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## **Executive summary**

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As part of its mandate from the Congress, each June the Commission reports on refinements to Medicare payment systems and issues affecting the Medicare program, including broader changes in health care delivery and the market for health care services. In the 10 chapters of this report, we consider:

- **Rebalancing Medicare Advantage benchmark policy.** The Commission evaluates the way benchmarks are set for Medicare Advantage (MA) plans and recommends a number of changes to MA benchmark policy. Our recommended approach would reduce MA benchmarks to capture some of the efficiencies generated by MA with relatively few disruptions to supplemental benefits.
- **Streamlining CMS's portfolio of alternative payment models.** The Commission examines the performance of alternative payment models (APMs) over the last decade and recommends that Medicare move toward implementing a smaller, more harmonized portfolio of APMs.
- **Private equity and Medicare.** In response to a congressional request, the Commission identifies gaps in Medicare's ability to collect information about private equity investments in health care and examines how such investments have affected Medicare beneficiaries, providers, and MA plans.
- **The skilled nursing facility value-based purchasing program.** As directed by the Protecting Access to Medicare Act of 2014, the Secretary of Health and Human Services began to implement a value-based purchasing program for skilled nursing facilities in October 2018. In this congressionally mandated report, the Commission finds that the current program is flawed and recommends that it be replaced with a value incentive program that follows the Commission's principles for performance programs.
- **Medicare beneficiaries' access to care in rural areas.** In this congressionally requested interim report, the Commission examines rural beneficiaries' access to care, using Medicare claims data, survey data, and interviews with stakeholders. We also examine rural hospital closures, a trend that has become more prominent over the last decade and could affect access to care for beneficiaries living in rural areas.
- **Revising Medicare's indirect medical education payments to better reflect teaching hospitals' costs.** The Commission raises several concerns about Medicare's current indirect medical education (IME) payment policy and recommends a new approach that would transition to empirically justified levels of IME payments while better aligning IME payments with the contemporary spectrum of settings in which residents train and patients receive hospital care.
- **Medicare vaccine coverage and payment.** The Commission recommends that the Congress move all preventive vaccine coverage to Part B without beneficiary cost sharing and improve the accuracy of Medicare's Part B payment for preventive vaccines by modifying the current payment method and collecting data to enable further improvements in the future.
- **Improving Medicare's policies for separately payable drugs in the hospital outpatient prospective payment system.** Medicare's outpatient prospective payment system bundles multiple services into one payment to create incentives for providers to be judicious about the cost inputs of the services they provide. In certain circumstances, some items are not bundled but are paid separately. The Commission recommends several changes to the policies that govern which drugs are paid separately to strike a better balance between promoting access to high-cost innovative treatments and maintaining pressure on providers to be efficient.
- **The impact of recent changes to Medicare's clinical laboratory fee schedule payment rates.** Beginning in 2018, Medicare sets clinical laboratory fee schedule (CLFS) payment rates based on the rates private payers pay for laboratory tests. In this mandated report, the Commission reviews the impact of the changes to the CLFS and explores possible modifications to the processes of collecting private-payer data from laboratories.
- **The relationship between clinician services and other Medicare services.** In June 2017, the Commission published an initial congressionally mandated report on the relationship between the use of and expenditures for services provided by physicians and other health professionals and total service use and expenditures under Part A, Part B, and Part D

of Medicare. In this final report, the Commission examines the relationship between clinician service use and nonclinician service use over the 2013 to 2018 period.

This report primarily focuses on Medicare's payment policies and recommends ways to improve those policies where appropriate. At the same time, the Commission is fully aware of the extraordinary challenges faced by the health care system, Medicare beneficiaries, and policymakers in dealing with the ongoing coronavirus public health emergency. The Commission is closely following developments related to the pandemic and incorporating lessons from the experience into our work. We remain ready to assist the Congress and CMS in responding to the pandemic as part of our mission to preserve beneficiaries' access to high-quality care, control Medicare spending growth, and provide sufficient payment for efficient providers.

### **Rebalancing Medicare Advantage benchmark policy**

In Chapter 1, the Commission recommends a number of changes to the way payment benchmarks are determined for the MA program. The current benchmarks have resulted in a very robust MA program with respect to plan participation, beneficiary enrollment, and the value of extra benefits provided to enrollees. But, in spite of the apparent relative efficiency of MA, no iteration of private plan contracting has yielded net aggregate savings for Medicare. The Commission estimates that Medicare currently spends 4 percent more per capita for beneficiaries enrolled in MA than it spends for similar enrollees in traditional fee-for-service (FFS) Medicare.

