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 seven chapters of this report, we consider:

- ***Realizing the promise of value-based payment in Medicare: An agenda for change.*** The Commission outlines a multiyear effort to lay out a strategic direction for Medicare payment policy and delivery system design that broaden the use of value-based payment.
- ***Challenges in maintaining and increasing savings from accountable care organizations (ACOs).*** The Commission evaluates past savings, examines strategies to increase savings, and recommends a technical change that will reduce the risk that program vulnerabilities might result in unwarranted shared savings payments to ACOs.
- ***Replacing the Medicare Advantage quality bonus program.*** Medicare's quality bonus program (QBP) for assessing and rewarding quality performance in the Medicare Advantage (MA) program is flawed and not consistent with the Commission's principles for quality incentive programs. In the June 2019 report to the Congress, we introduced an alternative MA value incentive program (MA–VIP). In this report, the Commission recommends that the Congress replace the QBP with an MA–VIP that includes five key design elements.
- ***Mandated report: Impact of changes in the 21st Century Cures Act to risk adjustment for Medicare Advantage enrollees.*** The 21st Century Cures Act of 2016 directs the Secretary to make several changes to the CMS hierarchical condition category (CMS–HCC) model, which CMS uses to calculate the enrollee risk scores that adjust MA capitated payments. We assess how each of those changes affects the ability of the CMS–HCC model to predict costs for various Medicare beneficiary populations.
- ***Realigning incentives in Medicare Part D.*** The Commission proposes a package of recommendations to reform Part D and realign plan and manufacturer incentives. The recommendations will limit enrollees' out-of-pocket spending; help restore the role of risk-based, capitated payments; and eliminate features of the current program that distort market incentives. These changes will better align the incentives in Part D with the interests of the Medicare program and its beneficiaries.
- ***Separately payable drugs in the hospital outpatient prospective payment system.*** Medicare payment systems that bundle multiple services into one payment, such as the outpatient prospective payment system (OPPS), create incentives for providers to be judicious about the cost inputs of the services they provide. Paying for items outside the bundle—such as separately payable drugs—should be done only under certain circumstances, such as when a new drug exhibits clinical superiority over an existing drug. In future work, we will determine other criteria for identifying which drugs should be separately payable.
- ***Improving Medicare's end-stage renal disease prospective payment system.*** The Commission recommends (1) eliminating the payment adjustment for certain new drugs and (2) replacing the separate low-volume and rural payment adjustments with a single payment adjustment—a low-volume and isolated payment adjustment—that will protect isolated, low-volume dialysis facilities that are critical to ensure beneficiary access.

Although this report sets out a vision for the direction of Medicare payment systems in the future and makes specific recommendations for needed changes in today's Medicare payment systems, the Commission realizes that the Congress and CMS are currently coping with the profound challenges facing Medicare and the entire health care system as they contend with the reality of the coronavirus pandemic. We will provide whatever advice and assistance that we can at this time to the Congress and to CMS as the Medicare program adapts to today's realities. In the future, we will attempt to take lessons learned from today's experience into our assessments of Medicare's payment systems as we help the Congress grapple with the difficult task of controlling the growth of Medicare spending while preserving beneficiaries' access to high-quality care and providing sufficient payment for efficient providers.

Realizing the promise of value-based payment in Medicare: An agenda for change

In Chapter 1, the Commission outlines a multiyear effort to establish a strategic direction for Medicare payment policy and delivery system design that could be implemented by the Congress and CMS. This work will be aimed at identifying changes that broaden the use of value-based payment (which characterizes methods of paying for health care services that provide stronger incentives than fee-for-service to control overall costs while maintaining or improving quality) by encouraging more providers to organize into "accountable entities." Such entities would be capable of receiving payments from Medicare and accepting accountability for both the cost and the overall health of a group of beneficiaries. Medicare Advantage and accountable care organizations could serve as vehicles to broaden the use of value-based payment, but both programs need to be improved to realize that potential. This work will be guided by the same fundamental principles that serve as the foundation for all of our policy development: ensuring that beneficiaries have access to high-quality care in an appropriate setting, paying providers equitably and giving them incentives to supply efficient and appropriate care, and assuring the best use of the taxpayer dollars that finance most of Medicare's spending.

