The Honorable Cathy McMorris Rodgers

1. I was encouraged to read in the 2023 Medicare Trustees Report that CMS actions, most notably removing hip and knee procedures off the "inpatient only list" and allowing patients to receive and doctors to perform additional services in the more efficient and less expensive outpatient setting have reduced total Medicare expenditures and contributed to extending the program's solvency a little longer through 2031. How should Congress think about additional actions to enhance patient and provider choices by encouraging more services to be safely administered in the outpatient setting?

1. **Would allowing more procedures to be done in outpatient settings, like Ambulatory Surgery Centers, enhance competition among providers and encourage hospitals to compete with ASCs and other hospitals who offer outpatient services?**

   Recent empirical analysis has emphasized the importance of provider competition in moderating the growth of health costs.[1] In many areas, competitive concerns are especially pronounced within the inpatient hospital market, placing particular emphasis on procompetitive policies that affect this market. Allowing a greater number of procedures to be done outside of the inpatient setting would generally help improve competition for these types of services. Indeed, one would expect this kind of dynamic to emerge in a well-functioning health care market. As services become less likely to make use of inpatient services, payers would have a strong incentive to encourage enrollees to make use of more competitive, lower-cost settings. It is worth noting that under its current criteria for removing procedures from the IPO list, CMS considers whether most outpatient departments or ASCs are equipped to provide it.[2] Thus, one would expect relatively immediate competition from such a change.

2. **Does research and existing data suggest patients would still be able to receive quality and safe care for certain additional services in outpatient settings?**

   The continued advance of technology and improvements to clinical practice all but ensure that the answer to this question is "yes." This is particularly true since health care providers can still make clinical judgements about site of service on a case-by-case basis. Moreover, this consideration is reflected in CMS' approach to removing items from this list. As they note,[3] "…over time, given advances in technology and surgical technique, we would continue to evaluate services to determine whether they should be removed from the IPO list. Our goal is to ensure that inpatient only designations are consistent with the current standards of practice. We have asserted in prior rulemaking that, insofar as advances in medical practice mitigate concerns about these procedures being performed on an outpatient basis, we would be prepared to remove procedures from the IPO list and provide for payment for them under the OPPS (65 FR 18443)."

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[1] For a discussion, see Loren Adler and Benedic Ippolito "Procompetitive Health Care Reform Options for a Divided Congress," *American Enterprise Institute and The Brookings Institution* (March 16, 2023).

[2] See https://public-inspection.federalregister.gov/2022-23918.pdf

[3] https://public-inspection.federalregister.gov/2022-23918.pdf

The Honorable Earl L. "Buddy" Carter

As a pharmacist, I've seen firsthand the obstacles patients face in filling their prescriptions. Manufacturer copay assistance is one of the ways many patients today are able to better afford their prescription medicines. According to a recent study, manufacturer copay assistance was found to close important affordability gaps, increasing utilization by 4.8 to 16.7 percent which in turn raised health outcomes by 1.0 to 3.3 percent. Unfortunately, "copay accumulator" schemes that PBMs have developed pocket a patient's copay assistance; my bill, the HELP Copays Act, would ban this practice. Dr. Ippolito, you have written about the need for more transparency in the role of PBMs for plan sponsors or insurers. However, pharmacists like me see patients struggle with PBM transparency too, including understanding their coverage and benefits which often hide details on tactics like copay accumulators with hard to understand language.

1. **Dr. Ippolito - Do you think there is a role for increased PBM transparency for patients so that they can actually understand their pharmacy benefit and accurately predict their out- of-pocket costs for their plan year so they don't experience copay surprise from accumulator programs?**

   Well-functioning markets require that consumers understand the costs and benefits of products which they buy. Within health insurance markets, it is critical that consumers understand the premiums, coverage, and cost sharing obligations of different insurance plans. Copay accumulators can play an important role in patients' cost sharing, so efforts to make them more transparent are sensible and can help consumers make more informed decisions that better reflect their preferences. In particular, one could imagine consumers weighing a tradeoff between greater protection against large out-of-pocket shocks you describe and other plan features, like premiums.

The Honorable Dan Crenshaw

One of the most under-discussed supply-side barriers to competition are state certificate-of-need laws. My state of Texas recognizes the burden and does not have them, but in the more than 30 states that maintain these laws (Certificate of Need State Laws (ncsl.org)), new health care providers are typically prohibited from entering the market without a government-ordained "certificate-of-need." Nearly 20 years ago, the FTC said these laws were not successful in containing costs, and that they can actually increase prices by fostering anticompetitive barriers to entry (Improving Health Care: A Dose of Competition (ftc.gov)). Dr. Ippolito, unsurprisingly these well-intentioned but misguided laws are a result of poor federal policy, specifically incentives created in 1970s for states to adopt these laws.

1. Do you believe that they are contributing to increased federal spending on health care? Should Congress engage in a conversation about the merits of these state laws today?