Current MA benchmark policy uses a quartile system that generates geographic variation in plan payments, including plan subsidies of varying size in most geographic areas, that are not necessary for maintaining affordable supplemental coverage and that fail to capture savings for the Medicare program. The quartile-based benchmarks support higher payments to MA plans in areas where FFS spending is low. Despite most plans bidding below FFS spending in these areas, payments are 9 percent higher than the areas' FFS spending, and MA enrollment is disproportionately higher than in many other areas. At the same time, the quartile system insufficiently leverages plan efficiency in areas where FFS spending is high. Plans in these areas bid lower relative to their benchmarks and thus receive disproportionately more rebate dollars—the

amount of which equals a share of the difference between a plan's bid and its benchmark.

Because plan bids are at levels well below FFS spending, the Medicare program could share in plan efficiencies by making appropriate reductions in payment benchmarks. A better MA benchmark policy would rebalance benchmarks to allow the Medicare program to capture some MA efficiencies while mitigating potential decreases in plan participation and benefits. In Chapter 1, the Commission recommends that the Congress implement a new MA benchmark policy that does the following:

- ***Uses a relatively equal blend of per capita local area FFS spending and standardized national FFS spending.*** Relative to current policy, benchmarks in low-FFS-spending areas would be aligned more closely with (but remain above) local FFS spending. On average, benchmarks in areas with high FFS spending would modestly decrease relative to current policy, allowing the program to capture additional efficiencies in areas where plan bids are lowest relative to their benchmarks.
- ***Uses a rebate of at least 75 percent.*** The rebate percentage (i.e., the share of the difference between the plan bid and benchmark) that is paid to plans for funding extra benefits would be decoupled from the MA quality bonus program and would increase for all plans to create greater incentives for plan efficiency.
- ***Integrates a discount rate of at least 2 percent.*** A discount rate would reduce the local–national blended spending amounts, explicitly integrating the efficiency of MA into the benchmark calculation. A discount rate of at least 2 percent would help ensure that the Medicare program shares in the efficiencies generated by MA.
- ***Applies the Commission's prior MA benchmark recommendations—using geographic markets as payment areas, using the FFS population with both Part A and Part B in benchmarks, and eliminating the current pre-Affordable Care Act cap on benchmarks.*** This approach would use geographic markets (e.g., multicounty areas) as payment areas to help ensure stability in benchmarks, calculate benchmarks using the FFS population with both Part A and Part B coverage to ensure comparability with the MA-eligible population, and eliminate caps on benchmarks that disproportionately affect areas where FFS spending is low.

The chapter contains findings from simulations of our recommended benchmark policy, comparing it with existing policy. The simulations demonstrate that CMS could feasibly implement our recommended policy with likely little impact on plan participation; doing so would generate about 2 percentage points in savings to the Medicare program, relative to current policy.

### **Streamlining CMS’s portfolio of alternative payment models**

In Chapter 2, the Commission recommends that Medicare implement a smaller, more harmonized portfolio of APMs. Most of CMS’s APMs are operated by its Center for Medicare and Medicaid Innovation (CMMI), which was established in 2010 by the Affordable Care Act (ACA) to implement and study new payment and care delivery models. (CMS’s largest APM, the Medicare Shared Savings Program, was created as a permanent program by the ACA and is not operated by CMMI.) CMMI’s APMs are temporary demonstrations that can be expanded into permanent programs only if they are found to either reduce spending in Medicare, Medicaid, or the Children’s Health Insurance Program while preserving care quality or if they improve care quality without increasing spending. In CMMI’s first 10 years, almost all of its accountable care organization and episode-based payment models generated small gross savings for the Medicare program before model payments (e.g., performance bonuses) were taken into account. This promising indicator suggests that these models’ incentives may have been able to encourage provider organizations to induce clinicians to alter their care patterns—changing the quantity or the mix of health care services they furnish or prescribe. After bonuses were paid, savings were reduced and in some cases Medicare expenditures in the APM exceeded what they would have otherwise been.

