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October 2, 2020

Seema Verma, MPH  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue SW  
Washington, DC 20201

**RE: File code CMS-1734-P**

Dear Ms. Verma:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule entitled: “Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA–PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy,” published in the *Federal Register*, vol. 85, no. 159, pages 50074 to 50665. We appreciate your staff’s ongoing efforts to administer and improve payment systems for physician and other health professional services (including implementing the Quality Payment Program (QPP) and Medicare Shared Savings Program), particularly considering the competing demands on the agency. We hope that our comments are helpful in those endeavors.

Our comments address the following provisions in the proposed rule:

- Refinements to values for certain services to reflect revisions to payment for office/outpatient evaluation and management (E&M) visits and promote payment stability during the COVID-19 pandemic
- Telehealth expansions
- Scope of practice and related issues

- Medicare Shared Savings Program: Quality measure set
- CY 2021 updates to QPP
- Part B drug payment for drugs approved through the pathway established under section 505(b)(2) of the Food, Drug, and Cosmetic Act

### **Refinements to values for certain services to reflect revisions to payment for office/outpatient evaluation and management visits and promote payment stability during the COVID-19 pandemic**

In the Part B final rule for 2020, CMS adopted new coding for office/outpatient E&M visits that will become effective on January 1, 2021.<sup>1</sup> Under this new coding framework, patient history and exam will no longer be used to select the code level for office/outpatient E&M visits. Instead, the selection of the code level will be based on either the level of medical decision-making or the total time spent by the practitioner on the day of the visit. CMS also deleted the code for a level 1 visit for a new patient (99201) because it was deleted by the Current Procedural Terminology Editorial Panel. CMS believes these new policies will reduce administrative burden, improve payment accuracy, and better reflect the current practice of medicine.

CMS's Part B final rule for 2020 also adopted new work relative value units (RVUs) and direct practice expense inputs for the office/outpatient E&M codes that will take effect on January 1, 2021. The work RVUs for most of these codes will be higher. For example, the work RVUs for a level 3 E&M visit for an established patient (99213) will increase from 0.97 to 1.3. This change in work RVUs for E&M codes was recommended to CMS by the American Medical Association's Relative Value Scale Update Committee (RUC), after conducting the largest survey in the RUC's history—of nearly 1,700 clinicians from over 50 specialties—and finding that E&M visits have become more complex for most clinicians and therefore need to be revalued.<sup>2,3</sup> The RUC has recommended adjustments to the work RVUs of clinician services since the early 1990s; each year, these adjustments (if adopted by CMS) are made in a budget-neutral manner, as required by law.

There are other services whose valuation is closely tied to the values for office/outpatient E&M visits. These services always include an E&M visit as part of the service, were originally valued relative to an E&M visit, or consist of assessment and management services that are similar to E&M visits. Therefore, to maintain payment accuracy, CMS proposes to increase the RVUs for these services so that they are aligned with the RVUs for E&M visits. These services include end-

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<sup>1</sup> Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2019. Medicare program; CY 2020 revisions to payment policies under the physician fee schedule and other changes to Part B payment policies; Medicare Shared Savings Program requirements; Medicaid Promoting Interoperability Program requirements for eligible professionals; establishment of an ambulance data collection system; updates to the Quality Payment Program; Medicare enrollment of opioid treatment programs and enhancements to provider enrollment regulations concerning improper prescribing and patient harm; and amendments to physician self-referral law advisory opinion regulations final rule; and coding and payment for evaluation and management, observation and provision of self-administered esketamine. Interim final rule. *Federal Register* 84, no. 221 (November 15): 62568–63563.

<sup>2</sup> Ibid.

<sup>3</sup> AMA/Specialty Society RVS Update Committee. 2019. Meeting Minutes. April 24-27, Chicago, IL. <https://www.ama-assn.org/system/files/2020-08/apr-2019-ruc-meeting-minutes.pdf>.

stage renal disease monthly capitation payments, transitional care management, maternity services, assessment and care planning for patients with cognitive impairment, annual wellness visits, emergency department visits, and therapy evaluations.

