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STATEMENT FOR THE RECORD

Examining Policies to Improve Seniors' Access to Innovative Drugs, Medical Devices, and Technology

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Statement of
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Committee on Energy and Commerce
U.S. House of Representatives

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The Medicare Payment Advisory Commission (MedPAC) is a congressional support agency established by the Balanced Budget Act of 1997 (P.L. 105–33) to provide independent, nonpartisan policy and technical advice to the Congress on issues affecting the Medicare program. The Commission's goal is to pursue Medicare policies that ensure beneficiary access to high-quality care, pay health care providers and plans fairly by rewarding efficiency and quality, and spend tax dollars responsibly. MedPAC does not take positions on proposed legislation but is providing information about relevant prior Commission work that may be helpful as the Committee confronts issues with how Medicare covers and pays for new technologies. The Commission would like to thank Chair Rodgers, Ranking Member Pallone, Chair Guthrie, Ranking Member Eshoo, and all Members of the Committee for the opportunity to submit a statement for the record today.

Background

The development of new technologies, such as prescription drugs and biologics (hereafter referred to as *drugs*), lab tests, and medical devices, can lead to significant improvements in health for Medicare beneficiaries. For example, new pharmacologic breakthroughs—such as immunotherapy for melanoma, second generation androgen receptor antagonists for prostate cancer, and new drugs for myeloma—have contributed to patients' increased life expectancy (Schnog et al. 2021). The Commission recognizes the importance of beneficiaries' access to new technologies that improve outcomes relative to the standard of care. In providing that access, policymakers must balance affordability for beneficiaries and taxpayers with appropriate reward for innovation. The goal of Medicare payment policy is to obtain good value for the program's expenditures, which means maintaining beneficiaries' access to high-quality services while encouraging efficient use of resources. Payment system incentives that promote beneficiaries' access to efficiently delivered high-quality care serve the interests of the taxpayers and beneficiaries who finance Medicare through their taxes, premiums, and cost sharing.

An important driver of growth in Medicare spending is the use of new technologies, including drugs, lab tests, medical devices, and other innovative therapies. The potential for manufacturers to earn a profit from the sale of a new technology provides incentive for them to invest in research and development (R&D). Manufacturers set launch prices based on what they believe the U.S. health care market will bear and, historically, have set high prices for many new treatments whether or not there is evidence that the technology is comparatively more effective than existing standards of care for improving the health of beneficiaries (Medicare Payment Advisory Commission 2023a). Likewise, prices for certain existing items and services are a concern. Some launched at high prices when first introduced to market, and prices have often grown rapidly, even for products with therapeutic alternatives, despite a lack of evidence of increased effectiveness. In addition, some new items and services disseminate quickly into routine medical care in fee-for-service (FFS) Medicare with little or no knowledge of whether or to what extent they outperform existing treatments. When new technologies are approved by the Food and Drug Administration (FDA), the evidence on their effectiveness is not always complete, particularly for technologies approved under expedited approval pathways.

For most new technologies for which Medicare makes a separate payment, Medicare is a price taker. Generally, Medicare has had only an indirect influence on how new technologies are priced and has few tools to set payment rates for new technologies. Thus, Medicare has been limited in its ability to strike a balance between providing financial rewards for innovation with value and affordability of care for beneficiaries and taxpayers. However, it is important to recognize that Medicare operates within a context involving other payers as well as federal and state laws, agencies, and policies. Many influences over new technology prices are outside of Medicare's purview but may affect the prices of new and existing technologies and thus have fiscal implications for Medicare beneficiaries and taxpayers. These influences include funding for biomedical R&D, patent policy, tax policy, and the FDA's drug and device approval process.

Policymakers face tradeoffs when considering changes to how Medicare covers and pays for new technologies. Because Medicare has only an indirect influence on how technologies are priced, extending coverage allows beneficiaries to access new technologies but has important fiscal implications for beneficiaries and taxpayers. Thus, if policymakers choose to expand Medicare coverage, they should consider the strength of the evidence on the product's effect on clinically meaningful health outcomes for the Medicare population (Jensen 2014, Medicare Payment Advisory Commission 2020b). Tools such as coverage with evidence development (as discussed below), setting payment using comparative clinical effectiveness data, and cost sharing are some tools that policymakers could consider as safeguards for beneficiaries and taxpayers.