In many cases, providers participate in multiple CMS APMs simultaneously, and Medicare beneficiaries are attributed to multiple models at the same time. This overlapping participation can have unintended consequences. For instance, savings that are generated for a beneficiary served by different sets of providers participating in different APMs can be allocated to providers in only one of these models, thus diluting financial incentives in the other models. Overlapping participation can also make it difficult for evaluators to accurately assess the impact of a given payment model on program spending and quality.

The strategy of implementing a plethora of models over the last decade has given the agency an opportunity to build up the evidence base about what works and what does not. While this strategy has yielded valuable information, the Commission contends that continuing to test a large number of independent APMs is likely to inhibit the ability of APMs to reach their full potential.

The Commission therefore recommends that CMS now implement a smaller, more harmonized portfolio of APMs that are designed to work together. A smaller portfolio of models could result in less overlap between different models; when overlap does exist, models should be designed to have incentives that do not diminish in strength when combined with other models. To minimize complexity, the payment models in CMS’s portfolio could use consistent model parameters (e.g., consistent methods for calculating spending targets and measuring quality).

### **Congressional request: Private equity and Medicare**

In Chapter 3, the Commission responds to a request from the chair of the Committee on Ways and Means to examine the role that private equity (PE) plays in the Medicare program. *Private equity* refers broadly to any activity where investors buy an ownership, or equity, stake in companies or other financial assets that are not traded on public stock or bond exchanges. One type of PE activity that has drawn growing attention in recent years involves investment firms that purchase companies and then try to improve their operational and financial performance so they can later be sold for a substantial profit. These types of acquisitions have become increasingly common in many parts of the economy, including the health care sector.

In responding to the request, we examined four issues related to private equity and Medicare: gaps in Medicare data that create challenges in tracking private equity investments; private equity funds’ business models when investing in health care; how private equity investments may have affected Medicare costs and quality of care; and private equity investments in companies that participate in the MA program.

- **Gaps in Medicare data**—Understanding which individuals or entities own a Medicare provider and their track record of operations could help to improve oversight and safeguard patient care. CMS primarily collects data on provider ownership to support the

enrollment process, payment, and fraud prevention, rather than research on the prevalence of different types of ownership. Observers have noted for many years that the ownership data submitted to CMS are incomplete and sometimes inaccurate. One obstacle is capturing ownership data for providers (such as nursing homes and some hospitals) that are part of complex corporate structures with multiple levels and subsidiaries. CMS’s ownership data typically do not indicate a parent organization atop a hierarchy of legal entities. More complete ownership data and greater transparency of ownership are highly important. However, under constrained resources, the feasibility of CMS identifying parent organizations for large numbers of Medicare providers and suppliers is a difficult challenge.

- ***PE funds’ business models***—We examined PE business models in three key sectors: hospitals, nursing homes, and physician practices. PE firms use several common strategies to make the providers they own in these sectors more profitable. Many of these strategies are also used by for-profit providers that are not PE owned. Some of those strategies focus on increasing revenues while others focus on reducing costs. Other strategies are more relevant to individual sectors, such as selling off a nursing home’s real estate or creating larger physician practices by acquiring a “platform” practice and then buying smaller practices in the same market.
- ***The effect of PE investment on Medicare costs and quality of care***—We examined evidence of the effects of PE investments in hospitals, nursing homes, and physician practices. We found that PE-owned hospitals tended to have lower costs and lower patient satisfaction than other for-profit and nonprofit hospitals. However, our cross-sectional analysis cannot be used to conclude that PE ownership caused the lower costs or satisfaction. A recent longitudinal study found that PE-owned hospitals had above-average growth in charges after being acquired by a PE firm. Findings on hospital quality were mixed. For nursing homes, the research literature is somewhat dated, and the findings on the effects of PE ownership on financial and quality of care indicators are mixed. For physician practices, there is a lack of peer-reviewed, empirical evidence of the impact of PE ownership on Medicare spending, quality of care, and patients’ experience.

- ***PE investments in companies that participate in MA***—We found that PE funds own about 2 percent of the companies (6 out of 309) offering MA plans in January 2021. In addition, PE firms (largely venture capital firms) have invested in a range of companies that work for MA plan sponsors. Many of these companies provide services or care management to enrollees, and several are paid using value-based contracts where they bear some financial risk for enrollees’ overall health costs. We did not find any research that examines the effects of PE investments in MA companies on Medicare costs. Such an analysis would be very difficult to conduct due to various data limitations.

