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January 8, 2021

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The Honorable Markwayne
Mullin
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Dear Representatives Bera, Kelly, Kind, and Mullin:

On behalf of the National Health Council (NHC), I want to thank you for your leadership of the Health Care Innovation Caucus and your efforts to move the health care system to one focused on value, not volume. We share your vision for our health care system and appreciate the opportunity to provide feedback on your efforts to ensure important protections such as the Stark Law, Anti-Kickback Statute (AKS), and Medicaid Best Price do not pose undue barriers to innovative contracting that rewards products and services based on their value. While we share your views that these protections serve as barriers and should be modified, it is important to ensure that new guardrails, tailored to the types of contracts being considered, are enacted to protect patients and public health programs.

Created by and for patient organizations 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, sustainable health care. Made up of more than 140 national health-related organizations and businesses, the NHC's [core membership](#) includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic drug, and payer organizations.

The NHC appreciates the Innovation Caucus' efforts to facilitate transformation toward a value-based health care delivery and payment system. We agree with the desire to

move our system toward one that relies on improved care coordination, improved patient outcomes, and lower costs to patients. We recognize that the regulatory frameworks implementing the Stark Law, AKS, and Medicaid Best Price have become burdensome for providers and impedes the adoption of the care-coordination efficiencies inherent to successful value-based arrangements. We support pragmatic solutions that balance Medicare program integrity concerns with provider burden reduction and enhance access to and quality of care for patients with chronic conditions.

The NHC has previously commented on the Administration's proposals related [Stark](#), [AKS](#), and [Medicaid Best Price](#) regulations. Please see those previous comments in the associated links. In general, we support the aims of these rules, though we believe that all three lack requirements that contracting entities engage with patients to better understand outcomes that matter to them, ensuring contracts are appropriately rewarding manufacturers and providers for delivering care that best addresses patients' needs and priorities. We also note that the Stark and AKS regulations exempt prescription drugs, despite both regulations creating barriers to outcomes- and value-based arrangements. Therefore, we agree that legislation is needed. Specifically, we support:

- Requiring substantive input from patients when establishing criteria for "evidence-based measures" or "outcome-based measures," and in defining "substantial" to ensure that value-based payments demonstrate desired outcomes for patients;
- Engaging with a broad set of stakeholders to assess the potential impact of VPBs on patients;
- Enabling patients to participate and understand treatment plans and make empowered decisions;
- Aligning providers on a patient's chosen treatment plan through coordination of providers along the patient journey;
- Incentivizing providers to offer tools for patients to be more involved in their care and encourage coordination and collaboration among providers, and patient engagement in the development of those tools; and
- Information-sharing among providers, facilities, and other stakeholders in a manner that protects patient access to data, privacy, and promotes efficient care.

We appreciate the opportunity to provide input on this important issue. Please do not hesitate to contact Eric Gascho, NHC's Vice President of Policy and Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org.

Sincerely,



Eleanor Perfetto, PhD, MS
Interim Chief Executive Officer and
Executive Vice President, Strategic Initiatives