Attachment—Additional Questions for the Record

Subcommittee on Health Hearing on
"Innovation Saves Lives: Evaluating Medicare Coverage Pathways
for Innovative Drugs, Medical Devices, and Technology "

July 18, 2023

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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?

      Policymakers should encourage competition between sites of care to encourage patients and physicians to seek care where it is most clinically appropriate, be it in the clinic or home. Policy should not favor one infusion site over another, rather it should setup a dynamic competitive model to encourage home infusion to compete with on-site infusion with the patient receiving the right care, at the right time, in the right location best suited for their personal needs.

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

      A few key principles:
      1. Clinically appropriateness should drive site of care
      2. Discourage payment policy arbitrage
      3. Payment models should be based upon competition as opposed to administrative pricing with levels directly set by Congress or dictated by CMS

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?

Both paying for new technologies and addressing Medicare payment policy arbitrage by implementing site neutral payment could promote innovation, lower costs, and increase access. A lack of site neutral payment means that hospitals are able to charge the Medicare program higher rates for care in a variety of clinical sites even if there is no meaningful difference in the care delivered or operational changes in how a facility runs. Site neutral payment is a pragmatic payment policy that could help combat consolidation:[1] elimination of a significant payment policy will cause hospitals to shed clinics and drive competition to lower prices. In addition to broader effects on competition and market dynamics, the Committee for a Responsible Federal Budget estimates that site neutral payment could save $153 billion in direct spending for the Medicare program over a decade.[2]

Coupling site neutral payment with creative coverage of technology could improve labor productivity through the augmentation of human capital, in addition to driving healthy competition between technology- and human-driven processes. Automation of portions of or complete automation of administrative tasks in healthcare (e.g. patient charting, billing/coding, prior authorization) would improve labor productivity. Automation of portions of clinical tasks (e.g. reading of low-risk imaging studies, interpretation and diagnosis of well-defined cancers on pathology slides) would similarly improve the productivity of human capital, transforming physicians into managers of people, process, and technology via the principles of innovation and competition.

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

Policymakers should look to encourage Medicare coverage of technology in order to both augment and drive more efficient, lower cost care delivery. As coverage is critical to creating a pathway to the market for entrepreneurs, a systematic framework to address coverage of technology is critical. For example, policymakers could consider adding a modifier to the Medicare physician fee schedule, providing it a value between 0 and 1, allowing CMS to value telehealth along with technology-driven or even autonomous service to be both valued and paid for at a price lower than purely human capital-driven service. In conjunction with this, policymakers will need to consider if technology enterprises should be considered a Part B provider, which would drive competition and help ensure that beneficiaries receive access to the most efficient, effective, and beneficiary-centric service. Technology could also be deployed in existing service bundles, with an aim to avoid add-on payments in order to drive programmatic savings.

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?

Repealing the ban on physician-owned hospitals would increase competition in consolidated hospital markets, lowering costs and improving quality.[3] Further policy efforts to promote competition in the market for integrated care delivery by providing an exception to Stark Law solely for beneficiaries participating in managed care[4] (i.e. Medicare Advantage and Medicaid Managed Care Organizations) would increase competition while taking advantage of the population-based payment inherent in risk-adjusted capitation along with managed care utilization review practices, both of which serve as a built-in safeguards against induced demand.

These two policy actions would serve to improve competition in the market for care delivered by community hospitals and specialty hospitals, in addition to the market for integrated care delivery. As physicians are well-positioned - along with nurses, pharmacists and other clinical professionals - to identify opportunities for

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[1] https://www.aei.org/wp-content/uploads/2022/11/Policy-Solutions-for-Hospital-Consolidation.pdf?x91208
[2] https://www.crfb.org/papers/equalizing-medicare-payments-regardless-site-care
[3] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4350105
[4] Miller BJ, Ehrenfeld JM, Wu AW. Competition or Conflict of Interest—Stark Choices. *JAMA Health Forum.*2021;2(2):e210150. doi:10.1001/jamahealthforum.2021.0150

improvements in clinical operations, uses of technology, and customization of care for patients, coupling increased flexibility in ownership with coverage of new technologies and therapies will supercharge medical care promoting competition, personalization, and thus lower cost and higher quality.