### **Mandated report: Evaluating the skilled nursing facility value-based purchasing program**

In Chapter 4, the Commission recommends replacing the skilled nursing facility value-based purchasing (VBP) program, in response to a mandate in the Protecting Access to Medicare Act of 2014 to review the progress of the VBP program for skilled nursing facilities (SNFs) and make recommendations as appropriate. By statute, the VBP program uses a single measure (hospital readmissions) to gauge SNF performance. Each SNF’s performance on the measure determines (1) whether it receives a reward, a penalty, or no change in payment and (2) the size of the payment adjustment. The VBP program is funded by a 2 percent reduction to payments each year (not cumulative), and Medicare retains a portion of the amount withheld as savings.

Our assessment of the SNF VBP program revealed fundamental design flaws that recent legislated changes do not fully correct. First, the single outcome measure does not capture the multidimensions of health care quality. Second, the minimum stay counts to include providers in the program are too low to ensure that the program rewards performance rather than random variation. Third, the performance scoring includes “cliffs”—that is, preset numeric thresholds (also required by statute)—that may not provide enough encouragement for improvement. Fourth, the design does not address variation across SNFs in the social risk factors of their patient populations, disadvantaging SNFs with high social risk populations. Indeed, we found that SNFs treating high shares of fully dual-eligible beneficiaries or SNFs whose beneficiaries

were medically complex were more likely to be penalized under the program, which could create incentives for providers to avoid admitting these beneficiaries. Finally, the SNF VBP program does not distribute the entire pool of incentive payments (a statutory requirement) but instead retains a portion as program savings. Our analysis found that payments were lowered for almost three-quarters of providers and the rewards and penalties were relatively small.

Analyzing these flaws, the Commission concluded that the current SNF VBP program should be immediately eliminated and a replacement program established as soon as feasible. In place of the SNF VBP, the Commission recommends a SNF value incentive program (VIP) design based on the Commission's principles for quality measurement and our previous work on redesigning Medicare quality incentive programs. Our recommended SNF VIP would:

- **Score a small set of performance measures.**
- **Incorporate strategies to ensure reliable measure results**, such as using a higher reliability standard for determining the minimum number of stays required for a SNF to be included in scoring. To include low-volume providers in the program, the SNF VIP could score multiple years of performance.
- **Establish a system for distributing rewards with minimal “cliff” effects.** A continuous performance scale would result in every SNF having an incentive to improve.
- **Account for differences in patients’ social risk factors using a peer-grouping mechanism** that stratifies providers into peer groups based on the social risk factors of their patient population. A provider’s payment adjustment will vary based on its performance on a national performance scale and its performance relative to its peers. Providers in peer groups with high social risk patient populations will receive larger adjustments for attainments in quality compared with other providers.
- **Distribute the entire provider-funded pool of dollars as rewards** based on provider performance. Though not explicitly designed to achieve program savings, improved provider performance (e.g., fewer readmissions) may lower program spending.

For illustrative purposes using currently available data, we modeled a VIP design for scoring SNF performance and adjusting SNF payments accordingly. Our illustrative modeling found that a SNF VIP design is feasible. Across providers with similar shares of patients at social risk, the SNF VIP would increase payments for SNFs with better performance and reduce payments for those with worse performance. Also, unlike the current program, the SNF VIP would result in more equitable payments across SNFs and reduce the incentive to avoid admitting beneficiaries with high social risk factors or clinically complex beneficiaries. We found that hospital-based providers would perform better than freestanding facilities under the SNF VIP but otherwise found few differences in the SNF VIP payment adjustments by provider characteristics.

### **Congressional request: Medicare beneficiaries’ access to care in rural areas (interim report)**

In Chapter 5, in response to a request by the House Committee on Ways and Means, we provide an interim report on rural beneficiaries’ access to care. The Commission’s annual survey of Medicare beneficiaries and CMS’s Medicare Current Beneficiary Survey suggest that rural and urban beneficiaries have similar access to care, although some minor differences exist and those differences may increase as rurality increases. Likewise, our analysis of Medicare claims data indicates rural and urban beneficiaries generally have comparable utilization rates among the types of services we examined—clinician visits, hospital inpatient admissions, hospital outpatient visits, home health episodes, and skilled nursing facility days. Similar to our 2012 report, we found substantial variation across geographic regions of the country, and those differences often were far larger than differences between rural and urban beneficiaries in a given region.