How Medicare covers new technologies

Section 1862(a)(1)(A) of the Social Security Act requires that the Medicare program cover Part A and Part B items and services that are included in a Medicare benefit category, are not statutorily excluded, and are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

FFS Medicare covers many new items and services without an explicit coverage policy. If a new item or service falls under a Medicare benefit category and can be reimbursed on the basis of an existing billing code or a bundled payment system (e.g., inpatient prospective payment system), Medicare may cover it without an explicit coverage policy. Alternatively, either CMS (at the national level) or the Medicare Administrative Contractors (MACs) (at the local level) may make explicit national or local coverage determinations, respectively, under which a formal review of the medical, technical, and scientific evidence is conducted to evaluate the relevance, usefulness, and medical benefits of an item or service to Medicare beneficiaries. The process of developing national coverage determinations and most local coverage determinations provides opportunities for public comment, and information on both types of coverage determinations are available in the Medicare Coverage Database on CMS's website. Outcomes of an explicit coverage determination include: Medicare coverage of an item or service with no restrictions, coverage for beneficiaries with specific clinical conditions or when furnished by specific providers or facilities, leaving the coverage determination to the discretion of the MACs, or precluding Medicare coverage. In the absence of an explicit coverage determination, the MACs may

cover items and services on a claim-by-claim basis according to statutory and regulatory provisions.

A small subset of national coverage determinations links a new service's national coverage to participation in an approved clinical study or to the collection of additional clinical data. This policy is referred to as *coverage with evidence development* (CED), and its goal is to expedite early beneficiary access to innovative technology while ensuring that patient safeguards are in place. CED allows coverage of certain items or services when additional data gathered in the context of clinical care would further clarify the effect of these items and services on the health of Medicare beneficiaries. Because CED provides Medicare the opportunity to generate clinical evidence that otherwise might not have been collected, it enables the program to ultimately develop better, more evidence-based policies.

Under Part C, Medicare Advantage (MA) plans are required to provide the same set of benefits that are available under FFS Medicare, except that FFS Medicare covers hospice care and certain services associated with clinical trials under Medicare's Clinical Trials Policy for MA enrollees. However, MA plans are permitted to use medical management tools not available in FFS Medicare, such as requiring providers to seek prior authorization to have a service covered. Plans also have leeway in controlling utilization through beneficiary cost sharing.

How Medicare pays for new technologies

There are various methods that Medicare uses to pay for new Part A or Part B items and services based on current law and regulations:

- *Separate payment under an existing billing code (i.e., a shared billing code that includes more than one product).* For example, for multi-source drugs covered under Part B, both the brand-name drug and its generics are paid under a single billing code.

- *Separate payment under a billing code that is unique to the item or service and that meets Medicare's coverage criteria.* For example, each new single-source drug, biologic, or biosimilar product covered under Part B is paid under its own billing code. Likewise, some new lab tests and devices are also assigned to their own unique billing code.

- *As part of a broader payment bundle for a specified set of items and services provided in certain settings.* Medicare pays a predetermined rate for a set of items and services in its prospective payment systems (PPSs) for: inpatient and outpatient services; post-acute care services (e.g., skilled nursing facility, home health, and inpatient rehabilitation services); hospice services; and outpatient dialysis services. Often, a new technology is included in a bundle of related items or services with no change in payment, though over time the payment for the bundle is adjusted to reflect changes in the health care provider's underlying costs. In certain payment systems (including the inpatient and outpatient hospital and outpatient dialysis

PPSs), a temporary add-on payment is made for qualifying new technologies, typically for a two- to three-year period, after which the technology is included in bundled PPS payment. According to CMS, temporary add-on payment policies for new technologies aim to ensure beneficiary access to new items and services, provide adequate payment for new technology, and support providers' use of new technologies while they are new and innovative to the market (Centers for Medicare & Medicaid Services 2018). In addition, the two- to three-year temporary add-on payment period provides CMS sufficient opportunity to obtain and analyze claims data for the rate-setting process.