In the Part B final rule for 2020, CMS created a new add-on code (GPC1X) for office/outpatient E&M visits, which pays for “visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient’s single, serious, or complex chronic condition.” This new code will become effective on January 1, 2021, and its work RVUs will be 0.33.

CMS created this new add-on code because it contends that the revised office/outpatient E&M codes do not adequately reflect the resources associated with primary care and certain types of specialty visits. In particular, CMS posited that the revised E&M codes do not recognize the resources involved in providing team-based, coordinated care to patients on an ongoing basis that results in a comprehensive, continuous relationship with patients. Although CMS assumes that certain specialties provide these types of visits more than others, it did not restrict billing based on specialty.<sup>4</sup> Since CMS created this code, some stakeholders have commented that the definition of this service is unclear. As a result, CMS is seeking comment on what aspects of the code definition are unclear and how to address those concerns.

As required by statute, CMS is implementing all of these changes (and changes to other codes not discussed in this section) in a budget-neutral manner. To accomplish budget neutrality, CMS proposes to reduce the fee schedule’s conversion factor (a standard dollar amount that is used to determine payment rates) by 10.61 percent for 2021. For specialties that provide a high share of office/outpatient E&M visits, the increase in work RVUs for these visits will more than compensate for this conversion factor decrease, resulting in higher Medicare payments. For example, CMS projects that payments for endocrinology will increase by 17 percent, rheumatology by 16 percent, and family practice by 13 percent. In contrast, specialties that provide relatively few E&M visits will receive lower payments. For example, estimated payments for radiology, pathology, and cardiac surgery will decline by at least 9 percent.

### *Comment*

The Commission strongly supports the changes to the E&M office/outpatient visit codes and the revised work RVUs for these codes that CMS adopted in the Part B final rule for 2020.<sup>5</sup> We also

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<sup>4</sup> CMS assumes the following specialties would bill this add-on code with 100 percent of their office/outpatient E&M visit codes: family practice, general practice, internal medicine, pediatrics, geriatrics, nurse practitioner, physician assistant, endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, interventional pain management, cardiology, nephrology, infectious disease, psychiatry, and pulmonary disease.

<sup>5</sup> Medicare Payment Advisory Commission. 2019. MedPAC comment on the Centers for Medicare & Medicaid Services’ interim final rule entitled “Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid

strongly support CMS's proposal to implement these changes in a budget-neutral manner because the Commission has determined that procedures, broadly, are overvalued.

The Commission has long been concerned that E&M office/outpatient visits are undervalued relative to other services in the fee schedule. The fee schedule's work RVUs, which account for the amount of clinician work required to provide a service, are based on an assessment of how much time and intensity services require relative to one another. Some types of services—such as procedures, imaging, and tests—experience efficiency gains over time, as advances in technology, technique, and clinical practice enable clinicians to deliver them faster. However, E&M office/outpatient visits do not lend themselves to such efficiency gains because they consist largely of activities that require the clinician's time. When efficiency gains reduce the amount of work needed for a service, but the work RVUs for the affected service are not decreased, the service becomes overvalued. Under the budget-neutral fee schedule, a reduction in the RVUs of these overvalued services would raise the RVUs for all other services, such as E&M visits. But because of problems with the process of reviewing overpriced services and the data used to set prices, this two-step sequence tends not to occur.<sup>6</sup> As a result, E&M office/outpatient visits have become passively devalued over time. This mispricing may lead to problems with beneficiary access to these services and may influence the pipeline of physicians in specialties that tend to provide a large share of E&M services. By substantially increasing the work RVUs for E&M office/outpatient visits, CMS will help remedy several years of passive devaluation of these services.

CMS should implement these changes in a budget-neutral manner—a fundamental principle underlying construction of the fee schedule as enacted by the Congress in 1989. We strongly support budget-neutral implementation for several reasons.

