January 24, 2018

Mr. John R. Graham
Acting Assistant Secretary for Planning and Evaluation
Room 415F
U.S. Department of Health and Human Services (HHS)
200 Independence Avenue, SW
Washington, D.C. 20201

RE: REQUEST FOR INFORMATION - PROMOTING HEALTHCARE CHOICE AND COMPETITION ACROSS THE UNITED STATES

Dear Acting Assistant Secretary Graham:

The American Pharmacists Association (APhA) and the National Alliance of State Pharmacy Associations (NASPA) appreciate the opportunity to provide feedback on HHS's December 26th "Request for Information – Promoting Healthcare Choice and Competition Across the United States," to help HHS comply with Executive Order 13813, "Promoting Healthcare Choice and Competition Across the United States," to reduce the regulatory burden and improve competition and health insurance options under the Patient Protection and Affordable Care Act (ACA).

APhA, founded in 1852 as the American Pharmaceutical Association, represents 64,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

NASPA, founded in 1927 as the National Council of State Pharmacy Association Executives, is dedicated to enhancing the success of state pharmacy associations in their efforts to advance the profession of pharmacy. NASPA's membership is comprised of state pharmacy associations and over 70 other stakeholder organizations. NASPA promotes leadership, sharing, learning, and policy exchange among its members and pharmacy leaders nationwide.

Our organizations support HHS's search for ways to positively impact patients and health care through regulatory flexibility. Accordingly, we believe our goal to increase access to health care through patient access to and coverage of pharmacists' patient care services and safe and affordable medications aligns with HHS's efforts. We also strongly encourage policies that do not unnecessarily restrict choice, allowing patients to access care from the provider, including pharmacist or pharmacy, of their choice.

I. Improved Access to Health Care

As HHS considers regulatory opportunities intended to improve competition and choice in patient care, our organizations emphasize that pharmacists are the most accessible health care providers as 91% of all Americans live within five miles of a community pharmacy.[1] In addition to being medication experts, pharmacists also provide a broad array of services beyond dispensing medications, including disease state and medication management, smoking cessation counseling, health and wellness screenings, preventive services, and immunizations. However, due to legislative and regulatory barriers such as references to "provider," "eligible professional," or similar terms under Medicare that do not include pharmacists in their definition, pharmacists are often an underutilized health care resource, which limits beneficiaries' choices to qualified health care practitioners and pharmacists' quality patient care services. Therefore, our organizations request that HHS employ its regulatory discretion, similar to efforts the Centers for Medicare and Medicaid Services (CMS) applied for chronic care management (CCM) and transitional care management (TCM) services, to remove barriers preventing qualified providers, like pharmacists, from being fully utilized by our nation's Medicare beneficiaries. Such regulatory action has helped alleviate some of the restrictions preventing pharmacists from providing these services, which also positively impacts their inclusion on patient-care teams and in value-based delivery models.

CMS has stated that it does not have the authority to authorize Medicare coverage for many pharmacists' services due to existing statutory limitations. Accordingly, our organizations request the HHS Secretary exercise its regulatory authority to better include qualified practitioners, such as pharmacists, as it has done for other providers and for needed services, to enhance choice, competition and the infrastructure essential to the effective delivery of health care. Doing so will improve patient access and choice, and increase efficiencies in the delivery of services, which is especially important as health care payment and delivery models become more value-based. In addition, we also recommend that HHS consider clarifying processes, such as evidence or literature standards, relevant to the creation of new billing codes to further flexibility and efficiencies, and increase the ability of beneficiaries to choose from the maximum amount of pharmacist-provided patient care services available.

Pharmacists' medication management services have also been shown to be beneficial for Medicaid beneficiaries. For many years, a handful of states have seen success[2,3] with programs that utilize pharmacists to provide valuable medication management services. As is seen in other patient populations, when patients have access to pharmacists' services, health outcomes improve and overall health costs go down. However, the spread of this innovation has been slow—states face barriers in implementing programs that include compensation for pharmacist-provided services due to federal and state legislative and regulatory barriers that do not recognize pharmacists as providers (see discussion above). Our organizations encourage HHS to streamline

[1] NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.
[2] Isetts B. Evaluating Effectiveness of the Minnesota Medication Therapy Management Care Program. December 14, 2007. Available at: https://www.leg.state.mn.us/docs/2008/mandated/080113.pdf
[3] Collins S. Many happy returns: Ohio-based Medicaid plan pays pharmacists for MTM, saves money. *Pharmacy Today*. May 1, 2014. Available at: https://www.pharmacist.com/many-happy-returns-ohio-based-medicaid-plan-pays-pharmacists-mtm-saves-money

Medicaid waiver processes and highlight state success stories utilizing pharmacists to stimulate the spread of pharmacist-provided services to other state Medicaid programs.