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

In order for an item (drug, device, technology) or service to obtain Medicare coverage, it must have a code, coverage, and price. If an item or service does not have a code, does not fit into an existing defined code, or does not have a pathway to obtaining a code, the item or service does not have a pathway to coverage. Thus, coding practices can serve to restrict or eliminate patient access to innovation.

a) 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?

Policymakers should look to modernize coding and billing practices. For example, to promote site neutral payment, site of service distinctions could be eliminated from some codes -- thus reducing cost. In other circumstances, a modifier could be added to codes to denote how the service is delivered (e.g. telehealth, automated service, tech-assisted human capital-driven service), attaching a relative value to the payment and promoting competition between service delivery modalities while reducing costs.

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?

The Inflation Reduction Act or IRA addresses drug pricing with a "one size fits all" approach deploying centralized, administrative pricing. The IRA applied administrative pricing in several forms, notably through the requirement for drug price negotiation for a pool of drugs selected from the 50 drugs each in Part B and Part D with the highest spending. While there are statutorily-specified exclusions (implemented through the CMS guidance), the subject of Medicare drugs to centralized administrative pricing tools will massively shift incentives for pharmaceutical product development.

In particular, novel therapeutics targeting unmet needs will face increasing financing pressure. While much of the focus has been on rare diseases and orphan indications affecting under 200,000 patients, diseases with unmet needs affecting large populations will also be negatively impacted.

Financing requirements for developing a new product are significant and range from three quarters of a billion dollars to nearly one and a half billion dollars.[5] In this vein, pharmaceutical product developers need to not only recoup the cost of development, but also the cost of prior failed product development and to fund future product development.

As the administrative pricing provisions in the IRA functionally cap the price and hence revenue of products, the IRA undermines the blockbuster model to drug development in therapeutic areas with significant unmet need. Consequently, the CBO (2019 report on HR3)[6] estimated that 8 fewer drugs would be developed over the 2020-2029 period and 30 fewer during the subsequent decade. This is in stark contrast to a 2021 working

[5] Wouters OJ, McKee M, Luyten J. Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. JAMA. 2020 Mar 3;323(9):844-853

[6] https://www.cbo.gov/system/files/2019-12/hr3_complete.pdf

paper[7] published by Thomas Philipson at the University of Chicago, which denotes a lower bound estimated loss of 167 new drugs during the same 20 year time period.

While the true answer is likely somewhere in between these estimates, it is clear that the IRA will massively change the incentives for product development, particularly in areas requiring significant bench and translational research. For patients with longstanding and disabling diseases such as Alzheimer's, the economics of industry research and development are likely to undergo significant disruption, as products that could be subject to IRA price negotiations or rebates will see less investment. Thus, the potential positive disruption for diseases like Alzheimer's - where progress has been made but much work is still needed - will be reduced, potentially taking away hope from millions of Americans and their families.

The great irony here is that in this new era of focused price regulation - a tool that has failed to control medical expenditure growth in over 60 years of fee for service Medicare spending and is reminiscent of many of the flaws in pricing for physician-administered drugs in Part B - the very same experts that championed the IRA also championed ARPA-H as a federal investment tool to promote innovation and disruption.

The greatest travesty of the IRA is that it obviates the need to have a nuanced discussion on drug pricing, painting all drug markets with the same brush. For example, novel cell and gene therapies may offer exceptionally high value to patients and thus merit high payment. Yet, paying large sums at a single point in time is both impractical and not necessarily prudent policy. Thus,, cell and gene therapies may require new value-based arrangements, paying for a range of outcomes over time.[8] Still, other pricing models such as the administered pricing model in Part B physician-administered drugs are a longstanding target for reform, with experts proposing ways to transform it into a competitive, managed benefit. Finally, other important tools such as changes in FDA product regulation (e.g. biosimilar interchangeability) or incentives for market entry (e.g. a priority review voucher for limited competition small molecule generic markets)[9] remain ignored.

Instead of doing the hard work to drive policy towards a dynamic solution, the IRA paints the challenge of drug pricing as a single point-in-time problem applying a static tool that we know does not work well over the test of time and has unintended consequences - administrative pricing.

