

July 16, 2018

Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Ave. SW, Room 600E
Washington, DC 20201

Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, 83 FR 22692

Dear Secretary Azar:

The Partnership to Improve Patient Care (PIPC) appreciates the opportunity to comment on the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. PIPC members, representing a diverse, broad-based group of health care stakeholders, are dedicated to working together to promote giving a voice to patients, giving choice to patients, and advancing value for patients. We support comparative clinical effectiveness research that protects patient access to innovative treatment options; informed healthcare that enables patients, doctors, and other health care professionals to choose the care that best meets the individual needs of the patient; and a health system that fosters continued medical innovation. Comparative clinical effectiveness research should work for patients to improve their health decisions, not against them by limiting their access in a one-size-fits-all health system. Therefore, policies to advance value-based health care must mitigate against restricting patient access to optimal care, undermining high quality physician/patient shared decision-making, and discouraging continued medical progress.

With this mission in mind, our comments will seek to define what it means to put patients first, a goal that we wholeheartedly support. We would like to emphasize the priorities for payment reform consistently advocated by PIPC for your consideration:

- Avoid one-size-fits-all policies;
- Codify criteria for patient-centeredness across HHS programs;
- Convene patient advisory panels;
- Focus on policies that advance informed healthcare.

Additionally, we agree with the Guiding Principles advanced by the Cancer Support Community and Friends of the Cancer Policy Institute:

“1. Policy changes should be considered in a broad context which places patients at the center. It is vital to understand the implications that each policy change will have on the health care system and in the lives of individual patients.

2. We urge HHS to pursue efforts to rein in drug pricing in concert with initiatives that address affordability and stability in the health care marketplace more broadly. We urge the Administration to revisit and halt any regulations and policies that are rolling back

consumer protections under the ACA, including Medicaid, which were improving affordability and access for Americans.

3. Policy changes should be transparent to all stakeholders.
4. Policy changes should improve patient access to appropriate therapies.
5. Policy changes should improve affordability for patients.
6. Policy changes should be accompanied with information to help patients understand the potential impact to them. Such information should be provided in language they can understand and process.
7. Patients should be given ample opportunity and time to understand policy changes, ask questions, and seek assistance necessary to maintain access to care.
8. Decision support tools should be provided to patients. These tools should be created with tremendous input from patients and caregivers, evaluated on an ongoing basis by patients and caregivers, and updated as necessary when new information becomes available.”

As HHS advances consideration of each of its proposed policies, we urge consideration of these Guiding Principles collaboratively with patients and people with disabilities that receive care within the relevant program.

Avoid One-Size-Fits-All Policies

We appreciate the explicit focus within the Blueprint on access, affordability and innovation, and agree with the statement, “It is time to realign the system in a way that promotes the development of affordable innovations that improve health outcomes and lower both out-of-pocket cost and the total cost of care.” Yet, we are concerned that proposals to shift from volume to value often rely on policies reflective of the traditional one-size-fits-all culture of how we pay for health care - lowering one element of costs by limiting access and choices, while increasing the costs associated with adverse events, hospitalization, disability, inability to work, caregiving, etc. Alternatively, we urge HHS to change the fundamental culture of how we pay for healthcare to empower patients and people with disabilities to play a more active role in their own healthcare decisions, and advance payment and delivery models that achieve outcomes that matter to each individual.

To advance volume over value, HHS states that it may provide Medicare providers, payers and states with additional tools to manage spending for high cost therapies. Unfortunately, providing plans “full flexibility to manage certain high cost drugs” will likely translate into plans creating more barriers to accessing high cost treatments, regardless of the profile of the individual and whether such treatment provides value to that unique person. This administration has an opportunity to advance policies that better match patients and treatments by:

- Advancing the National Quality Forum’s work creating standards for high quality shared decision-making and patient decision aids;
- Testing use of high quality shared decision-making and patient-reported outcome measures in demonstrations and alternative payment models;
- Ensuring appropriate diagnostic testing for patients that may then be matched to a targeted therapy, consistent with the goals of personalized medicine;
- Engaging patients and providers as part of the Meaningful Measures Initiative to ensure that care is provided that is aligned with achieving the outcomes that matter to patients;
- Supporting the conduct of comparative clinical effectiveness research by the Patient-Centered Outcomes Research Institute (PCORI) that provides an evidence base for patients and people with disabilities to determine the treatment that works best on individuals sharing their unique characteristics and goals.
- Considering out-of-pocket costs and total cost of care over the long-term, including ancillary medical costs associated with treating symptoms (additional doctor visits, hospitalizations, etc) and personal costs such as risk of disability, caregiving, transportation, etc. when considering the value of a treatment.