First, budget-neutral implementation will help rebalance the fee schedule from services that have become overvalued to services that have become undervalued—thus improving payment accuracy. Because of advances in technology, technique, and clinical practice, efficiency improves more easily for procedures, imaging, and tests than for E&M office/outpatient visits, which are composed largely of activities that require the clinician's time and so do not lend themselves to efficiency gains.<sup>7</sup> Contractors working for CMS and the Assistant Secretary for Planning and Evaluation in the Department of Health and Human Services have found ample evidence of overvaluation of a broad range of services, particularly imaging, procedures, and tests.<sup>8</sup> If the

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Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations.” Letter to the Administrator. September 13. [http://www.medpac.gov/docs/default-source/comment-letters/09132019\\_cms\\_1715p\\_physician\\_medpac\\_comment\\_v2\\_sec.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/comment-letters/09132019_cms_1715p_physician_medpac_comment_v2_sec.pdf?sfvrsn=0).

<sup>6</sup> Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

<sup>7</sup> Ibid.

<sup>8</sup> Merrell, K., C. Schur, T. Oberlander, et al. 2014. *Analysis of physician time use patterns under the Medicare fee schedule*. Report prepared for the Assistant Secretary for Planning and Evaluation. Washington, DC: Social & Scientific Systems and the Urban Institute.

Zuckerman, S., K. Merrell, R. Berenson, et al. 2016. *Collecting empirical physician time data: Piloting an approach for validating work relative value units*. Report prepared for the Centers for Medicare & Medicaid Services. Washington, DC: The Urban Institute.

E&M visit revaluations are not made in a budget-neutral manner, the fee schedule will remain out of balance. Payment rates for E&M services would go up, but there would not be a compensating decrease in the fees for other services. Some passive devaluation of E&M services would remain.

Second, implementing this change in a budget-neutral manner will go further in reducing the large gap in compensation between primary care physicians (who had a median income of \$243,000 in 2018) and specialists such as surgeons (whose median income was \$426,000 in 2018).<sup>9</sup> This large income gap may decrease the appeal of a career in primary care. The U.S. has over three times as many specialists as primary care physicians, which could explain why MedPAC's annual survey of Medicare beneficiaries has repeatedly found that beneficiaries who are looking for a new physician report having an easier time finding a new specialist than a new primary care provider.<sup>10</sup> Access to primary care physicians could worsen in the future as the number of primary care physicians in the U.S., after remaining flat for several years, has actually started to decline.<sup>11</sup> Implementing the planned E&M visit revaluations in a budget-neutral manner will maximize the redistributive effects of this policy change.

Third, not only will budget neutrality reduce both under- and over-payment, which is our main consideration, it will also reduce the financial burden on beneficiaries and taxpayers who finance the program. As we note each year in our March report to the Congress, Medicare spending has been growing as a share of federal spending, contributing to the country's growing debt, and Medicare premiums and cost sharing have been consuming an increasing share of beneficiaries' Social Security benefits. The Commission does not believe there is a need to add aggregate dollars to the physician fee schedule (PFS). When the Commission examines beneficiary surveys and other indicators of payment adequacy, we do not see any indication that the current aggregate level of physician payments is insufficient to ensure overall access. For example, 92 percent of Medicare beneficiaries reported no trouble accessing care in the latest round of CMS's Medicare Current Beneficiary Survey (and when they do experience trouble, the *cost* of care is the main barrier—not the availability of clinicians willing to serve them) and access is best for specialist services.<sup>12</sup> That said, given the reduction in fees for some services, we will continue to monitor access to identify any unintended consequences.

Moving on to other provisions in the proposed rule, we agree with CMS's proposal to increase the RVUs for services that are closely tied to E&M office/outpatient visits so that they are consistent with the higher RVUs for E&M visits. This proposal will help ensure that the RVUs for similar services are aligned and therefore will improve payment accuracy.

However, as described in our comment letter on the Part B final rule for 2020, we do not support the creation of a new add-on code (GPC1X) for office/outpatient E&M visits to account for the

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<sup>9</sup> Medicare Payment Advisory Commission. 2020. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

<sup>10</sup> These results appear in the "Physician and other health professional services" chapter of MedPAC's annual *Report to the Congress: Medicare payment policy*.

