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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-1736-P

Dear Ms. Verma:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit comments on CMS's proposed rule entitled: "Medicare program: Hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs; new categories for hospital outpatient department prior authorization process; clinical laboratory fee schedule: laboratory date of service policy; overall hospital quality star rating methodology; and physician-owned hospitals" published in the *Federal Register* on August 12, 2020 (85 FR 48772–49082). We appreciate your staff's ongoing efforts to administer and improve the payment system for hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), particularly considering the agency's competing demands.

This proposed rule documents changes in the composition of some of the ambulatory payment classifications (APCs) used to classify services provided in HOPDs and ASCs and proposes changes to the relative weights based on analyses of claims and cost report data. The rule also proposes a calendar year 2021 update to the conversion factors used to make payments in the outpatient prospective payment system (OPPS) and the ASC payment system.

Among other policies discussed, this rule:

- Requests public comment on whether to extend the length of time that medical devices currently eligible to receive pass-through payments can receive separate payments. CMS has made this request in response to a concern that the COVID-19 public health emergency (PHE) has reduced the extent to which hospitals provide the procedures that involve these devices.
- Proposes to change the basis of setting OPPS payment rates for most separately payable non-pass-through drugs that are obtained through the 340B Drug Pricing Program from

ASP – 22.5 percent to ASP – 28.7 percent. Payment rates for separately payable non-pass-through drugs that are obtained outside the 340B program would continue to be based on ASP + 6 percent. In addition, rural sole community hospitals, children’s hospitals, and the 11 PPS-exempt cancer hospitals would be exempt and would be paid for all drugs at a rate of ASP + 6 percent.

- Proposes to phase out the inpatient-only (IPO) list, which is a list of services that can be provided to Medicare beneficiaries only on an inpatient basis, and, therefore, cannot be provided to Medicare beneficiaries in HOPDs or ASCs. The phaseout of the IPO list would begin on January 1, 2021, and end on January 1, 2024. CMS also proposes that the first year of the phaseout would involve removing only musculoskeletal services from the IPO list.
- Proposes to permanently change the minimum required level of physician supervision of nonsurgical extended duration therapeutic services (NSEDTS) provided in HOPDs from direct supervision to general supervision. CMS has already reduced the required level of supervision for these services to general supervision for the duration of the COVID-19 PHE.
- Proposes to allow direct supervision of pulmonary rehabilitation services, cardiac rehabilitation services, and interactive cardiac rehabilitation services using interactive telecommunications technology. CMS has already allowed this type of physician supervision for the duration of the COVID-19 PHE.
- Proposes two alternatives for modifying the approach for adding surgical procedures to the ASC covered procedures list (CPL)—a nomination process and a revision of the regulatory requirements at 42 CFR 416.166. CMS proposes to implement only one of these alternatives, and the agency seeks public comment as to which should be adopted.
- Proposes to require prior authorization of services in two categories—cervical fusion with disc removal and implanting spinal neurostimulators—before coverage under the OPPI is approved.

We focus our comments on the topics listed above.

Extend the length of time devices can be eligible for pass-through payments in response to the public health emergency

The purpose of the policy for pass-through payment for medical devices is to ensure hospitals receive adequate payment when using innovative new devices while CMS collects the data necessary to incorporate the cost of those devices into the payment rates of the associated procedures. By statute, pass-through payments for devices can be made for a period of two to three years.

In response to the COVID-19 PHE, CMS has received inquiries from stakeholders about possible adjustments to the pass-through payments. According to these stakeholders, the PHE has resulted in reduced use of the pass-through devices. The stakeholders argue that this reduced use will result in fewer claims that list these devices, which will hinder CMS’s ability to calculate appropriate payment rates for services that involve these devices.

In response to the stakeholders' inquiries, CMS is requesting public comment on whether the agency should use its equitable adjustment authority under section 1833(t)(2)(E) of the Social Security Act to provide separate payment for pass-through devices for some period of time after their pass-through status ends to account for the reduced use of the devices during the PHE.