In Chapter 5, we also examine the growing number of rural hospital closures, a trend that could affect beneficiaries’ access to care. To study the causes and effects of rural hospital closures, we conducted interviews with stakeholders (including community members, hospital executives, and clinician leaders) from three communities that experienced a recent hospital closure and analyzed a cohort of 40 rural hospitals that closed between 2015 and 2019.

- Stakeholders from the three communities suggested that, prior to closure, patients commonly bypassed their local hospital for inpatient care, often due

to perceived deficits in capabilities. Stakeholders from these communities reported that after their local hospital closed, the communities focused on maintaining access to emergency department (ED) care, urgent care, and primary care. In the three communities in which we conducted interviews, Federally Qualified Health Centers were critical to maintaining access to primary care, and sometimes urgent care, after the local hospital closed.

- Among the cohort of 40 recently closed hospitals, we found large declines in all-payer inpatient admissions (across a broad range of service lines) in the years before closure. From 2005 to 2014 (a period that began at least a decade before closure), the cohort averaged a 54 percent decline in all-payer inpatient admissions. By 2014, the median number of annual all-payer admissions at the 40 hospitals had fallen to 488—about 1.3 admissions per day. Most of this decline was attributable to patients bypassing their local hospital in favor of other hospitals. In contrast, up to the date of closure, Medicare beneficiaries continued to use these 40 hospitals to access ED and outpatient care.

To address the most recent increase in rural hospital closures, some stakeholders have proposed options that would seek to preserve inpatient services. In 2018, the Commission recommended that Medicare allow isolated freestanding EDs to bill Medicare and provide such EDs with annual payments to assist with fixed costs. Along these lines, the Congress recently enacted a program that will allow certain hospitals to convert to a “rural emergency hospital.” These new rural emergency hospitals will not provide inpatient care but will provide round-the-clock ED care and will be able to furnish other services, such as outpatient services, nursing facility services, and ambulance services. Medicare will pay these new providers a monthly fixed rate, enhanced outpatient rates, and standard rates for other types of care. In addition to the newly established rural emergency hospital designation, the Congress recently enacted other provisions designed to increase access to care among rural beneficiaries, including more than doubling Medicare’s payment rate cap for certain rural health clinics. Any future analyses on rural communities’ access to care will need to account for these substantial policy changes, which are likely to help maintain or increase access to care for rural beneficiaries.

This interim report will be followed by a final report in June 2022. In response to our congressional mandate,

over the next year, the Commission plans to expand our utilization analyses to include information on beneficiaries who are dually eligible for Medicaid and Medicare, have multiple chronic conditions, or reside in a medically underserved area.

### **Revising Medicare’s indirect medical education payments to better reflect teaching hospitals’ costs**

In Chapter 6, the Commission recommends a new approach to Medicare’s indirect medical education (IME) payment policy. IME payments are designed to support teaching hospitals’ higher costs of inpatient care and are implemented through IME adjustments in the inpatient operating and inpatient capital prospective payment systems. In fiscal year 2019, the roughly 1,100 acute care teaching hospitals received over \$10 billion in IME payments, which is well above the empirically justified level. (Medicare also supports teaching hospitals through direct medical education payments, which help finance the direct costs of residency programs, such as resident stipends, supervisory physician salaries, and administrative overhead expenses. In 2019, direct graduate medical education payments to hospitals totaled nearly \$4 billion.)

The Commission has two key concerns with Medicare’s current IME payment policy. First, IME policy is “inpatient-centric”—that is, it focuses exclusively on teaching hospitals’ additional costs of inpatient services—and does not reflect the range of hospital settings in which residents train and patients receive care. Second, IME payments do not accurately reflect the effect of teaching on patient care costs across settings, resulting in IME payments above teaching hospitals’ additional costs for patient care in inpatient settings but below their additional costs for patient care in hospital outpatient settings. Together, these two features of current IME payment policy create financial penalties in the form of lost IME revenue when teaching hospitals safely shift care from inpatient to outpatient settings.

In response to these concerns, the Commission has included the following in its principles for IME reform:

- IME payments should be made for both inpatient and outpatient prospective payment system (PPS) services;
- IME payment adjustments should be based on hospitals’ ratio of residents to patients; and

- Medicare should transition to empirically justified levels of IME payments, such as by maintaining aggregate IME payments equal to current policy until such time that they match empirically justified levels.