<sup>11</sup> Medicare Payment Advisory Commission. 2020. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

<sup>12</sup> Medicare Payment Advisory Commission. 2020. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

additional resource costs inherent in furnishing some kinds of E&M visits.<sup>13</sup> CMS has not defined these additional resources or the types of visits that require additional resources in sufficient detail. Without a more detailed description of this code, how will clinicians document that they are billing it appropriately? CMS assumes that many specialties will bill this code with every E&M visit. If so, CMS should further increase the work RVUs for E&M office/outpatient visits as opposed to creating an add-on code.

Further, this add-on code originated with CMS's decision to combine the Level 2–5 E&M office/outpatient visit codes into one composite code, as described in the Part B final rule for 2019. Because this change would have had significant impacts on aggregate Medicare payments by clinician specialty and revenue for individual clinicians, CMS also created two add-on codes to be used with E&M visits: a visit complexity code for primary care services and a visit complexity code for certain specialty care. CMS later combined these two add-on codes into a single add-on code (GPC1X). In the Part B final rule for 2020, CMS reversed its decision to combine the Level 2–5 E&M codes into one composite code. Instead, CMS decided to retain separate codes for Level 2–5 E&M visits. Therefore, it no longer makes sense to keep this new add-on code. Because clinicians can use different levels of E&M codes to indicate whether an E&M visit took more time or required more complex medical decision making, there no longer needs to be an add-on code to account for the additional resources required for more complex visits.

### **Telehealth expansions**

Under the PFS, Medicare covers a limited set of telehealth services in rural locations. During the coronavirus public health emergency (PHE), CMS has expanded Medicare's coverage of telehealth services on a temporary and emergency basis under the Section 1135 waiver authority, as well as additional authority given by Congress under the Coronavirus Preparedness and Response Supplemental Appropriations Act and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). CMS has temporarily added dozens of services to the list of allowable telehealth services. CMS is proposing to permanently add nine of these service codes (e.g., group therapy, home visits, neurobehavioral status exam, care planning for patients with cognitive impairment) to the list of allowable telehealth services because they are similar to telehealth services that were previously allowable.

CMS also proposes to create a temporary category of telehealth services that will remain on the list of allowable services for the remainder of the calendar year in which the PHE ends. This proposal is intended to allow stakeholders more time to submit information to CMS about whether these telehealth services have contributed positively or negatively to the quality of care provided to

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<sup>13</sup> Medicare Payment Advisory Commission. 2019. MedPAC comment on the Centers for Medicare & Medicaid Services proposed rule entitled "Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations." Letter to the Administrator. September 13. [http://medpac.gov/docs/default-source/comment-letters/09132019\\_cms\\_1715p\\_physician\\_medpac\\_comment\\_v2\\_sec.pdf?sfvrsn=0](http://medpac.gov/docs/default-source/comment-letters/09132019_cms_1715p_physician_medpac_comment_v2_sec.pdf?sfvrsn=0).

beneficiaries during the PHE so that CMS can understand which services should be retained on the Medicare allowable services list. Examples of the 13 services codes in this temporary category include psychological and neuropsychological testing and nursing facilities discharge day management.

During the PHE, CMS has removed the frequency limitation for subsequent nursing facility visits that allowed the visits to be delivered through telehealth only once every 30 days. CMS also has allowed initial nursing facility visits to be performed by telehealth. After the PHE, initial nursing facility visits will again be required to be in-person, but CMS is seeking comment on whether Medicare should permanently change the subsequent nursing facility visits policy to allow for a telehealth visit every three days or have no limit on the number of subsequent visits that can be delivered by telehealth.

During the PHE, CMS also has established separate payment for audio-only telephone E&M services. Under current policy (which predates the PHE), virtual check-ins (which receive a payment of about \$15) are available to established patients and cover a 5- to 10-minute interaction via telephone or other telecommunications device. CMS is not proposing to continue to recognize audio-only telephone codes for payment under the PFS after the PHE ends. However, CMS speculates that the need for audio-only interactions could remain as beneficiaries continue to try to avoid potential sources of infection, such as a doctor's office. CMS is therefore seeking comment on whether the agency should develop coding and payment for a service similar to the virtual check-in but for a longer unit of time and subsequently with a higher value. CMS seeks input on the duration of the service and the resources (both in terms of work and practice expenses) associated with furnishing it, and whether this new, longer virtual check-in should be a provisional policy to remain in effect until a year after the end of the PHE or if the policy should be permanent.