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

Policymakers should require CMS to publish and regularly update (e.g. every 5 years) guidance on the following:
1. How CMS decides to commission an external technical assessment of a drug, device, technology, or service
2. Circumstances and conditions that warrant a convening of the Medicare Evidence Development Coverage Advisory Committee (MEDCAC)
3. Factors that warrant consideration of deferral on coverage to MACs (i.e. undertaking a Local Coverage Determination instead of a National Coverage Determination)

Furthermore, policymakers should subject CMS to clear, statutorily binding timelines, transparency requirements, and regular opportunity for public input for all coverage decisions.

The Honorable Earl L. "Buddy" Carter

[7] https://bfi.uchicago.edu/wp-content/uploads/2021/09/BFI_WP_2021-108.pdf
[8] Miller BJ, Zima SC. Exceptions for Exceptional Cures—Modernizing the Medicaid Drug Rebate Program. *JAMA Health Forum.* 2020;1(8):e201058. doi:10.1001/jamahealthforum.2020.1058
[9] https://www.healthaffairs.org/content/forefront/priority-review-voucher-program-fuel-generic-drug-development

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?

   While plasma-derived blood products are statutorily excluded from the drug negotiation process as part of the Inflation Reduction Act, the 198-page long June 2023 CMS guidance document[10] denotes a variety of categories such as cell and gene therapies that do not necessarily qualify for the plasma-derived product exclusion. Specifically, in Section 30.1.3, the updated guidance notes that single source plasma-derived products have a statutory exception, and that CMS will refer to information on the FDA approved blood products web site and FDA online label repository.

   However, manufactured as opposed to derived products may not qualify for this exception. Products such as the variety of monoclonal antibiotics that were a critical product early in the pandemic could potentially be eventually subject to IRA administrative pricing through the "negotiation" process. More concerning, as you pointed out, such products could potentially be subject to the inflation-indexed rebates, with government policy thus depressing prices and discouraging both market entry and upstream development. Not only will this decrease market incentives for product development, it may have measurable public health harms and decrease pandemic preparedness.

   Administrative, static rebates written into statute add layer upon layer of administrative complexity in drug pricing, creating opportunities for payment policy arbitrage, reduce innovation, and create additional inefficiencies that are then unfortunately frequently corrected through further legislative interventions. This creates a near-endless cycle of problems solved with solutions that create additional problems, as policy experts continue to apply static solutions to a dynamic world. The existing Medicaid Drug Rebate program - which has good intentions of offering low cost drugs to those least able to afford them - and the new inflation-indexed Medicare drug rebate both suffer from these same problems and cognitive framework.

   Congress can take several steps to address this. In addition to revising the statutory exception to the IRA for plasma-derived products, policymakers could promote dynamism by tying participation in a value-based arrangement[11] to an exception to both the Medicare and Medicaid Drug Rebate programs. This could promote payment for outcomes and prevent administrative pricing from obliterating innovation in some areas with significant unmet clinical needs.

   More importantly, policymakers should reorient the conversation around drug pricing towards encouraging a more dynamic market, as opposed to stacked static interventions that either transfer costs from public to private markets or encourage payment or regulatory policy arbitrage (340B, abuse of the FDA citizen petition process etc.). Sound policy should promote dynamic solutions that age well over time and direct industry energy towards product development instead of regulatory arbitrage.

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[10] https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf

[11] Miller BJ, Zima SC. Exceptions for Exceptional Cures—Modernizing the Medicaid Drug Rebate Program. *JAMA Health Forum.* 2020;1(8):e201058. doi:10.1001/jamahealthforum.2020.1058

The Honorable Dan Crenshaw

1) 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? 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?

   Policymakers should require CMS to publish and regularly update (e.g. every 5 years) guidance on the following:
   1. How CMS decides to commission an external technical assessment of a drug, device, technology, or service
   2. Circumstances and conditions that warrant a convening of the Medicare Evidence Development Coverage Advisory Committee (MEDCAC)
   3. Factors that warrant consideration of deferral on coverage to MACs (i.e. undertaking a Local Coverage Determination instead of a National Coverage Determination)

   Furthermore, policymakers should subject CMS to clear, statutorily binding timelines, transparency requirements, and regular opportunity for public input for all coverage decisions.

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?

   I am unaware if CMS undertakes any analysis of impacts on access to rural and underserved populations before the agency decides to restrict Medicare coverage of FDA-approved therapies and devices.

   Policymakers should consider requiring CMS to undertake and publish this analysis as part of the coverage determination process in order to ensure that populations have equal access to Medicare-covered therapies.