II. Network Adequacy

While our organizations emphasize the need for pharmacy network adequacy and access standards, we also suggest granting additional flexibility to patients regarding the provider of their choice. We also appreciate CMS's recent actions to clarify the "any willing pharmacy"[4] requirements for Medicare Advantage (MA) and Part D plans. As the prevalence of both narrow provider and pharmacy networks has increased under the ACA, patient preferences may not be fairly considered. Consequently, our organizations request HHS ensure adequacy and access standards are met, and patient choices and competition are expanded through policies granting health plans additional flexibility to include pharmacists when satisfying network adequacy and access standards. Better inclusion of pharmacists will improve care delivery and health outcomes by increasing access, enabling patients to obtain care from the provider, including pharmacist, and patient care services of their choice.

III. Essential Health Benefits

Our organizations understand that many stakeholders have requested additional flexibility pertaining to Essential Health Benefits. We request that HHS maintain prescription drug benefits, preventive and wellness services, and chronic disease management as essential services that should be included in offered plans. Any allowed flexibility should maintain patient access to the aforementioned essential health benefits and permit patients to access services and medications from the health care provider, including pharmacists, of their choice if within the practitioner's scope of practice.

IV. Innovative Practice and Payment Models

The ACA established different opportunities to test alternative or innovative practice models, such as the Part D Enhanced Medication Therapy Management (MTM) Model and 1332 State Innovation Waivers. However, expansion or modification of these models is often limited and delayed by the need to meet certain metrics. We recommend that HHS consider reviewing processes for innovative care models to be more easily tested and broadly implemented to increase competition between providers to meet beneficiaries' need for patient care services.

The ACA also aimed to shift payment from volume to value by utilizing accountable care organizations (ACOs). Consequently, there is a greater emphasis on integrated, team-based care. Pharmacists often form collaborative practice agreements with physicians and other health care providers to expand access to care. However, pharmacists are not directly reimbursed for these services, limiting their uptake despite the growing primary care provider shortage.[5] Therefore, our organizations request that HHS consider opportunities to enable reimbursement for pharmacists providing patient care services to expand beneficiaries' access and choice of additional health care practitioners.

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[4] CMS. Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program. FR Vol. 82 56408-11. November 28, 2017. Available at: file:///C:/Users/mbaxter/Downloads/CMS-2017-0156-0046%20(3).pdf

[5] *See* Gums, John. Can pharmacists help fill the growing primary care gap? UF News. January 5, 2016. Available at: http://news.ufl.edu/articles/2016/01/can-pharmacists-help-fill-the-growing-primary-care-gap.php

V. Value

Our organizations have been strong supporters of recent efforts to insert value into care delivery, payment and coverage. We encourage HHS, when setting policies, to look beyond isolated components of health care to determine value. Because health insurance coverage is frequently analyzed by the benefit type such as inpatient, outpatient, and drug coverage, a patient's overall services, costs and outcomes may never be reviewed comprehensively. HHS and other policymakers cannot continue to consider drug and medical coverage, and their related costs and outcomes separately if we are to achieve true value in health care. As HHS is aware, the U.S. spends nearly $300 billion dollars annually on medication-related problems, many of which are preventable and better addressed by breaking down the many silos within our health care system.[6] Accordingly, health care coverage, payment, and delivery policies need to be better integrated to measure and achieve value in our Nation's health care system.

Thank you for the opportunity to provide comments regarding regulatory burdens that, if removed, may enhance competition and choice to improve health care and empower patients. As you move forward, please do not hesitate to use APhA and NASPA as resources as we share HHS's goal to maximize its regulatory flexibility to improve patient care, which will also help strengthen and sustain the health care system. For questions or additional information, please contact Michael Baxter, Director, Regulatory Affairs by e-mail, at mbaxter@aphanet.org or by phone at (202) 429-7538.

Sincerely,

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cc: Stacie Maass, BSPharm, JD, Senior Vice President, Pharmacy Practice and Government Affairs
The Honorable Seema Verma, Administrator, CMS

[6] New England Healthcare Institute. Thinking Outside the Pillbox: A System-Wide Approach to Improving Patient Adherence for Chronic Disease. August 2009. Available at: http://www.nehi.net/publications/17-thinking-outside-the-pillbox-a-system-wide-approach-to-improving-patient-medication-adherence-for-chronic-disease/view