Following the principles above, we modeled an illustrative inpatient and outpatient IME policy that would more accurately reflect teaching hospitals' additional costs. Under the revised IME policy, inpatient and outpatient IME payments would be based on empirically justified levels and then scaled such that aggregate IME payments equaled those under current policy. The revised policy would result in a small aggregate change in total inpatient and outpatient FFS payments for most teaching hospitals and for most groups of teaching hospitals. However, the revised policy would shift IME payments toward teaching hospitals with additional costs not accounted for in the current policy, including most hospitals that currently treat a larger share of Medicare patients in outpatient settings. Over time, as care continues to shift to outpatient settings, we anticipate that empirically justified IME payments would match and then exceed those under the current policy baseline; once that occurs, IME payments could be set at their (higher than current-law) empirically justified levels.

The Commission recommends transitioning to an empirically justified inpatient and outpatient IME policy such as the one we modeled. A revised IME policy would better align IME payments with the contemporary spectrum of settings in which residents train and patients receive hospital care; reduce the financial penalty of lost IME revenue when teaching hospitals treat Medicare beneficiaries in appropriate outpatient, rather than inpatient, settings; and make IME payments more equitable for teaching hospitals as they shift to providing more care and resident training in hospital outpatient settings. Moving forward, it will be important for CMS to monitor the effects of the revised IME policy and collect additional data to support further improvements to the accuracy of IME payments. At the same time, policymakers should continue to work toward broader graduate medical education reforms to support future workforce needs.

### **Medicare vaccine coverage and payment**

In Chapter 7, the Commission recommends improvements to Medicare's coverage and payment policies for preventive vaccines. Currently, Medicare covers vaccines under Part B and Part D. Part B covers preventive vaccines explicitly listed in statute—influenza, pneumococcal

disease, hepatitis B (for patients at high or intermediate risk), and COVID-19, as well as other vaccines when used to treat an illness or injury. Part D covers all commercially available preventive vaccines not covered by Part B, such as vaccines for shingles and hepatitis A.

In 2007, the Commission recommended that all preventive vaccine coverage be moved to Part B, and there continues to be a strong rationale for this approach. More Medicare beneficiaries are enrolled in Part B than in Part D. High cost sharing in some Part D plans may deter some beneficiaries from seeking recommended vaccines. A variety of health care providers bill Medicare Part B, offering more potential settings in which to vaccinate beneficiaries than under Part D. Finally, beneficiaries and even some providers can find it confusing to understand which vaccines are covered by Part B versus Part D. Thus, in this report, the Commission recommends that all preventive vaccine coverage be moved to Part B without cost sharing.

At the same time, however, the Commission is concerned about Medicare's payment method for Part B–covered preventive vaccines. Medicare pays for most preventive vaccines at a rate of 95 percent of the average wholesale price (AWP), a list price that may have little relationship to market prices. In the short term, payment accuracy for Part B vaccines could be improved by basing payment on wholesale acquisition cost (WAC)—the price at which the manufacturer sells the vaccine to the wholesaler. Medicare's AWP-based payment rates for Part B vaccines significantly exceed WAC. Thus, in addition to recommending that all preventive vaccine coverage be moved to Part B without cost sharing, the Commission recommends that the Congress shift the basis of payment for Part B vaccines to 103 percent of WAC. Doing so would generate savings for beneficiaries and taxpayers and bring payment rates closer to market prices.

Although WAC is a better measure of drug prices than AWP, WAC does not incorporate any discounts or rebates that may be available. Ultimately, a payment rate based on average sales price (ASP)—the average price realized by the manufacturer for the vaccine net of rebates, discounts, and other price concessions—might be most appropriate because it would reflect the average market price rather than an undiscounted wholesale price. However, because ASP is an average, we cannot assess how much the acquisition prices for vaccines vary across purchasers such as physicians and pharmacies. In addition, it is

unclear how the two-quarter lag in ASP data would affect Medicare payment rates for vaccines, especially given the seasonality of the influenza vaccine. Therefore, more study is needed before moving to an ASP-based payment rate for vaccines. The Commission recommends that Medicare require manufacturers to report ASP data for vaccines to facilitate this study. Once the study is completed, the Commission urges the Secretary to make the results of the analysis public and seek statutory authority to adopt an ASP-based payment rate for preventive vaccines if it would improve payment accuracy.

