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ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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August 9, 2023

Dr. Brian Miller, MD, MBA, MPH
Nonresident Fellow, American Enterprise Institute
Assistant Professor of Medicine, Johns Hopkins University School of Medicine
3730 Windom Place N.W.
Washington, DC 20016

Dear Dr. Miller:

Thank you for appearing before the Subcommittee on Health on Tuesday, July 18, 2023, to testify at the hearing entitled "Innovation Saves Lives: Evaluating Medicare Coverage Pathways for Innovative Drugs, Medical Devices, and Technology".

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Wednesday, August 23, 2023. Your responses should be mailed to Jolie Brochin, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Jolie.Brochin@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Brett Guthrie
Chair
Subcommittee on Health

cc: Anna Eshoo, Ranking Member, Subcommittee on Health

The Honorable Cathy McMorris Rodgers

1) The home infusion provisions in the 21st Century Cures Act and the Bipartisan Budget Act of 2018 encouraged movement into the home for infusion when safe to do so, so that patients with limited mobility have access to care in the lowest-cost setting. The traditional "fee-for-service" Medicare home infusion benefit has been utilized by a relatively limited number of Medicare beneficiaries. I understand that Medicare Advantage plans may cover Part B drugs, nursing and related home infusion services and supplies in the home setting as an option that traditional Medicare patients may not have access to.

   In 2020, the Trump Administration proposed language within a Durable Medical Equipment (DME) rule that would, as described by CMS, "clarify that in those circumstances in which an individual is unable to self-administer certain drugs that meet the criteria described above, such drug can be covered as a supply necessary for the effective use of an external infusion pump under the DME benefit," and that "both the pump and the associated supplies can be covered under the DME benefit if reasonable and necessary, but only if the associated home infusion therapy services are also furnished and covered by Medicare." This would have granted expanded access to this benefit to some of Medicare's most vulnerable patients, while saving the government and taxpayers money. Unfortunately, this provision has not yet been finalized to provide an option for home infusion in Medicare fee-for-service.

   a) How should Congress and the administration think about access to home infusion services for Medicare patients and how can we encourage care in more efficient and low-cost settings when appropriate?

   b) What principles should guide Congress and executive branch policymakers when seeking to expand access to home infusion services?

2) Could improvements and flexibilities in paying for new technology complement payment policies, including addressing Medicare payment arbitrage through site neutral payment policies, promote service delivery innovation to lower costs and increase access for Medicare beneficiaries?

   a) How should Congress think about Medicare payment policy in tandem with forward-thinking coverage policies to prudently incentivize innovation?

3) How would these improvements and flexibilities for new technologies complement flexibilities for physician ownership of health care facilities promote greater innovation and lower costs for patients in need of these cutting-edge therapies and diagnostic tools?

4) How do Medicare coding policies affect incentives and patient access to medical innovations?

   b) How should Congress think about modernizing billing and coding practices to balance the importance of encouraging medical innovation with its responsibility to improve the financial standing and long-term sustainability of the Medicare program?

The Honorable Robert E. Latta

1) Do you believe that such a policy incentive shift like the IRA led by the Biden Administration will limit R&D investment for the over 220,000 Ohio seniors battling Alzheimer's disease, many of whom view this R&D as their best hope for a cure?

2) In your testimony, you talked about how TCET is a band-aid to a broken process at CMS. Will you speak to how the guidance can be strengthened and expanded?

The Honorable Earl L. "Buddy" Carter

This committee reported legislation to reauthorize many of our pandemic preparedness programs. Yet at the same time, I worry that some of the policies being implemented as part of the Inflation Reduction Act will make it that much harder to react should we face a similar challenge in the future.

I'm thinking specifically of the Inflation Reduction Act's Part D rebates provision which increase rebates 10 times beginning in 2025, and especially their impact on plasma-derived medicines, which were a key component of our initial COVID-19 response. I'm concerned that without legislative changes to the IRA, or similar commitments from the administration, that we simply won't have tools like convalescent plasma should we find ourselves facing another COVID-like crisis.

1) Dr. Miller - Does increasing rebates in this drastic manner best position us to address future outbreaks? If not, are there steps Congress or the administration should take, perhaps revisiting the harshness of these rebates for plasma derived medicines, to ensure we're on the best public health footing we can be?

The Honorable Dan Crenshaw

1) Dr. Miller, in your testimony you talked about how TCET is a band-aid to a broken process at CMS - can you speak to what are areas where the guidance should be strengthened and expanded?

2) To your knowledge, *before* restricting Medicare coverage of FDA-approved therapies and devices to participants in clinical trials and studies does, does CMS do any analysis of the potential impacts on access to rural or other underserved populations? If so, is that information publicly available?