The Commission contends that policymakers will need new approaches to both how Medicare pays providers and how services are organized and delivered to address the currently unsustainable trends in Medicare spending. In 2018, Medicare accounted for 3.6 percent of the country's gross domestic product, and that figure will grow to 4.7 percent by 2027. As the population ages, the number of workers per Medicare beneficiary is expected to decline—from 3.0 in 2019 to a projected 2.5 in 2029—making the financing of the program more challenging. For example, the program's Part A trust fund is projected to exhaust its reserves in 2026, which will force Medicare to sharply reduce payment rates for hospitals and other Part A providers unless policymakers take some other action. These trends could result in dramatic changes to the Medicare program and its financing if deliberate changes are not made to how Medicare pays for care and to how care is organized and delivered.

Challenges in maintaining and increasing savings from accountable care organizations

CMS has made it a priority to move more Medicare beneficiaries into alternative payment models in which providers are responsible for the cost and quality of care. One such model is the accountable care organization (ACO). ACOs are now responsible for 23 percent of Medicare beneficiaries with both Part A and Part B coverage. Given the rapid growth in ACOs, it is important to evaluate whether they are generating savings for the Medicare program and thus helping make the program more sustainable. In Chapter 2, the Commission evaluates past savings, examines strategies to increase savings, and recommends a technical change that will reduce the risk that program vulnerabilities might result in unwarranted shared savings payments to ACOs that exceed the rate of savings achieved to this point.

To date, ACOs have generated modest savings, with most evaluations estimating 1 percent to 2 percent reductions in spending from existing ACO models. Some have expressed a concern that the ability of Medicare ACOs to achieve savings has been limited because key constituencies are not sufficiently engaged with ACOs and have incentives that run counter to those of ACOs. CMS and others have expressed an interest in trying to enhance ACOs' ability to generate savings by creating greater engagement with beneficiaries and specialists, reducing hospital incentives to increase services, and aligning incentives for ACOs and prescription drug use under Part D. However, all of these strategies involve implementation challenges.

Because Medicare savings from Medicare Shared Savings Program ACOs have been relatively small thus far (although still greater than most care coordination demonstrations), there is a risk that those savings could be eroded, or even completely offset, by unwarranted shared savings payments. Patient selection in ACOs could result in unwarranted shared savings payments, whether the selection is intentional or not. For example, if high-cost beneficiaries are disproportionately shifted out of an ACO in its performance year—while remaining in the baseline years—performance-year spending will decrease in relation to the ACO's benchmark. This phenomenon could occur if clinicians with high-cost beneficiaries bill under a taxpayer identification number (TIN) that is not part of the ACO or if a clinician bills for patients with low spending under the ACO's TINs and bills for patients with higher spending relative to their risk score under a non-ACO TIN.

The Commission does not believe widespread patient selection occurred in the program's early years. However, the current system allows an ACO to strategically change the composition of its TINs to increase the likelihood of receiving unwarranted shared savings relative to benchmarks, creating a vulnerability for the Medicare program.

To reduce the incentives to select patients and providers, and to reduce the potential mismatch between the clinicians considered in an ACO's baseline years and its performance years, the Commission recommends that the Secretary determine an ACO's historical baseline spending using the same national provider identifiers that are used to compute the ACO's performance-year spending. While there will always be some shared savings payments due to random variation, we should minimize opportunities for unwarranted shared savings payments due to intentional favorable provider and patient selection. Properly matching the clinicians included in an ACO's baseline and performance years will allow a more accurate assessment of an ACO's performance and reduce opportunities for unwarranted shared savings.

Replacing the Medicare Advantage quality bonus program

The Commission maintains that Medicare program payments should take into account the quality of care delivered to beneficiaries, and the Commission has formalized a set of principles for designing Medicare quality incentive programs. Medicare's quality bonus program (QBP) for assessing and rewarding quality performance in the Medicare Advantage (MA) program is not consistent with these principles, and in Chapter 3 we recommend replacing it with a new quality program: the MA value incentive program (MA–VIP).

In our June 2019 report to the Congress, we outlined multiple significant flaws in the QBP program. Those flaws must be addressed so Medicare can have confidence that the MA program encourages and appropriately rewards high quality in a manner that ensures that program dollars are wisely spent. In 2019, MA's QBP cost $6 billion and is projected by the Congressional Budget Office to cost $94 billion over 10 years.