### **Improving Medicare’s policies for separately payable drugs in the hospital outpatient prospective payment system**

In Chapter 8, the Commission recommends an improvement to the system of drug payment in the outpatient prospective payment system (OPPS). The unit of payment in the hospital OPPS is the primary service, which is a service that is the reason for which a patient has a visit to a hospital outpatient department (HOPD). Drugs that are furnished during HOPD visits can be the reason for the visit (the primary service itself) or can be ancillary supplies to a primary service. Medicare pays separately for most drugs that are the reason for an HOPD visit, whereas most drugs used as supplies to a primary service are packaged into the payment rate of the applicable service. Packaging drugs used as supplies and other ancillary items with the primary service encourages efficient delivery of care.

The OPPS has two policies that provide separate payment for drugs: the pass-through policy and the separately payable non-pass-through (SPNPT) policy. Although both policies provide separate payments for drugs, they serve somewhat different purposes. The pass-through policy is focused on drugs that are new to the market and have costs that are high in relation to the OPPS payment rates for the applicable services. The intent of the pass-through policy is to provide temporary separate payments to ensure adequate reimbursement for these drugs while CMS collects the data needed to establish accurate packaged payments. In contrast, the SPNPT policy is intended to provide adequate payment for relatively high-cost drugs that are already established in the drug market—meaning the drug has been on the market too long to be eligible for the pass-through policy.

The Commission is concerned that the criteria for drugs to be eligible for separate payment under the OPPS do not strike an appropriate balance between promoting access to high-cost innovative treatments and maintaining pressure

on providers to be efficient. Specific concerns include the following:

- The pass-through policy does not include a requirement that a drug show clinical superiority over similar treatments to qualify. Without a clinical superiority requirement, Medicare could pay separately for a drug no more effective than a competing drug already in use, even when the cost of the existing drug is reflected in the OPPS payment rate for the applicable service. This situation results in Medicare making additional payments for a drug that is no more effective than less costly drugs.
- Both the pass-through and SPNPT policies include drugs that are the reason for a visit. It would be more efficient administratively to pay separately for drugs that are the reason for a visit through a single policy.
- The payment rates for drugs that are the reason for a visit can differ depending on whether the drug is paid separately under the pass-through or SPNPT policy. By statute, OPPS payment rates for pass-through drugs are set at ASP + 6 percent, while CMS has established a policy of setting the payment rates for SPNPT drugs obtained through the 340B Drug Pricing Program at ASP – 22.5 percent. Consequently, providers that obtain their OPPS drugs through the 340B program—which account for more than 50 percent of Medicare spending for separately payable drugs in the OPPS—have a financial incentive to use pass-through drugs rather than similar SPNPT drugs.

To improve the system of drug payment in the OPPS, the Commission recommends that the Congress modify the pass-through policy so that it includes only drugs that are supplies to a service and requires drugs to be clinically superior to other therapeutically similar drugs to be eligible for pass-through status. The Commission also recommends that the Secretary modify the SPNPT policy so that it is explicitly focused on drugs that are the reason for a visit, including those that are new to the market.

### **Mandated report: Assessing the impact of recent changes to Medicare’s clinical laboratory fee schedule payment rates**

In Chapter 9, the Commission responds to a mandate in the Further Consolidated Appropriations Act of 2020 requiring us to examine the methodology CMS used to set private payer–based payment rates for clinical laboratory fee schedule (CLFS) services and report on the least burdensome data collection process that would result

in a representative and statistically valid data sample of private market rates from all laboratory market segments, including independent, hospital, and physician-office laboratories.

Beginning in 2018, CMS set CLFS payment rates based on the rates private payers paid for laboratory tests. To establish these rates, a large number of laboratories were required to submit private-payer rate data to CMS for analysis. However, the Commission found that independent laboratories were overrepresented in the data, and hospital and physician-office laboratories were underrepresented.

The Commission concludes that collecting private-payer data using a survey could produce accurate estimates of payment rates for independent, hospital, and physician-office laboratories and substantially reduce the number of laboratories that would be required to report private-payer data. However, despite being technically feasible, incorporating private-payer rates from a representative sample of all types of laboratories may not be prudent. Medicare should set payment rates that ensure beneficiary access to high-quality laboratory tests, while maintaining incentives for laboratories to be efficient to make better use of taxpayers' and beneficiaries' resources. To do that, Medicare should ensure that payment rates are sufficient to cover the costs of relatively efficient laboratories and not increase rates solely to accommodate laboratories that receive high private-payer rates.