### *Comment*

We recognize the unique and difficult circumstances in which CMS currently operates under the PHE. CMS has offered flexibilities that aim to allow providers to effectively respond to the public health threats posed by the spread of COVID-19. We understand that CMS has had to make these policy changes quickly. However, we are concerned about the broader implications of continuing these changes once the PHE has ended. When that time approaches, we urge CMS to carefully consider and weigh how making any of these changes permanent will affect the quality and safety of care beneficiaries receive, the willingness of providers to continue to participate in the Medicare program, and the already challenging fiscal solvency and program integrity of the Medicare program.

In our March 2018 report to the Congress, the Commission recommended that policymakers should be cautious in expanding coverage of telehealth services by evaluating whether individual telehealth services balance the principles of cost, access, and quality.<sup>14</sup> For example, expanding the coverage of tele-mental health services at urban originating sites could increase program

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<sup>14</sup> Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

costs substantially with expanded access to care, but it is unclear whether the quality of care beneficiaries receive would improve. As CMS considers whether there should be a 30-day limit, 3-day limit, or no limit on the frequency of subsequent telehealth physician visits during a nursing facility stay, CMS should balance the desire to improve access, lower costs, and to provide high-quality care.

We recognize that CMS began paying for audio-only communications between clinicians and beneficiaries during the PHE to help ensure that providers continue to have the resources needed to serve beneficiaries. Since the expansion of telehealth under the PHE, the Commission has been extensively evaluating whether and how these expansions should be included in the Medicare program permanently, including audio-only visits. The Commission is continuing its work and has not yet finalized a proposal. Therefore, if CMS does create a longer and higher-valued virtual check-in service, it should be a provisional policy (for example, through the end of the calendar year in which the PHE ends). The valuation of a new, longer virtual check-in service should take into account that virtual check-ins require fewer resources than in-person visits. Because clinicians cannot interact as fully with patients when they use communication-based technology as when they see a patient in person, we are skeptical that the level of intensity is the same as for in-person services.

### **Scope of practice and related issues: Provision of maintenance therapy by therapy assistants**

CMS proposes to permanently allow physical and occupational therapists to delegate the performance of maintenance therapy sessions to physical and occupational therapy assistants paid under Part B. CMS notes that this is already allowed under Part A (i.e., for care provided by skilled nursing facilities and home health agencies) and has been temporarily allowed under Part B during the PHE.

#### *Comment*

The Commission supports this proposal because it would promote consistency across payment systems and reduce financial incentives to provide care in particular settings.

### **Medicare Shared Savings Program: Quality measure set**

For performance year 2021, CMS is proposing that accountable care organizations (ACOs) participating in the Medicare Shared Savings Program (MSSP) would need to report only one set of quality metrics that would meet requirements under both the Merit-based Incentive Payment System (MIPS) and MSSP. The total number of measures in the ACO quality measure set (also used in the MIPS's new "Alternative Payment Model (APM) Performance Pathway" for reporting) would be reduced from 23 to 6 measures, and the number on which ACOs are required to actively report would be reduced from 10 to 3 (the remaining three measures are calculated using claims or survey data). The six measures include: (1) Consumer Assessment of Healthcare Providers and Systems (CAHPS<sup>®</sup>) patient experience survey results (e.g., getting timely care); (2) rate of diabetic patients with poor hemoglobin A1c control; (3) rate of patients screened for depression with a follow-up plan developed if needed; (4) rate of hypertensive patients with blood pressure



controlled; (5) 30-day, all-cause unplanned readmission rate; and (6) rate of risk-standardized, all-cause unplanned admissions for patients with multiple chronic conditions.

### *Comment*

We support CMS's proposal to reduce the MSSP measure set to one focused on clinical outcomes and patient experience that is less burdensome for providers to report. This proposal is consistent with our June 2018 report to the Congress, in which the Commission formalized a set of principles for designing Medicare quality incentive programs.<sup>15</sup> Our principles include that quality incentive programs should score a small measure set tied to clinical outcomes as well as patient experience. These measures should not be unduly burdensome for providers, and they should generally be calculated or administered by CMS, preferably with data that are already reported, such as claims, encounters, and patient survey data. These principles informed our recommended redesigns of Medicare's acute-care hospital and Medicare Advantage quality programs. Moreover, we are supportive of monitoring and possibly further refinement as more data and analysis becomes available.