Codify Criteria for Patient-Centeredness Across HHS Programs

As you know, Section 1115A of the Affordable Care Act calls for evaluation of alternative payment models (APMs) against “patient-centeredness criteria” – yet no such criteria have been formally developed or publicly released for comment. Therefore, while patients and people with disabilities have their own definition for the term “patient-centered,” it has no official definition for policymakers. We have consistently and strongly urged CMMI to develop criteria for patient-centeredness so that there are clear standards against which demonstrations can be held accountable. We believe developing such criteria is a first step for HHS to measure whether it has put patients first across its programs, thereby avoiding unintended consequences of program changes for patients and people with disabilities.

Specifically, we also encourage the development of criteria to evaluate Medicaid programs for patient-centeredness. For example, the President’s FY 2019 Budget calls for new Medicaid demonstration authority for up to five states to test drug coverage and financing reforms that build on private sector best practices. Yet, there is no benchmark for defining a best practice in the context of also putting patients first. Instead, best practices are often defined to be those that simply keep patients from accessing high-cost treatments, thereby lowering treatment costs and potentially increasing other costs such as those related to adverse events, as opposed to ensuring that the right patient gets the right treatment at the right time. Patient-centeredness criteria should be explicitly tied to care delivery that seeks to understand and achieve individual patients’ goals for their care.

Establishment of patient-centeredness criteria will provide a structured patient-focused framework to guide the agency’s work and put patients first, thereby committing to clear standards and safeguards for future models that will help protect access to care for patients. By applying these standards, HHS would be building an infrastructure for patient engagement that

goes beyond a notice and comment period and that provides a model for all payers seeking to achieve care that patients value. Criteria could include:

- Identify and test patient-centered quality and performance measures for use in new payment models;
- Protect patients and people with disabilities by prohibiting application of cost-effectiveness and quality-adjusted-life-years (QALYs) as the basis for coverage and care decisions;
- Create robust mechanisms to protect quality and access for patients that are subject to demonstrations, such as ensuring that initial demonstrations are limited in size and scope;
- Ensure patients are fully informed when they are subject to a CMMI test or other demonstration, and are made aware of mechanisms to opt out or seek assistance; and
- Advance use of decision-support tools (e.g., shared decision-making) that meet criteria for patient-centeredness and are consistent with the standards of the National Quality Forum.

Convene Patient Advisory Panels

For each reform being advanced by HHS, whether as part of a Medicaid demonstration, within the fee-for-service Medicare program, or as an Innovation Center model, representatives of patients and people with disabilities impacted by potential policy changes should be engaged in evaluating them against appropriate measures of patient-centeredness. Individuals on the panel should have experience sufficient to identify the measurable outcomes that matter to patients and people with disabilities served by the relevant part of the health system. Engagement of the panel must begin early in the process of designing the new payment policy to ensure support and buy-in from people impacted by the potential changes.

Focus on Policies that Advance Informed Healthcare

We applaud HHS' efforts to ensure patients and people with disabilities are informed consumers. When patients do not have access to information that allows them to assess the best available treatment for them, our health care system bears the cost of reduced treatment adherence, increased hospitalization and other acute care episodes, as well as the societal costs of decreased productivity, increased disability, and lower quality of life over time. While insurers may see those costs in different buckets, patients do not. Your work could drive a more holistic perspective of healthcare centered on the patients and people with disabilities that are the ultimate beneficiaries of healthcare.

PIPC has long advocated for patients to have access to information about all their treatment options, the evidence about those treatment options for patients sharing their characteristics and preferences, the out-of-pocket costs associated with each treatment option (including personal and future costs), and any financial incentives influencing their provider's care recommendations. Therefore, we agree with HHS that "patients have the right to know what their prescription drugs will really cost before they get to the pharmacy or get the drug." With

easier access to this out-of-pocket cost information, patient decision aids could incorporate it alongside information about each treatment option allowing individuals to make a truly informed decision. We also want consumers, especially patients and people with disabilities, to be empowered to seek value when choosing and using their benefits. Doing so requires they have information not just on their formulary options, but on *all* their treatment options.

Conclusion

To truly put patients first will require a significantly higher level of engagement of patients and people with disabilities than has been done in prior administrations. By incorporating our recommendations and Guiding Principles into your evaluation of new payment policies, HHS would be building an infrastructure for patient engagement that goes beyond a notice and comment period and that provides a model for all payers seeking to achieve care that patients value. We look forward to engaging with HHS in this important work as it evolves.



Tony Coelho
Chairman, Partnership to Improve Patient Care