For new items and services that are separately billable under a billing code unique to the product (including technologies paid for under add-on policies), Medicare FFS largely acts as a price taker and under current law can do little to affect the amount the program pays for these products. These prices may have little relationship to the cost of production and may even exceed the value of the innovation, reflecting instead what the market will bear. For example, for newly launched Part B drugs, Medicare's payment is based on the price established by the manufacturer (106 percent of the manufacturer's average sales price (ASP)). Payment for a new high-cost laboratory test is another example that demonstrates the challenges associated with establishing payment rates for new technologies. Medicare's approach to setting payment for lab tests relies on using commercial prices. For high-cost, sole-source tests, private payers may have little leverage to negotiate prices. Under Medicare, lab tests also have no cost sharing. Thus, there are few constraints on prices that laboratories may charge for new higher-cost lab tests (Medicare Payment Advisory Commission 2021).

Refining and improving Medicare's coverage and payment processes

The Commission has recommended or discussed a number of ways to refine or improve Medicare's coverage and payment processes for drugs and for new technologies more broadly. With respect to Medicare's coverage process:

- The Commission recognizes the unique roles various federal agencies play with respect to approving new technologies for marketing in the U.S. and in the coverage and payment for those technologies for Medicare beneficiaries. CMS's role as a payer is distinct and separate from the role the FDA plays in approving or clearing medical devices and drugs. The FDA approval process may or may not include the new device's or pharmaceutical product's safety or effectiveness with regard to the Medicare population. Participation in FDA's approval pathways on its own does not necessarily reflect improvements in outcomes nor the appropriateness of increased payment for Medicare beneficiaries (Medicare Payment Advisory Commission 2019). By contrast, the Commission asserts that CMS should make Medicare coverage and payment determinations based on the specific needs (i.e., diagnosis and treatment) of the Medicare population (Medicare Payment Advisory Commission 2023b). The evaluation of whether a new item or service should be covered, based on the

evidence of whether a new technology improves Medicare beneficiaries' outcomes, should rest with CMS (Medicare Payment Advisory Commission 2023b, Medicare Payment Advisory Commission 2023c).

- For new items and services with a limited evidence base specific to beneficiaries, Medicare should apply CED policies (Medicare Payment Advisory Commission 2020b, Medicare Payment Advisory Commission 2018a, Medicare Payment Advisory Commission 2010). As noted above, CED is a tool that addresses instances in which some new items and services, including some technologies that the FDA approves, have limited evidence about their effectiveness in the Medicare population. In those situations, it is important for policymakers to balance access to new treatments that may have value for certain beneficiaries, while collecting more information to improve understanding of the effectiveness of the new technology and inform Medicare coverage and payment policies.

With respect to how Medicare pays for new and existing items and services:

- For new technologies, including drugs, biologics, devices, and lab tests, policymakers should design payment policies that strike an appropriate balance between creating incentives for innovation and ensuring that the program is getting good value for beneficiaries and taxpayers, including promoting access and affordability for beneficiaries who pay cost sharing, which is often based on Medicare's payment rate (Medicare Payment Advisory Commission 2023a).

- Medicare should use broader payment bundles (i.e., payment bundles that encompass more items and services associated with an episode of care) where feasible to create incentives for greater efficiency and more holistic care (Medicare Payment Advisory Commission 2003).

- When Medicare PPSs include temporary add-on payments for new technologies, those add-on payments should be conditioned on the product representing a substantial clinical improvement (Medicare Payment Advisory Commission 2020c).

- Medicare should pay similar rates for similar care (Medicare Payment Advisory Commission 2023a).

The Commission has supported a number of specific policies to refine or improve coverage or payment for new technologies in Medicare as discussed below.