Certificate of Need (CON) laws were originally motivated by the concern that if health care investments were unchecked, they might lead to excessive use of unneeded services or a wasteful "arms race" over costly services with dubious value. Moreover, they were advertised as a mechanism to direct investments where they were most needed, potentially increasing access to care in certain areas. However, as you note, they also represent a barrier to entry that can raise serious concerns. CON laws directly increase the costs of market entry by requiring a potential entrant to spend time and resources navigating the process. In addition, it allows states to block potential entrants. This latter feature can be particularly concerning if CON laws provide an opportunity for regulatory capture by dominant, incumbent providers who seek to limit their own competition. This concern has grown more pronounced over time as consolidation in many parts of the health care market—but particularly hospital markets—has increased. Given the long history of CON laws, including the elimination of these laws in many states, one would expect ample evidence of their purported benefits. Instead, the evidence tends to support concerns that CON laws have an overall negative effect on health care markets.[4] As you note, available evidence has prompted federal antitrust agencies to express significant concerns with CON laws. Given this, it strikes me as reasonable to consider whether Congress has a role in encouraging the remaining states to move away from these policies.

The Honorable Frank Pallone, Jr.

1. **There is little insight into how PBMs negotiate arrangements and rebates with drug manufacturers and what impact this has on health plans and patients. Increasing transparency with respect to contracting arrangements between PBMs and drug manufacturers has been proposed as a mechanism for lowering drug prices. Can you describe what benefit more transparency would have here?**

   Across markets it is very difficult for purchasers to compare products when their costs and benefits are unclear. This is a potentially significant issue in the market for PBM services. In particular, the relatively complex and opaque fee structure (including, but not limited to, rebates) can make it difficult to assess the true cost of a PBM contract. This also makes it more challenging to compare one PBM against another, potentially muting competition between them. Greater transparency in this area can help plan sponsors better evaluate contracts and generate more competition between PBMs.

2. **As you mentioned in your testimony, there have been bipartisan proposals in Congress that would require PBMs to disclose certain information to plan sponsors and employers. Do you believe this is a proposal that would effectively lower costs**

[4] For a discussion, see Mitchell, Matthew "Certificate-of-Need Laws: How They Affect Healthcare Access, Quality, and Cost." Mercatus Center. May 21, 2021.

while also providing plan sponsors with additional information to leverage better arrangements?

Prior legislative efforts, like the Lower Health Care Costs Act of 2019, have included provisions that would require PBMs to disclose more information about rebates, costs, and fees.[5] Providing clearer information about these contract features to plan sponsors and employers should help them better assess the costs and benefits of different contracts and generate more cost competition between PBMs. All else equal, this should reduce costs. This expectation is shared by the Congressional Budget Office, which estimated that prior proposals along these lines would lower federal deficits.[6]

3. **What role has market consolidation played with respect to PBMs? Do you believe consolidation has increased anti-competitive contracting arrangements?**

The PBM market is relatively consolidated, with three firms controlling roughly 80 percent of the market.[7] Fewer, larger PBMs has the potential to increase their leverage when negotiating with drug makers, but also allow PBMs to potentially retain a larger share of spending than would occur in a more competitive market. These countervailing forces are worth policy attention. Beyond horizontal consolidation, the major PBMs are also vertically integrated with other entities in the health care market, including insurers, specialty pharmacies, and providers. Vertical integration has the potential to influence the way that PBMs behave with regards to other parts of the health care market. For example, it is possible that they may engage in behavior that benefits other parts of the vertically integrated company (e.g., by preferencing their own specialty pharmacy or otherwise driving volume and spending towards firms that are part of the same vertically integrated entity). These types of behaviors can potentially increase coordination or avoid double marginalization, but also raise competitive concerns. Whether these types of vertical relationships result in anticompetitive behavior is worth attention and is likely a case where greater transparency would help policymakers better assess the validity of these concerns.

4. **You discussed in your testimony how consolidation is leading to increased costs for consumers and employers. Can you describe some of the consolidation that is occurring and how this is impacting our health system at large?**

