Prescriptions for a Healthy America
"A Partnership for Advancing Medication Adherence"

February 10, 2015

Chairman Fred Upton
Committee on Energy & Commerce
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton,

Prescriptions for a Healthy America (P4HA; www.adhereforhealth.org) appreciates the opportunity to comment on your draft 21st Century Cures legislation. P4HA is a multi-stakeholder alliance representing patients, providers, pharmacies, pharmacists, employers and life science companies. We joined together to raise awareness on the growing challenges posed by medication nonadherence and to advance public policy solutions that will help reduce health care costs and improve the lives of patients across the nation through improved medication adherence.

Poor medication adherence, or non-adherence, limits effective management and control of chronic illnesses. Non-adherence increases the likelihood of preventable disease progression, increased hospitalizations, avoidable doctor and emergency room visits, and other problems arising from poor health, which can significantly increase costs. At least 125,000 Americans die annually due to poor medication adherence. We know that as adherence declines, emergency room visits increase and hospital stays increase. Poor medication adherence results in 33% to 69% of medication-related hospital admissions in the United States, at a cost of roughly $100 billion per year. This is why CBO has changed its methodology related to adherence by recognizing health services savings resulting from increased utilization of prescription medications.

P4HA strongly supports the Committee's proposal for accelerating the discovery, development, and delivery of promising new treatments and cures for patients. Because treatments do not work in patients who do not take them, patient engagement during the delivery of care is essential. Policies and models that therefore aim to improve proper medication adherence, defined as when a patient takes their medications as directed, have considerable potential to reduce health spending and improve health outcomes and should be considered within the 21st Century Cures initiative.

Our comments are outlined below:

Title I. Subtitle M- New Therapeutic Entities
Sec. 1241- Extended exclusivity period for certain new drug applications and abbreviated new drug applications.

Section 1241 extends the exclusivity period for new drug applications if the new therapy has been reformulated or redesigned to promote greater patient adherence relative to the previously approved formulation of the drug. While we applaud the Committee for recognizing the importance of improving patient adherence, we believe that there is not enough guidance in the draft legislation on how to determine whether the redesigned products improve adherence enough to receive the additional patent exclusivity. We suggest providing parameters around the incentive to help ensure it is targeted appropriately at those products that truly improve medication adherence.

Medication adherence is commonly measured in Medicare Part D based on the proportion of days covered (PDC), which has been endorsed by both the Pharmacy Quality Alliance (PQA) and the National Quality Forum (NQF). This measurement, however, is based on pharmacy fill data for chronic medications and may not adequately measure adherence to new therapies.

Instead, the Committee should explore a more integrated measure of increased adherence by coordinating the medical or clinical outcomes data to pharmacy fill data. This method would correlate improved adherence with improved clinical outcomes, thus illustrating a more meaningful measure for the value of improved patient adherence to treatments. Linking the medical data to pharmacy data will also allow for a more adequate snapshot of the monetary value of improved adherence.

We look forward to working with the Committee to ensure this section of the bill is more robustly developed.

Title II. Subtitle E- Sensible Oversight for Technology Which Advances Regulatory Efficiency
Sec. 2061- Medical and Health Software Defined

Section 2061 clarifies that software intended for use by patients for self-management or self-monitoring of a disease or condition, including management of medications is defined as 'health software' and is therefore not regulated by the FDA. P4HA supports this provision as it helps to clarify current uncertainty in the regulatory environment. This clarity helps to foster continued innovation in health software that can be further leveraged for increased patient engagement in the management of their medication regimens and health outcomes.

Title II, Subtitle F – Building a 21st Century Data Sharing Framework

We appreciate the Committee's focus on the use and sharing of data to improve health and health outcomes. P4HA believes that as medication adherence is researched in the marketplace, data that links patient medical outcomes to patient pharmacy interventions is missing.

For example, currently, the Medicare Part D Medication Therapy Management (MTM) program is one of the only federal interventions in place that specifically aims to improve

medication adherence. CMS has tailored the program to target 25 percent of Medicare Part D beneficiaries, but only 9 percent of those beneficiaries opt in to the program. CMS, Medicare Part D plans, and Part D MTM providers are all limited in their ability to optimize the Part D MTM program because there is limited evidence on both program effectiveness and cost effectiveness. In order to gain a more accurate snapshot of why the program is not reaching its intended audience (i.e. the target criteria are outdated and inadequate, the beneficiaries are not notified appropriately, the intervention is not ideal, and/or beneficiaries do not benefit medically from the program, etc.), we believe the Committee should include the following provisions:

1. Collect and release data for the purpose of analyzing the MTM program (include in *Section 2086. Empowering patient research and better outcomes through CMS data)*

    - CMS data on Medicare Part D plans should be made available to external researchers. All qualified researchers in the private or public sectors should be permitted access.

    - The MTM data file should include identifiers that allow direct linkages to the traditionally available CMS chronic condition warehouse research identifiable files, including CMS beneficiary administrative records, Parts A, B, and D claims data, and plan characteristics files. In particular, data elements should include: indicators for eligibility and participation in MTM and receipt of a Comprehensive Medication Review (CMR) or Targeted Medication Review (TMR); characteristics of the MTM services provided (e.g. setting, mode of delivery, date and duration of service, initial vs. follow up); provider characteristics; and characteristics of outreach efforts (e.g. frequency, method).

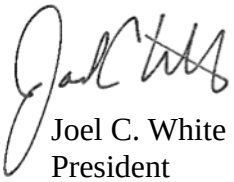
    - Data on medical service use should also be made available for Medicare Advantage enrollees to allow for broader analysis of this and other programs.

2. PDPs should have timely access to Parts A and B data for their enrollees (include in *Section 2085. Expanding availability of Medicare data)*

    - PDPs are limited in their ability to identify beneficiaries who are most likely to benefit from MTM or other adherence improving activities because they cannot observe Medicare Parts A and B claims data, which can provide critical information about enrollees' use and spending on medical services, risk for adverse health events, and transitions in care. These data should be provided to PDPs on a regular basis in a format that is readily accessible to PDPs in their quality improvement efforts (e.g. flags indicating beneficiaries who recently experienced a hospital readmission).

Thank you for the opportunity to comment on the draft legislation. We look forward to working with you to further improve 21st Century Cures and ensure patients are properly adhering to those cures. If you have any questions or would like to discuss further, please do not hesitate to reach out via email (joel.white@cahc.net) or phone (202-559-0192).

Sincerely,



Joel C. White
President