The Commission recommends that the Congress replace the QBP with an MA–VIP that includes the following five key design elements:

- ***Scores a small set of population-based measures.*** The measure set would be tied to clinical outcomes as well as patient/enrollee experience.
- ***Evaluates quality at the local market level.*** Evaluating MA plan quality at the local market area level provides information about the quality of care delivered in the localities in which beneficiaries seek and receive care.
- ***Uses a peer-grouping mechanism to account for differences in enrollees' social risk factors.*** Comparing performance among groups of beneficiaries (e.g., fully dual-eligible beneficiaries) with similar characteristics accounts for social risk factors without masking disparities in plan performance, as would be the case if measure results themselves were adjusted by population social-risk characteristics.
- ***Establishes a system for distributing rewards with no "cliff" effects.*** The use of continuous performance-to-points scales allows plans that improve to earn points and avoids the cliff effect, whereby only those plans achieving a certain level of quality receive bonuses.
- ***Distributes plan-financed rewards and penalties at the local market level.*** The MA–VIP redistributes a pool of dollars (made up of a percentage of plan payments within the market areas) as rewards and penalties based on a plan's performance compared with the market area's other plans.

To test the proof of concept of the MA–VIP design, we modeled a prototype MA–VIP using currently available data. In stratifying results by peer groups, the MA–VIP accounts for differences in social risk factors of plan populations and allows plans the potential to earn more rewards for higher quality care provided to populations identified by the presence of certain social risk factors. Our results indicated that an MA–VIP was feasible. An illustrative withhold of 2 percent of payments yielded small penalties and rewards for each peer group for most parent organizations in a market area. To drive quality improvement, policymakers would need to choose an appropriate amount of payment to fund the reward pool and an effective performance-to-points scale methodology.

Mandated report: Impact of changes in the 21st Century Cures Act to risk adjustment for Medicare Advantage enrollees

In Chapter 4, the Commission responds to a mandate in the 21st Century Cures Act that directs it to evaluate the impact of the changes CMS has made to the CMS hierarchical condition category (CMS–HCC) model that is used to risk adjust payments in the MA program.

The Medicare program pays managed care plans that participate in MA a monthly capitated amount to provide Medicare-covered services to its Medicare enrollees. Payment for each enrollee has two parts: a base rate and a risk score. The base rates vary by county, and the base rate for a given county reflects the payment for an MA enrollee in that county with the health status of the national average beneficiary in fee-for-service (FFS) Medicare. The risk score indicates how costly the enrollee would be expected to be in FFS Medicare, relative to the national average FFS beneficiary.

The 21st Century Cures Act of 2016 directs the Secretary to make or consider several changes to the CMS–HCC model, which CMS uses to calculate the risk scores used to adjust MA capitated payments for enrollees. CMS has implemented the changes incrementally: different adjustments for full-benefit and partial-benefit dual-eligible beneficiaries in 2017; adjustments for mental health and substance abuse disorders and chronic kidney disease in 2019; and adjustments for the number of beneficiaries' conditions in 2020.

We have evaluated the impact of the changes that CMS has made to the CMS–HCC model (and the use of two years of diagnosis data, which CMS has not yet implemented) and found the following:

- Each change produces accurate payment adjustments for groups that have characteristics defined by variables in the model.
- Making distinctly different adjustments for full-benefit dual-eligible beneficiaries and partial-benefit dual-eligible beneficiaries eliminates systematic underpayments for the full-benefit dual-eligible beneficiaries and systematic overpayments for the partial-benefit dual-eligible beneficiaries that had occurred in previous models that did not distinguish between these two populations.
- Adding variables to the CMS–HCC model for mental health and substance abuse disorders and chronic kidney disease improves how accurately the model adjusts payments for beneficiaries who have those conditions. However, adding such variables to the CMS–HCC model can provide additional opportunities for MA plans to increase revenue by coding more medical conditions.
- Adding indicators for the number of medical conditions for each beneficiary improves the model's accuracy in adjusting payments for beneficiaries who have no conditions indicated in the model and those who have many conditions.
- Using two years of diagnosis data to determine beneficiaries' conditions is a straightforward and effective method for addressing problems related to differences in coding intensity of medical conditions between MA and FFS Medicare.
- All of the models produce underpayments for beneficiaries with very high levels of Medicare spending and overpayments for those with very low levels of Medicare spending. These payment inaccuracies have been a persistent issue for MA risk adjustment.