The Commission supports using CED for certain new technologies to improve the evidence base specific to the diagnosis and treatment of the Medicare population

The Commission has supported coverage via CED, where necessary, for certain technologies (including drugs and devices) that lack clear evidence showing their clinical effectiveness in the Medicare population, including for the following new biologics: monoclonal antibodies directed against amyloid for the treatment of Alzheimer's Disease

(Aduhelm) and chimeric antigen receptor T-cell (CAR-T) therapies. In comments on the fiscal year (FY) 2021 inpatient PPS proposed rule, the Commission encouraged CMS to reconsider its decision to not implement CED with a requirement for registry participation for CAR-T therapies in its national coverage determination (Medicare Payment Advisory Commission 2020d). The Commission also supported CMS's proposal to apply CED to cover monoclonal antibody drugs directed against amyloid for the treatment of Alzheimer's Disease, including Aduhelm, given the uncertainty of the clinical benefit of Aduhelm and the potential for serious side effects (Medicare Payment Advisory Commission 2022). In both cases, the Commission supported CED as a way to provide beneficiaries access to new technologies while generating clinical evidence on the product's safety and effectiveness specific to Medicare beneficiaries (including older individuals and racial minorities who are often underrepresented in clinical trials) and to enable the program to develop more evidence-based policies.

Limit or better target add-on payments for new technologies within prospective payment systems

Several Medicare prospective payment systems that involve bundled payments include transitional add-on payments for new technologies under certain circumstances. The Commission has made recommendations to limit or better target transitional add-on payments for new drugs in several payment systems to ensure that only products that represent a clinical improvement relative to existing treatments receive transitional add-on payments and that add-on payments are not duplicative of existing payments for drugs already included in bundled payment rates.

Under the hospital outpatient prospective payment system (OPPS), drugs that are used as supplies to a primary service are packaged into the payment rate of the applicable service. The OPPS includes a pass-through policy for new drugs that provides temporary separate payments (referred to as *pass-through payments*) to ensure adequate reimbursement while CMS collects the data needed to establish accurate packaged payments. In June 2021, the Commission recommended that the Congress modify the pass-through policy to require drugs to be clinically superior to other therapeutically similar drugs in order to receive pass-through payments (Medicare Payment Advisory Commission 2021). Without a clinical superiority requirement, Medicare could pay separately for an item or service that is no more effective than a competing service already in use, even when the cost of the existing service is reflected in the PPS packaged payment rate, increasing program spending and beneficiary cost sharing and premiums.

Under the end-stage renal disease (ESRD) prospective payment system, new ESRD drugs receive transitional add-on payments in several circumstances. Beginning in 2020, CMS established two-year transitional add-on payments for new ESRD injectable products (with the exception of certain drugs, including generics) that are in one of 11 existing ESRD-related functional categories. The Commission recommended elimination of these add-on payments because they are duplicative of the payment that is already made as part of the ESRD bundle (Medicare Payment Advisory Commission 2020c). Eliminating these add-on payments would maintain the integrity of the ESRD PPS bundle, better ensure that providers are judicious in the items and services furnished to beneficiaries, and create

incentives for drug manufacturers to constrain the growth of prices for new and existing ESRD drugs. If CMS retains add-on payments for new drugs in an existing ESRD functional category, the Commission urged CMS to better target these payments by conditioning them on a clinical improvement standard and by reducing the add-on payment to take into account the payment associated with drugs in the same functional category already included in the base rate; the Commission also suggested that CMS consider paying a reduced percentage of the estimated incremental cost of the new drug as a way to share risk with dialysis providers (Medicare Payment Advisory Commission 2019, Medicare Payment Advisory Commission 2018b). The Commission made similar comments in response to the calendar year (CY) 2024 ESRD proposed rule, in which CMS proposed creating additional add-on payments for new qualifying ESRD drugs for three years after the initial two-year transitional add-on period expires (Medicare Payment Advisory Commission 2023).

Once new items and services, including drugs and devices, are paid for under the PPS bundle, the adequacy of Medicare's payment can be assessed on an annual basis to ensure that Medicare's payments cover the cost of efficient providers. As part of the Commission's mandate, we assess payment adequacy on an annual basis for Medicare's FFS payment systems, including hospital inpatient and outpatient services, physician and other health professional services, post-acute care services, hospice services, and outpatient dialysis services. To the extent that new technologies alter the cost structure for providers, this annual process provides an opportunity for a review of whether aggregate payments are adequate for a particular sector or whether adjustments are warranted.

Cap payment for certain new drugs with a limited clinical evidence base and pay similar rates for drugs with similar health effects

In our June 2023 report to the Congress, the Commission recommended policies to improve how Medicare pays for Part B drugs. One policy would address Medicare's payments for new drugs approved under the FDA's accelerated approval pathway and another would spur price competition among drugs with similar health effects, including new drugs that have similar effects to existing drugs (Medicare Payment Advisory Commission 2023a).