### **CY 2021 updates to Quality Payment Program**

MACRA created two new policies: an incentive payment for qualifying participants in advanced alternative payment models (A-APMs) and MIPS. CMS refers to these two programs collectively as the Quality Payment Program. Most clinicians are in the MIPS track, which means they receive increases or decreases to their Medicare PFS payments based on their performance on measures of quality, cost, improvement activities, and promoting interoperability. Clinicians are exempt from MIPS's reporting requirements and performance-based payment adjustments if they achieve threshold levels of payments or patients in an A-APM (e.g., Comprehensive Primary Care Plus, the Next Generation ACO Model); these clinicians instead receive an incentive payment worth 5 percent of their prior year's Medicare revenues.

In the proposed rule, CMS reiterates its plan to move away from the hundreds of performance measures it currently permits clinicians to choose from in MIPS to curated measure sets designed for particular specialties or conditions. CMS refers to this shift as the "MIPS Value Pathways" (MVP) framework. CMS explains that it is moving to MVP measure sets because it has heard from clinicians that MIPS is "confusing" and "burdensome," and that it "does not allow for sufficient differentiation of performance across practices due to clinician quality measure selection bias." CMS acknowledges that "[t]hese aspects [of MIPS] detract from the program's ability to effectively measure and compare performance, provide meaningful feedback, and incentivize quality."

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<sup>15</sup> Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC

However, in light of the coronavirus pandemic, CMS states that it has limited the changes it proposes making to MIPS for performance year 2021, including delaying the use of the MVP measure sets until performance year 2022.

### *Comment*

The Commission continues to be concerned about many aspects of MIPS—including, for example, its burdensome complexity. This complexity is evident in the proposed rule itself: in a year when CMS makes what it refers to as only a “limited” number of changes, it still takes over 200 pages to describe them. The clinician who searches for instructions on how to participate in MIPS in the 2020 performance year will find 70 manuals and guidance documents on CMS’s Quality Payment Program website. For the clinician who sifts through these documents to figure out what to do and what to report on to achieve a positive MIPS adjustment, the reward is small: the largest adjustment any clinician received in 2020 was a 1.68 percent positive adjustment to the payments they receive for the subset of their patients in original Medicare.<sup>16</sup>

Problems with MIPS led the Commission to recommend that the Congress eliminate the program in our March 2018 report.<sup>17</sup> In MIPS’s place, we recommended a Voluntary Value Program, through which groups of clinicians would receive increases or decreases to their PFS payment rates based on their performance on a uniform set of measures assessing outcomes, patient experience, and value. These measures would be calculated by CMS from claims and surveys—eliminating clinician reporting requirements.

That being said, the Commission continues to support CMS’s MVP framework, which attempts to improve MIPS within the constraints of the agency’s statutory authority. These improvements aim to reduce MIPS’s complexity and burden, incorporate more meaningful population-based outcome measures, promote apples-to-apples comparisons of at least some types of clinicians, and facilitate providers’ movement into A-APMs.

The commission agrees with CMS’s decision to postpone the rollout of MVP to 2022, which should allow clinicians to focus on addressing patients’ care needs during the coronavirus pandemic and give clinicians more time to propose specialty- and condition-specific MVP measure sets.

### **Part B drug payment for drugs approved through the pathway established under section 505(b)(2) of the Food, Drug, and Cosmetic Act**

A 505(b)(2) application is a type of new drug application (NDA) that contains full reports of investigations of safety and effectiveness, but where at least some of the information required for

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<sup>16</sup> Most clinicians (84 percent) subject to MIPS received positive adjustments ranging from 0.21 percent to 1.68 percent; another 13 percent received positive adjustments of 0.2 percent or less; and another 2 percent received negative adjustments of up to –5 percent. (See: Seema Verma, Administrator, Centers for Medicare & Medicaid Services. 2020. 2018 Quality Payment Program (QPP) Performance Results. <https://www.cms.gov/blog/2018-quality-payment-program-qpp-performance-results>.)