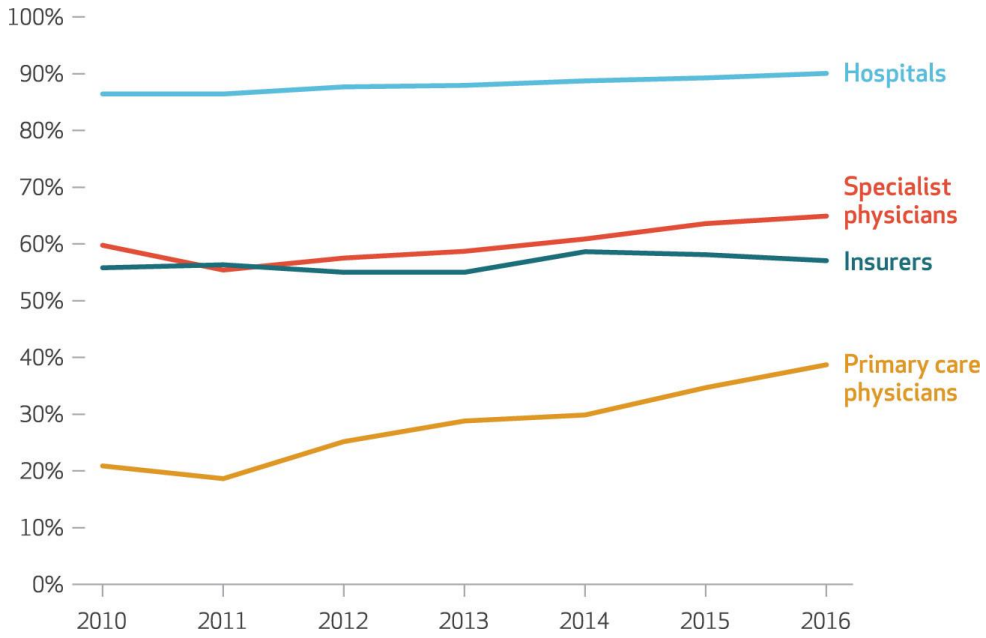
The very high level of U.S. health care spending would not represent a major problem if that spending accurately reflected the preferences of consumers. However, there is significant evidence that much of that spending instead reflects market imperfections, like highly consolidated markets.

For example, the following figure from Fulton (2017) illustrates the fraction of Metropolitan Statistical Areas that are considered highly consolidated (defined as an HHI

[5] For the complete text, see https://www.congress.gov/bill/116th-congress/senate-bill/1895.
[6] Congressional Budget Office, "S. 1895, Lower Health Care Costs Act,' July 26, 2019.
[7] Drug Channels. "The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger." April 5, 2022.

over 2,500) from 2010-2016. Consolidation is very high in many areas (e.g., hospital sector) and rising in others (e.g., many physician markets). Given additional mergers and acquisitions since the publication of this paper, these data likely understate the level of consolidation in the current market.

Figure: Percentages of MSAs with HHI over 2,500 for hospitals, physicians, and insurers



Note: Figure from Fulton (2017)

Markets with limited competition allow dominant firms—whether providers, insurers, PBMs, or any market actor—to charge high prices while facing less pressure to improve quality. These costs are ultimately borne by consumers in multiple ways. Particularly in the private market, consolidated entities increase the cost of insurance, which now stands over $22,000 per year for a family plan in the employer market.[8] Employees bear the burden of these costs in two ways. First, this can increase the premiums directly paid by employees and increase their out-of-pocket spending. Second, this reduces wage growth of employees. Even if employers nominally shoulder a large share of these costs, doing so increases the cost of employing a worker and reduces the amount they can pay in cash. Economic evidence has shown this link across multiple settings.[9] In short, by increasing health costs, consolidation has first-order implications for consumers.

5. Can you describe ways Congress can address market consolidation and help lower costs?

[8] KFF, “2022 Employer Health Benefits Survey.” October 27, 2022.
[9] For example, see Gruber, Jonathan. "The incidence of mandated maternity benefits." *The American economic review* (1994): 622-641.

Congress can consider a number of policies to attenuate market concentration and increase cost pressures throughout the health care market. (Many of the following policy options are discussed in greater detail in Adler and Ippolito, 2023).[10] First, it can change payment policies that currently incentive consolidation. This includes adopting site-neutral payments within the Medicare program where appropriate, reforming incentives created by drug payments in the Medicare Part B program, and altering the 340B program. Second, the federal government could in principle incentivize states to change a host of policies that can reduce competition. This includes Certificate of Need policies, Scope of Practice restrictions, and Certificates of Public Advantage. Third, Congress can consider changes to antitrust enforcement in these markets. Regulators could be given more insight into possible anticompetitive consolidation by lowering thresholds for required reporting of transactions and by requiring reporting in cases where a single owner engages in a large number of small transactions (in conjunction, they could work to improve transparency about ownership structures more generally). They could also consider strengthening antitrust statutes by reducing the bar for regulators to challenge a merger in these markets (e.g., some have proposed requiring only that a merger "meaningfully" or "materially" lessens competition rather than "substantially" so).[11]

[10] Adler, Loren and Benedic Ippolito. "Procompetitive Health Care Reform Options for a Divided Congress." AEI and Brookings. March 16, 2023.

[11] For a discussion, see Testimony of Leemore S. Dafny before the U.S. House Committee on the Judiciary Subcommittee on Antitrust, Commercial and Administrative Law on "How Health Care Consolidation Is Contributing to Higher Prices and Spending, and Reforms That Could Bolster Antitrust Enforcement and Preserve and Promote Competition in Health Care Markets"