To maintain financial rewards for innovation while improving access and affordability of care for beneficiaries and taxpayers and spurring manufacturers to complete their required confirmatory trials on time, the Commission recommended that Part B payment for certain accelerated approval drugs be capped in certain circumstances (Medicare Payment Advisory Commission 2023a). Specifically, the Commission recommended that the Congress require the Secretary to cap the payment rate of Part B accelerated approval drugs (with limited circumstances for exceptions) if postmarketing confirmatory trials are not completed in a timely manner, if the product's clinical benefit is not confirmed in postmarketing confirmatory trials, or if the product is covered under a CED policy. The Commission also recommended that the Secretary be given the authority to cap Medicare payment for such drugs if their price is excessive relative to the upper-bound estimate of their value. The cap could be set based on a drug's net clinical benefit and cost compared

with the standard of care, which would take into account a new drug's potential effect on beneficiaries' outcomes and costs. This recommendation would give Medicare tools to ensure that the program and beneficiaries are not overpaying for products approved on an accelerated basis if a product's clinical benefit is not confirmed. Further, this recommendation would give manufacturers an incentive to complete postmarketing confirmatory trials in a timely manner so that information about a product's effects on health is available as soon as possible to providers and beneficiaries.

To promote price competition among drugs and biologics with similar health effects, including new products, the Commission recommended that CMS be given the authority to use reference pricing to set a single ASP-based payment rate for groups of drugs and biologics with similar health effects (Medicare Payment Advisory Commission 2023a). The Secretary could begin with those reference groups for which implementation would be the most straightforward: (1) biosimilars and originator biologics; (2) 505(b)(2) drugs and their related brand-name and generic drugs; and (3) drugs for which reference pricing has been implemented or considered previously, including erythropoietin-stimulating agents. This recommendation aligns with the Commission's principle of paying similar rates for similar care. It would also give the Medicare program a tool to spur price competition among certain drugs that are assigned to their own billing code and that do not currently face price competition in Medicare (Medicare Payment Advisory Commission 2023a).

The role of pharmacy benefit managers and potential conflicts of interest

Pharmacy benefit managers (PBMs) manage prescription drug benefits on behalf of health insurers and payers, including Part D plan sponsors. Some of the functions of PBMs require specialized technical and clinical expertise. For example, PBMs develop formularies, process claims, establish networks of pharmacies, and negotiate with drug manufacturers and pharmacies for postsale rebates and fees. PBMs combine purchasing leverage across payers to counter drug manufacturers' pricing power. By aggregating certain functions across payers, PBMs may also achieve economies of scale, such as in claims processing or mail-order dispensing.

At the same time, PBMs also benefit from growth in list prices of drugs. For example, a PBM's revenue may come primarily from manufacturer rebates and fees that are calculated as a percentage of list prices. Because of the confidentiality of these rebates and fees and the complexity of drug pricing, payers often face difficulty evaluating how well PBMs have performed at managing drug spending (Garthwaite and Morton 2017). Under Part D, however, plan sponsors and their PBMs must report and pass-through to plan sponsors all rebates and fees received from manufacturers and pharmacies as direct and indirect remuneration. In recent years, PBMs that contract with Part D plans have retained less than 1 percent of the rebates they have negotiated for plan sponsors, instead earning revenues through volume-based and per member fees (Government Accountability Office 2019). While PBMs operating in Part D may not retain rebates, the plan sponsors with which they contract typically use rebates to reduce premium costs for all enrollees. The Medicare program consequently also benefits from lower premium subsidies. It is

important to note, however, that the rebates that PBMs negotiate generally are not used to reduce the price Part D enrollees face at the pharmacy counter. When enrollee cost sharing is calculated based on the pharmacy price, enrollees who use rebated drugs pay disproportionately high cost sharing relative to the cost of their medicines net of rebates; in these situations, Medicare also spends relatively more on reinsurance subsidies and on low-income cost-sharing subsidies.