<sup>17</sup> Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. In some cases, drugs approved under section 505(b)(2) share significant portions of labeling with generic drugs that are paid as multiple source drugs under section 1847A of the Act. The 505(b)(2) pathway is a hybrid between the generic approval process (under 505(b)(j)) and a full NDA under 505 (b)(1). According to Freije (2020), most 505(b)(2) applications consist of changes to a previously approved drug product (e.g., a new dosage form, new route of administration, etc.).<sup>18</sup>

CMS is proposing to codify the process that it has used for at least 12 years for assigning a 505(b)(2) drug to a multiple-source billing code and to revise the definition of a multiple source drug in regulation text by amending the text to state that multiple source drugs may include drugs described under section 505(b)(2). CMS assigns a 505(b)(2) drug to a multiple source or single source drug billing code by comparing information about the 505(b)(2) drug to the descriptors for existing multiple source codes to which the drug may be assigned, as well as information about the drug already assigned to that descriptor. This information includes the products' active ingredients and labeling, particularly the prescribing information, how the products are prescribed and used clinically, and, if necessary, additional sources such as the FDA's Approval Summary Review, which is a part of the FDA's application review files, and drug compendia.

CMS's proposal addresses the agency's concern about high payments for 505(b)(2) drugs if they are assigned to unique separate HCPCS codes despite being described by existing multiple source drug billing codes. CMS is also concerned about the effect of high payment amounts on beneficiaries' cost sharing for these products. According to the proposed rule, two recently introduced 505(b)(2) drugs that appear to be comparable to drugs in existing multiple source drug codes (using the approach described in the section earlier) have Medicare payment rates that are approximately 10 times higher than that of the existing multiple source code.

### *Comment*

We support CMS's proposal to codify its process for assigning 505(b)(2) drugs into billing codes. Such a policy should spur price competition among drugs with similar health effects and reduce prices. In the Commission's June 2017 report to the Congress, we recommended policies to improve the ASP payment system by promoting price competition among groups of drugs with similar health effects.

Given the increasing number of drugs approved under the 505(b)(2) pathway, CMS's proposal should yield savings for both beneficiaries and taxpayers in the future, without compromising beneficiary access to needed medications. According to CMS, the number of drugs approved through the 505(b)(2) pathway established has been growing, from about 40 per year from 2011 to 2016, to about 60 in 2017, and 70 in 2018. According to Darrow et al. (2019), applications

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<sup>18</sup> Freije, I., S. Lamouche, M. Tanguay. 2020. Review of drugs approved via the 505(b)(2) pathway: Uncovering drug development trends and regulatory requirements. *Therapeutic Innovation & Regulatory Science* 54, vol. 1 (January): 128–138.

submitted under the 505(b)(2) pathway were the majority of new drug approvals in 2017.<sup>19</sup> Its increasing use over time may be driven by a number of factors, including exclusivity incentives that generally do not apply to generic drugs and lower research and development costs compared to drugs approved under the FDA's 505(b)(1) pathway.<sup>20</sup>

## Conclusion

MedPAC appreciates your consideration of these issues. The Commission values the ongoing collaboration between CMS and MedPAC staff on Medicare policy, and we look forward to continuing this relationship.

If you have any questions regarding our comments, please do not hesitate to contact James E. Mathews, MedPAC's Executive Director, at 202-220-3700.

Sincerely,



Michael E. Chernew, Ph.D.  
Chair

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<sup>19</sup> Darrow, J. J., M. He, K. Stefanini 2019. The 505(b)(2) drug approval pathway. *Food and Drug Law Journal* 74, no. 3: 403–438.

<sup>20</sup> Camargo. What is 505(b)(2)? <https://camargopharma.com/resources/what-is-505b2/>; Ryan Chandanais, “505 (b)(2) Regulatory Pathway for New Drug Approvals,” *Pharmacy Times*, Nov. 1, 2017. <https://www.pharmacytimes.com/contributor/ryan-chandanais-ms-cpht/2017/11/505-b2-regulatory-pathway-for-new-drug-approvals->.