For most routine tests, policymakers should consider setting laboratory payment rates based on private-payer data from certain types of laboratories (e.g., independent laboratories) while excluding the data from others (e.g., hospital laboratories). Through the first two years of setting Medicare rates based on the private-payer data in which laboratories with lower private-payer rates were overrepresented, the use of laboratory tests remained relatively unchanged among Medicare FFS beneficiaries, suggesting stable access in spite of lower Medicare rates for many services. However, to the extent potential access issues arise, policymakers should consider implementing targeted payment adjustments instead of incorporating private-payer data from all laboratories that receive high private-payer rates. Targeted payment adjustments could help ensure access in particular circumstances without overpaying for all laboratory tests.

For many new, high-cost tests, basing Medicare rates on private-payer rates may present challenges. The

Commission's analyses suggest that private payers may not be able to negotiate lower prices for newer, more expensive laboratory tests in the same manner as they do for more routine tests, which could result in overly generous private-payer rates. In the future, the Commission will explore ways to improve how Medicare sets prices for new high-cost technologies, including certain pharmaceuticals, devices, and laboratory tests.

### **Mandated report: Relationship between clinician services and other Medicare services**

In Chapter 10, the Commission completes the second of two reports mandated by the Medicare Access and CHIP Reauthorization Act of 2015 on the relationship between use of and expenditures for services provided by physicians and other health professionals (whom we refer to as "clinicians") and total service use and expenditures under Part A, Part B, and Part D of Medicare. This final report updates the analyses conducted for the initial report (submitted in June 2017) using more recent years of data. Because the legislation does not direct us to evaluate Medicare Part C (Medicare Advantage), we report on service use and spending for the Medicare FFS population only.

We found that unadjusted spending on clinician services as a share of Medicare unadjusted spending on all Part A and Part B services decreased from 2013 through 2019, indicating that spending on clinician services grew at a slower rate than spending on all Part A and Part B services. However, because unadjusted Medicare spending reflects various price and payment policies—which distorts any relationship between the use of clinician and other services—comparisons of service use are more meaningful than comparisons of spending when evaluating whether a given service is a complement to or a substitute for clinician services.

Therefore, we estimated per capita service use in 2013 and 2018 for geographic areas based on metropolitan statistical areas (MSAs). We estimated service use for each geographic area by adjusting Medicare program spending for regional differences in Medicare prices and for beneficiary differences in demographics and health status.

Our analysis of service use found the following:

- In aggregate, from 2013 to 2018, use of clinician services as a share of all Part A and Part B services slightly declined from 24.3 percent to 23.8 percent.

- Among geographic units in our analysis, there was a weak negative correlation between per capita use of clinician services and per capita use of nonclinician Part A and Part B services. This finding implies that increasing clinician services results in only a slight reduction in use of other Part A and Part B services.
- For each of the geographic areas in our analysis, we estimated the percentage change from 2013 to 2018 in per capita use of clinician services and per capita use of nonclinician Part A and Part B services (total Part A and Part B services net of clinician services). We found a weak (almost neutral) relationship between percentage change in clinician services and percentage change in nonclinician Part A and Part B services.

Our analysis also showed that from 2013 through 2018, Medicare unadjusted spending on services covered under the physician fee schedule remained flat while unadjusted spending on drugs covered under the Part D benefit grew by 26 percent. Nearly all the growth in drug spending was due to higher prices and launches of new drugs rather

than an increase in the number of prescriptions filled by beneficiaries, a change from the 2008 through 2013 period when spending growth mostly reflected an increase in the number of prescriptions filled.

For the subset of FFS beneficiaries who received their drug coverage through the Part D program, we used a regression-based method to examine the relationship between the rate of growth and level of clinician service use and drug use (drug spending adjusted for demographic characteristics and health status) across the MSA-based geographic areas. For changes in service use from 2013 through 2018, clinician service use was positively correlated with the area's change in drug use. However, the regression model explained only 8 percent of the variation, suggesting a weak relationship between the rates of growth in clinician service use and drug use. Consistent with our previous analysis, in 2018, there was a modest positive correlation between the levels of clinician service use and Part D drug use. This finding is not surprising, given that most prescriptions are written by clinicians during office visits. ■