Over the years, the PBM industry has consolidated and changed significantly through mergers and acquisitions. Today, many of the largest plan sponsors participating in Part D are vertically integrated with their own PBMs and mail-order, specialty, and sometimes retail pharmacies. Vertical integration may reduce transaction costs between upstream and downstream entities and increase plan sponsors' visibility into highly proprietary information about drug prices, allowing them to overcome information asymmetry. However, a PBM that both administers pharmacy benefits for a payer and operates a pharmacy may face conflicting interests: On the one hand, payers contract with the PBM to lower pharmacy benefit costs. On the other hand, the pharmacy revenue depends on greater prescription volume and higher reimbursement from the PBM. In some cases, pharmacies may also receive discounts and service fees directly from manufacturers of specialty drugs.

Under Part D, discounts and fees received by PBM subsidiaries, such as mail-order and specialty pharmacies, are not reported to CMS, and, as a result, the prices established between the PBM and its pharmacies are less transparent to CMS and other third-party payers (Office of Inspector General 2021). In a competitive market, this lack of transparency may not result in excessive profits earned by the PBMs and their pharmacies. However, the Part D market has become increasingly concentrated among the largest sponsors that own (or are owned by) a PBM and pharmacies. In 2021, the four largest PBMs served nearly 90 percent of Part D's enrollment (Medicare Payment Advisory Commission 2023a). This level of concentration raises a concern that the prices of certain specialty pharmaceuticals may be substantially higher than they would be in a market with greater competition among PBMs. In such circumstances, those higher prices would translate into both higher premiums and cost sharing for Part D enrollees and Medicare.

References

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2018. Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS. *Federal Register* 83, no. 220 (November 14): 56922–57073.

Garthwaite, C., and F. Morton. 2017. Perverse market incentives encourage high prescription drug prices. *ProMarket* blog. November 1. https://promarket.org/perverse-market-incentives-encourage-high-prescription-drug-prices/.

Government Accountability Office. 2019. *Medicare Part D: Use of pharmacy benefit managers and efforts to manage drug expenditures and utilization.* Washington, DC: GAO.

Jensen, T., Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014. CMS coverage perspective diagnostic tests. https://mdic.org/wp-content/uploads/2014/06/Role-of-Regulatory-Science-MDIC-in-Molecular-Diagnostics_A-CMS-Perspective.pdf.

Medicare Payment Advisory Commission. 2023a. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2023b. MedPAC comment on CMS's proposed rule on ESRD PPS update for CY 2024. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2023c. MedPAC comment on CMS's notice entitled, "Medicare Program; Transitional Coverage for Emerging Technologies." August 25.

Medicare Payment Advisory Commission. 2022. MedPAC comment on CMS's proposed NCD decision memorandum on monoclonal antibodies that target amyloid for the treatment of Alzheimer's disease. February 10.

Medicare Payment Advisory Commission. 2021. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2020a. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission 2020b. MedPAC comment on CMS's coverage of innovative technology. October 29.

Medicare Payment Advisory Commission 2020c. MedPAC comment on CMS's proposed rule on ESRD PPS update for CY 2021. September 2.

Medicare Payment Advisory Commission 2020d. MedPAC comment on CMS's proposed rule on the hospital inpatient prospective payment systems for acute care hospitals and the long-term care hospital prospective payment system for FY 2021. July 2.

Medicare Payment Advisory Commission. 2019. MedPAC comment on CMS's proposed rule on ESRD PPS update for CY 2020. September 20.

Medicare Payment Advisory Commission. 2018a. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2018b. MedPAC comment on CMS's proposed rule on ESRD PPS update for CY 2019. August 30.

Medicare Payment Advisory Commission. 2010. *Report to the Congress: Aligning incentives in Medicare.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2003. *Modernizing the outpatient dialysis payment system.* Washington, DC: MedPAC.

Office of Inspector General, Department of Health and Human Services. 2021. *CMS should strengthen its prescription drug event guidance to clarify reporting of sponsor margin for Medicare Part D bids.* A-03-17-00001. Washington, DC: OIG.

Schnog, J. B., M. J. Samson, R. O. B. Gans, et al. 2021. An urgent call to raise the bar in oncology. *British Journal of Cancer* 125, no. 11 (November): 1477–1485.