Healthy Future Task Force
Treatments Subcommittee – Request for Information

The Treatments Subcommittee of the Republican-led Healthy Future Task Force in the U.S. House of Representatives is seeking information from stakeholders and other interested parties regarding medical innovation so that we can supercharge the availability and development of life-saving treatments, devices, and diagnostics, while addressing the rising costs to patients.

The Treatments Subcommittee has four primary goals:

- Goal 1: Evaluate potential innovative payment solutions for expensive curative therapies in Medicare and Medicaid.
- Goal 2: Encourage innovation and make the Medicare system more flexible to be able absorb new innovative drugs, devices, diagnostics while being good stewards of taxpayer dollars.
- Goal 3: Continue U.S. leadership in medical innovation.
- Goal 4: Increase access to medical innovation.

SUBMISSIONS: Individuals or groups wishing to respond to this RFI should fill out this form by March 11, 2022.

If you have any questions about this RFI, please reach out to Casey Quinn with Rep. Wenstrup, Matt Tucker with Rep. Joyce, or Elizabeth Teed with Rep. Westerman.

Goal 1: Evaluate potential innovative payment solutions for expensive curative therapies in Medicare and Medicaid

1. As new innovative drugs, diagnostics, and devices are developed, we anticipate they will be associated with both high costs and a high value to society through early detection or cures. How should government payors use innovative payment methodologies to pay for expensive new drugs, diagnostics, and devices?

2. Does the potential site of care delivery and corresponding federal Medicare reimbursements influence curative therapy development? For instance, CAR-T is typically delivered in the inpatient setting and reimbursed under the inpatient fee schedule. Antivirals to cure Hepatitis C are taken at home and are reimbursed through the Medicare Part D program. A future curative infusion therapy could be delivered in a physician's office or infusion site and be reimbursed under the physician fee schedule. These reimbursements are all calculated differently and result in variable costs for patients. Would a singular model for reimbursement of curative therapies help or hurt development?

3. On December 21, 2020, the Trump Administration finalized a rule to make updates to what Medicaid pays for drugs, titled "Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements." The rule would allow pharmaceutical manufacturers to report multiple best prices in the Medicaid program instead of a single price. This would allow manufacturers to enter into value-based arrangements without concerns over interaction with the Medicaid best

price program, avoiding any unintended punitive consequences for entering into these arrangements. On November 17, 2021, CMS announced that it is delaying implementation of the rule to July 1, 2022.

a. What did the rule get right?
b. What did the rule get wrong that can be fixed through legislation?
c. What should be expanded in the rule through legislation?
d. Do you think it's prudent that HHS finalize this rule?

4. The Democrat majority intends to advance a bill that would set the price of certain drugs in Medicare.

a. How could that bill impact future curative therapies? If there are negative projected effects, then what can Congress do to ameliorate them?
b. Republicans laid out a plan for drug pricing with H.R. 19 Lower Costs, More Cures Act of 2021. This includes over 30 bipartisan provisions to lower drug costs for seniors. Building off of this, what other policies should we consider to lower costs while maintaining access to lifesaving cures?

Goal 2: Encourage innovation and make the Medicare system more flexible to be able absorb new innovative drugs, devices, diagnostics while being good stewards of taxpayer dollars

1. What barriers to innovation in the drug, device, or diagnostic space should Congress address?

2. On October 29, 2021, the Biden Administration repealed the Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" final rule.

a. The Administration claimed that the rule was "not in the best interest of Medicare beneficiaries because the rule may provide coverage without adequate evidence that the Breakthrough Device would be a reasonable and necessary treatment for the Medicare patients that have the particular disease or condition that the device is intended to treat or diagnose." How can the policy be improved to respond to CMS' concerns? How can "adequate evidence" be gathered in the most efficient and effective way to show an innovative technology is reasonable and necessary for the Medicare population?
b. If the goals of this rule were to be met with legislation, what would you want to see? What did the rule get right, get wrong, and what should be expanded on?
c. What other types of products and technologies, besides FDA breakthrough devices, should be considered for expedited Medicare coverage under an MCIT-like paradigm? And what safeguards should accompany new or temporary coverage to protect the solvency of the Medicare program?
d. What kind of flexibilities in the Medicare Advantage program or other value-based programs within Medicare could be adopted to test enhanced coverage of innovative products and technologies in a fiscally responsible manner?
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3. On November 20, 2020, the Trump Administration finalized two rules as part of the Department of Health and Human Services (HHS) Regulatory Sprint to Coordinated Care. The HHS Office of Inspector General (OIG) issued the final rule "Revisions to the Safe Harbors Under the Anti-

Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements," and the Centers for Medicare and Medicaid Services (CMS) issued the final rule "Modernizing and Clarifying the Physician Self-Referral Regulations." In the rules, HHS removed some regulatory barriers to encourage increased participation in value based care, which can lead to improved care coordination, improved outcomes, and lower costs.

   a. As it relates to drugs, devices, and diagnostics, should Congress expand on these rules, and if so, how?
   b. Should the administration have allowed medical devices to participate in a value based enterprise (VBE)?
   c. Under the rules, digital innovators are eligible to participate in a VBE. Are digital innovators planning on using this exemption? Does it achieve the flexibility needed to enter into meaningful value-based arrangements?

4. What are the various categories of Digital Health that need to be recognized from the standpoint of reimbursement to begin exploring the mechanisms for coverage, coding, and payment that may already exist, and to understand where gaps remain under current regulatory and statutory frameworks?
   a. For example, would it be helpful to distinguish software applied to Durable Medical Equipment, from software applied to implantable devices?
   b. Are there important distinctions among AI, algorithms, software, and other types of Digital Health technology that should be contemplated?
   c. What current mechanisms are in place to facilitate initial access to Digital Health technologies under the Medicare fee-for-service payment systems? How can those be improved, and where are there gaps?
   d. For example, the New Technology Add-on Payment (NTAP) may be available for AI software used in hospital inpatient settings to help cover hospitals' costs for initial investment in technologies that meet certain standards. What improvements could be made to support adoption of Digital Health used in inpatient care? Are similar mechanisms needed in other settings, such as hospital outpatient departments?

5. How do plans under Medicare Advantage reimburse for Digital Health technologies? What is take-up of these technologies under Medicare Advantage?
   a. How can adequate reimbursement be ensured, and where are there access gaps?
   b. How should CMS approach pricing for AI used in physician office settings to ensure accurate and adequate payments in the long term?
   c. What mechanisms exist under alternative payment models to facilitate access to Digital Health technologies? What improvements could CMMI potentially pursue to specifically enable health systems to invest in Digital Health technologies?

Goal 3: Continue U.S. leadership in medical innovation

1. How does the FDA regulatory process compare to Europe when it comes to cell and gene therapies?

2. Does the existing FDA framework adequately facilitate innovation in digital health?

3. Is the National Institutes of Health efficiently distributing billions of taxpayer dollars to universities to invest in basic research? Are there ways to improve reproducibility with basic research, and should retractions be considered when grants are applied for?

4. How can we streamline and reduce red tape to access government grants for biomedical research?

Goal 4: Increase access to medical innovation

1. Should a focus of innovation be making more prescription products available over the counter, for example, naloxone?

2. What can be learned from the pandemic to speed up development of novel vaccines and treatments?

3. Can we continue decentralizing clinical trials and allow more patients to get access to innovative treatment in their communities and homes through remote monitoring? What regulations and laws must be addressed to facilitate continued progress?

Miscellaneous

1. How should Congress work to ensure continued patient access to treatments for antimicrobial-resistant infections?

2. Is there anything else the Treatments Subcommittee should consider?