, reduce reliance on opioids, and promote healthy immune response. Practitioners, manufacturers, and consumers are unclear about the regulatory status of FDA's policies on homeopathic medications. To put homeopathy back on stable regulatory ground, we recommend either:
 - Direct the FDA to reinstate CPG 400.400. In late 2019, the FDA abruptly withdrew policies known as Compliance Policy Guide (CPG) 400.400, which had successfully governed homeopathic medicines for over 30 years.
 - Direct Congress to codify CPG 400.400 into law. Congress has twice in the last decade recognized homeopathic medicines as unique and explicitly or by reference exempted them from regulations applied to pharmaceuticals, once in 2013⁵ and again in 2020.⁶

Substance Abuse and the Opioid Crisis

For two decades, buprenorphine has been used as a safe, effective and life-saving medication-assisted treatment (MAT) for individuals suffering from a substance use disorder. However, medical professionals need a special DEA waiver to prescribe buprenorphine to treat substance use disorder. If prescribing controlled substances is in the scope of practice of

⁵ 21 U.S.C. § 360eee(13).

⁶ Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, §§ 3851–3856, 134 Stat. 281, 435–58 (2020).

medical professionals as defined by state law, then they should be able to also prescribe buprenorphine for the treatment of opioid use disorder. In many states, licensed NDs can prescribe controlled substances but cannot apply for the DEA waiver.

Our recommendation to help address America's opioid crisis:

- Direct HHS to eliminate the special DEA waiver required to prescribe buprenorphine for substance use disorder treatment. In addition, ensure that all practitioners who are registered with the Drug Enforcement Administration (DEA) to prescribe controlled substances be allowed to prescribe buprenorphine for the treatment of opioid use disorder (OUD).
- Promote and expand the VA Whole Health System of Care to include licensed naturopathic doctors (NDs). Preliminary results of the 3-year Whole Health System of Care (WHSC) pilot program show that program had a positive impact on reducing opioid use among Veterans. In fact, opioid use among comprehensive Whole Health users decreased 38% compared with an 11% decrease among those who did not use Whole Health services. As experts in non-pharmacologic options in the treatment of disease, licensed NDs would enhance the VA's delivery of "personalized, proactive, and patient driven care," as these are the underpinnings of naturopathic medicine's principles of practice, core competencies in clinical training, and evidence-informed practice.

There are steps we can take to reduce our reliance on an already over-taxed healthcare system with an impending shortage of primary care providers where underserved populations are especially hard hit. Licensed naturopathic physicians can help guide the way. Our practices and therapies are effective and guided by a systematic and unique clinical model for preventive medicine and in chronic disease care. The profession stands ready to help, ready to integrate with other licensed healthcare providers, and ready to communicate its healthcare model to an increasingly receptive population.

Thank you for the opportunity to bring these concerns to your transition team's attention. We look forward to working with you to ensure that patients across the country have access to safe, effective and affordable healthcare. Again, we stand ready to serve as a resource to your team and to the new administration. Thank you for your consideration.

In Health,
Laura Culberson Farr
Executive Director, AANP