We commend the progress that CMS has made in implementing the changes to the CMS–HCC model mandated by the 21st Century Cures Act. We encourage CMS to continue its work on this issue to complete the requirements in the 21st Century Cures Act by the mandated date of January 1, 2022.

Realigning incentives in Medicare Part D

In Chapter 5, the Commission proposes a package of recommendations to reform Part D to limit enrollees' out-of-pocket (OOP) spending; realign plan and manufacturer incentives to help restore the role of risk-based, capitated payments; and eliminate features of the current program that distort market incentives. These reforms will better align the incentives in Part D with the interests of the Medicare program and its beneficiaries. The package of recommendations builds on the major changes the Commission recommended in 2016 to Part D's benefit structure that would have plan sponsors bear more financial risk for their enrollees' drug spending while, at the same time, providing sponsors with greater flexibility to use formulary tools. Changes in law and the expanded use of

high-priced drugs since that time have further eroded the competitive incentives for cost control and have made our new package of recommendations even more crucial.

We recommend restructuring Part D in the following ways:

- For spending below the catastrophic threshold, there would be a standard benefit for all enrollees in which plans would become responsible for 75 percent of spending between the deductible and the catastrophic threshold, with enrollees responsible for the remaining 25 percent through cost sharing. (The proposal would eliminate the manufacturers' coverage-gap discount that currently applies to enrollees without the low-income subsidy (LIS) and remove the coverage gap for LIS enrollees. Because cost sharing for LIS enrollees is limited to nominal copayments, Medicare's LIS would cover most or all of those enrollees' cost sharing.)
- For spending above the catastrophic threshold, the restructured benefit would provide enrollees with greater financial protection by adding an annual cap on beneficiaries' out-of-pocket (OOP) costs. The policy would shift insurance risk from Medicare to plan sponsors and drug manufacturers. Plan sponsors would be liable for more spending in the catastrophic phase than the current 15 percent. A new manufacturers' discount of at least 30 percent would be more likely to apply to drugs and biologics that command high prices, potentially acting as a drag on price growth. (The discount could be structured so that if prices of drugs that were subject to the discount increased faster than a benchmark, the discount rate would increase commensurately.)

The reduction in reinsurance payments and increase in plan liability for spending in the catastrophic phase would be phased in during a transition period so that plan sponsors could adjust to the new distribution of risk. The other elements of the new benefit structure—eliminating the coverage gap, establishing a new discount program in the catastrophic phase, and adding an annual cap on beneficiary OOP costs—would be implemented without a transition.

There are several consequences and actions that would result from these reforms. Sponsors would incorporate lower expected Medicare reinsurance subsidies and higher expected benefit liability into plan bids. Because Medicare's overall subsidy of basic benefits would remain at 74.5 percent, Medicare's capitated payments to plans would increase to incorporate their new higher benefit liability.

It would be critically important for CMS to recalibrate Part D's risk adjustment model to reflect the increased plan liability. The proposed reforms would result in higher capitated payments for all enrollees, with a larger impact, in dollar terms, for LIS beneficiaries. Given the structure of the risk adjustment model, we believe that CMS would be able to recalibrate the model to ensure that overall payment rates would be adequate for both LIS enrollees and other Part D beneficiaries and for smaller plan sponsors that enroll a higher share of LIS beneficiaries.

Finally, because plans will hold greater insurance risk under the reform, policymakers could consider making the Part D risk corridors more generous to temporarily provide plan sponsors with greater protection during a transition to the new benefit structure. Policymakers could also consider different risk-sharing percentages in the corridors to increase plans' aggregate stop-loss protection. While the enhanced protection would be available to all plans, in practice, the protection would be particularly valuable for smaller plan sponsors that do not have the scale to spread the insurance risk or the capital to reinsure themselves.

Separately payable drugs in the hospital outpatient prospective payment system

In Chapter 6, the Commission specifically considers separately payable drugs in the hospital outpatient prospective payment system (OPPS), although the issues we consider in the chapter have broader implications.

The unit of payment in the OPPS is the primary service (the reason for the visit) coupled with the ancillary items provided with the primary service. That is, the OPPS typically packages the cost of ancillary items into the payment rate of the related primary service. Combining a primary service and related ancillary items into a single payment unit encourages efficiency because the combination of inputs used to treat a patient determines whether the provider experiences a financial gain or loss. However, not all ancillary items are packaged.

