U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

September 11, 2017

TO: Members, Subcommittee on Health

FROM: Committee Majority Staff

RE: Subcommittee Markup

I. INTRODUCTION

The Subcommittee on Health will meet in open markup session on Wednesday, September 13, 2017, at 1:00 p.m., in 2123 Rayburn House Office Building to consider the following:

- H.R. 1148, Furthering Access to Stroke Telemedicine (FAST) Act of 2017;
- H.R. 2465, Steve Gleason Enduring Voices Act of 2017;
- H.R. 2557, Prostate Cancer Misdiagnosis Elimination Act of 2017;
- H.R. 3120, to reduce the volume of future electronic health record-related significant hardship requests;
- H.R. 3245, Medicare Civil and Criminal Penalties Act;
- H.R. 3263, to extend the Medicare Independence at Home Medical Practice Demonstration program; and,
- H.R 3271, Protecting Access to Diabetes Supplies Act of 2017.

In keeping with Chairman Walden's announced policy, Members must submit any amendments they may have two hours before they are offered during this markup. Members may submit amendments by email to peter.kielty@mail.house.gov. Any information with respect to an amendment's parliamentary standing (e.g., its germaneness) should be submitted at this time as well.

II. EXPLANATION OF LEGISLATION

A. H.R. 1148, Furthering Access to Stroke Telemedicine (FAST) Act of 2017

The Committee will consider an amendment in the nature of a substitute to H.R. 1148, introduced by Rep. Griffith (R-VA) and Rep. Beatty (D-OH), which would expand the ability of patients presenting at hospitals or at mobile stroke units to receive a Medicare reimbursed neurological consult via telemedicine. Currently, Medicare will only pay for such a consultation

if the originating site hospital is in a rural Health Professional Shortage Area or a county outside a Metropolitan Statistical Area. However, 94 percent of stroke patients live in urban and suburban areas. Stroke is currently the 5th leading cause of death and is projected to increase significantly; associated costs are projected to triple by 2030. However, with quick treatment, stroke patients can mitigate subsequent medical complications and disability, but every minute can count. The legislation will increase timely access to trained neurologists through telemedicine in the Medicare program so they can direct patient care at the earliest possible intervention point.

B. H.R. 2465, Steve Gleason Enduring Voices Act of 2017

H.R. 2465, introduced by Rep. McMorris Rogers (R-WA), Rep. Scalise (R-LA), and Rep. Larson (D-CT), would make coverage of speech generating devices under "routinely purchased durable medical equipment" permanent under the Medicare program. Previously, under rules issued by CMS, speech generating devices, which are uniquely configured for each eligible beneficiary, were categorized and covered under a capped rental payment. However, if the beneficiary entered a nursing home, hospital, or hospice, payment ended, which limited access to the device. Congress responded in 2015 by passing the Steve Gleason Act, which removed speech generating devices from the capped rental categorization. The bill would remove the 2018 sunset and make this payment category change permanent.

C. H.R. 2557, Prostate Cancer Misdiagnosis Elimination Act of 2017

H.R. 2557, introduced by Rep. Bucshon (R-IN) and Rep. Rush (D-IL), would provide for coverage of DNA Specimen Provenance Assay (DPSA) testing. Prostate cancer is diagnosed with a 10 to 12 needle biopsy samples to detect for cancerous cells, a protocol that became the clinical standard in 2010 and improved the detection rates of prostate cancer. However, despite rigorous lab protocols, a high rate (2.5 percent) of specimen provenance complications (SPCs) occur, where a test result is contaminated with tissue other than the patient's. As a result, approximately 1.28 percent of positive tests are in fact cancer free. DPSA is a diagnostic tool that can address the chances of a false diagnosis, preventing unnecessary and costly treatment protocols. DPSA compares the DNA of the patient to the DNA of the tissue sample tested for cancer. Currently, this test is not covered under the Medicare payment program due to its classification as "quality assurance" rather than a diagnostic test.

D. H.R. 3120, to reduce the volume of future electronic health record-related significant hardship requests

H.R. 3120, sponsored by Rep. Burgess (R-TX) and Rep. Dingell (D-MI), amends the Health Information Technology for Economic and Clinical Health (HITECH) Act in order to remove a requirement that requires the Secretary of Health and Human Services (HHS) to continue to make meaningful use standards more stringent over time. While the meaningful use program has been very successful in driving adoption of electronic health records (EHRs), many providers have struggled to meet the requirements of meaningful use. As the Secretary is mandated to continue to raise the standards overtime, more and more providers are likely to fall behind. When this happens, providers will often seek a hardship waiver to acknowledge they

could not meet the increased standards. This increases the burden further on HHS to process an ever increasing number of hardship requests. The bill simply removes the mandate that meaningful use standards become more stringent over time and allows the Department to be more deliberative in such evaluations.

E. H.R. 3245, Medicare Civil and Criminal Penalties Act

H.R. 3245, introduced by Rep. Bilirakis (R-FL) and Rep. Castor (D-FL), would update both civil and criminal penalties in the Medicare program. Many of these penalties were last updated 20 years ago.

F. H.R. 3263, to extend the Medicare Independence at Home Medical Practice Demonstration program

H.R. 3263, sponsored by Rep. Burgess (R-TX) and Rep. Dingell (D- MI), would extend the Independence at Home Medical Practice Demonstration Program (IAH), which provides a home-based primary care benefit to high-need Medicare beneficiaries with multiple chronic conditions, allowing them to avoid unnecessary hospitalizations, ER visits, and nursing home use, for two additional years. Currently in its fifth year, CMS has evaluated the program's success and found it to have saved money for the program in the first and second years (year 3 data is still being analyzed.) Under statute, the demonstration in total must generate savings, and any practice that does not generate savings of 5 percent faces removal from the demonstration. This extension will provide CMS with additional time to evaluate the program's effectiveness and any changes that may be needed so that Congress can weigh the benefits of the demonstration to program savings and beneficiary care and whether the program should be changed, extended, or made permanent.

G. H.R. 3271, Protecting Access to Diabetes Supplies Act of 2017

H.R. 3271, introduced by Rep. DeGette (D-CO) and Rep. Brooks (R-IN), addresses several issues beneficiaries face under the competitive bidding program regarding Diabetes Test Strips (DTS). Many of these issues stem from how CMS has enforced certain beneficiary protections. The competitive bidding program has several beneficiary protections that the legislation seeks to place into statute to ensure proper oversight and enforcement of these protections. For example, evidence has been presented that the 50 Percent Rule – established by Congress to ensure suppliers make available at least 50 percent of all types of DTS on the market before enactment of the competitive bidding program – has not been fully enforced by CMS. The legislation would codify these protections and provide enhanced reporting that will aid Congress and CMS in ensuring beneficiaries are receiving the diabetic testing supplies they need to manage their condition.

III. STAFF CONTACTS

If you have any questions regarding this markup, please contact Paul Edattel, Josh Trent, James Paluskiewicz, or Kristen Shatynski of the Committee staff at (202) 225-2927.