A category of ancillary items that has grown in importance in the OPPS is drugs covered under Medicare Part B. The OPPS has two distinct policies for paying some drugs separately from primary services: pass-through drugs and

separately payable non-pass-through (SPNPT) drugs. The pass-through program is intended to provide adequate payment to hospitals for drugs that are relatively costly and new to the market. In contrast, the SPNPT program is intended to provide adequate payment for relatively high-cost drugs that are already established in the drug market. Under both policies, each drug has its own payment rate. Total Medicare spending (combined program spending and beneficiary cost sharing) for pass-through drugs and SPNPT drugs has grown rapidly, increasing from $5.1 billion in 2011 to $12.9 billion in 2018. Most of that growth in drug spending—82 percent—was for cancer treatment drugs.

The current criteria for both pass-through drugs and SPNPT drugs have been in place for more than 15 years. We are concerned that the criteria for eligibility under both policies do not strike an appropriate balance between promoting innovation and maintaining pressure on providers to be efficient. Both policies use cost criteria to identify drugs for program eligibility. The cost criteria are different between the programs, but we are concerned that both allow eligibility for drugs that should be packaged. Also, neither policy requires drugs to show that they are clinically superior to competing drugs, even though a requirement for clinical superiority implicitly encourages innovation. As a result, Medicare could pay separately for a drug no more effective than an existing product, even when the cost of the existing product is reflected in the OPPS payment—resulting in double payments by Medicare.

At this point in our analysis, we conclude that an effective system of separately payable drugs should have two features:

- Some drugs should be paid separately because they are not ancillary. These drugs are the purpose for a visit, are high cost, treat a condition, and are usually administered by infusion.
- Drugs should show clinical superiority over other drugs to have separately payable status. A clinical superiority requirement is vital to prevent double payments by Medicare.

In future work, we will perform analyses to determine other criteria for identifying drugs that should be separately payable. We will also perform analysis to determine the parameters for those criteria.

Improving Medicare's end-stage renal disease prospective payment system

Medicare pays dialysis facilities under a prospective payment system (PPS) that is based on a bundle of services that includes end-stage renal disease (ESRD) drugs (including biologics), clinical laboratory tests, and other items and services. In Chapter 7, the Commission recommends two changes to current payment policy.

First, the Commission recommends that the Congress direct the Secretary to eliminate the transitional drug add-on payment adjustment (TDAPA) for new drugs that are in an existing ESRD functional category already included in the payment bundle. Eliminating the TDAPA would (1) maintain the structure of the ESRD PPS and avoid the introduction of incentives to unbundle services covered under the PPS and (2) create pressure for drug manufacturers to constrain the growth of prices for new and existing ESRD drugs. At market entry, such new drugs would be included in the ESRD PPS bundle without an update to the base payment rate. As new products are added to the bundle and diffused into medical practice, it will be important to monitor the use of ESRD drugs, changes in beneficiaries' outcomes, and the alignment of Medicare payments with providers' costs to evaluate whether a change in the bundled payment is warranted.

Second, the Commission recommends that the Secretary replace the current low-volume payment adjustment (LVPA) and the rural adjustment with a single payment adjustment for dialysis facilities that are isolated and consistently have low volume—where low-volume criteria are empirically derived. The Commission believes that neither the current LVPA nor the current rural adjustment accurately targets facilities that are both critical to beneficiary access and have high costs warranting a payment adjustment.

The Commission modeled a policy—the low-volume and isolated (LVI) adjustment—under which facilities that are low volume and isolated are defined based on both a facility's distance from the nearest facility and total treatment volume. In 2017, the illustrative LVI policy would have applied to 575 freestanding and hospital-based dialysis facilities, compared with 336 facilities receiving the current LVPA and 1,257 facilities receiving the rural adjustment. The LVI policy would not apply to facilities that furnish a high volume of treatments because their economies of scale generally result in lower average treatment costs compared with low-volume facilities.

The LVI policy would also not apply to facilities that are in close proximity to another dialysis facility since such facilities are not the sole providers of dialysis services in their communities and thus are not critical to maintaining access to care. Overall, the LVI policy would better target payment adjustments to the facilities that are most important for maintaining access to dialysis services and would improve the value of Medicare's spending. ■