Comment

The Commission does not support this proposed extension of pass-through payments for devices, largely because empirical evidence indicates the COVID-19 PHE resulted in only a brief reduction in HOPD services. In particular, preliminary Medicare 2020 claims suggest a substantial decline in April followed by a strong rebound in volume in May and June. For example, based on preliminary claims data, in January 2020 there were approximately 4,000 Medicare-covered hip replacements in hospitals each week, with another 1,000 hip replacements per week in ASCs. Hip replacements in hospitals fell to about 1,000 per week by the middle of April (a 75 percent decline) but rebounded to over 2,000 per week in May and over 3,000 per week in June. Adding together hospital and ASC hip replacement volume (which appears to have increased slightly), it appears that Medicare hip replacement volume almost completely recovered to approximately 5,000 cases per week by the middle of June (MedPAC analysis of preliminary Medicare claims data). Therefore, concerns that reduced use during the PHE will hinder CMS's ability to calculate appropriate payment rates for services that involve the devices in question seem unwarranted. Indeed, volume recovery appears to have been so complete that CMS should have enough data to calculate accurate payments even if the data collected during the early months of the PHE are determined to yield biased estimates and are excluded from the final calculations. Based on this general recovery of hospital volume, the Commission contends that CMS should maintain Medicare program integrity and not implement this proposed policy change.

Setting payment rates for separately payable non-pass-through drugs obtained through the 340B Drug Pricing Program based on survey data

The 340B Drug Pricing Program allows some hospitals and other health care providers (covered entities) to purchase "covered outpatient drugs" at discounted prices from drug manufacturers. Covered outpatient drugs include prescribed drugs and biologics other than vaccines. The 340B discounts for these covered drugs are substantial. According to the Health Resources and Services Administration (HRSA)—which administers the 340B program—the intent of the 340B program is to allow the covered entities to stretch scarce federal resources as far as possible to provide more care to more patients.

Before CY 2018, CMS set the payment rate for most separately payable non-pass-through drugs—including drugs obtained through the 340B program—on the basis of each drug's average sales price plus six percent (ASP + 6 percent). For CY 2018 through CY 2020, CMS established a policy of paying ASP – 22.5 percent for non-pass-through separately payable drugs that are obtained through the 340B Drug Pricing Program. Separately payable drugs that are not obtained through the 340B program continue to have payment rates set at ASP + 6 percent. CMS's rationale for this policy was to set drug payment rates that better align with the hospital acquisition costs.

The motivation for this policy was concern about the growth in the number of providers participating in the 340B program and the high and growing prices of separately payable drugs under Part B. This policy reduces the revenue that hospitals receive for separately payable drugs under the OPPS. To make this policy budget neutral, CMS increases the payment rates for all OPPS covered services by a uniform percentage.

CMS asserts it is appropriate for the Medicare program to pay for drugs purchased through the 340B program at a rate that approximates what hospitals actually pay to acquire the drugs. CMS's decision to pay for the separately payable drugs obtained through the 340B program at a rate of ASP – 22.5 percent was based on a Commission analysis that estimated a lower bound on the average discount on 340B drugs paid separately under the OPPS of 22.5 percent of ASP.¹ However, CMS sought a more accurate estimate of the cost of acquiring drugs through the 340B program. In response, CMS conducted a survey from April 2019 to May 2020 of 1,422 hospitals that participate in the 340B program. The intent of the survey was to determine the average discount relative to ASP on the drugs these hospitals obtain through the 340B program.

The method of the survey was somewhat complicated, but CMS stated that the method used produced a conservative estimate of the average discount. The final result from this analysis was an estimated average acquisition cost of ASP – 34.7 percent.

CMS believes it is reasonable to assume that a given drug will have similar overhead and handling costs regardless of whether it is obtained through 340B. Also, a drug add-on will ensure a level of payment parity with the add-on that applies to Part B drugs obtained outside the 340B program. Because CMS sets the OPPS payment rates for most separately paid drugs that are obtained outside the 340B program at ASP + 6 percent, CMS proposes to set the payment rates for separately payable non-pass-through drugs obtained through the 340B program at ASP – 28.7 percent (ASP – 34.7 percent plus 6 percent for overhead and handling costs). Rural sole community hospitals, children's hospitals, and the 11 PPS-exempt cancer hospitals would be exempt from this policy and continue to have the drugs they acquire through the 340B program paid at a rate of ASP + 6 percent.

Comment

The Commission recommended in a March 2016 report to the Congress that OPPS payment rates for all separately payable drugs that hospitals obtain through the 340B program should be reduced by 10 percent of ASP.² This policy would allow beneficiaries to share in the savings on 340B drugs through lower coinsurance. We also recommended that the program savings from these reduced payment rates be directed to the Medicare-funded uncompensated care pool, which would target hospitals providing the most care to the uninsured, and in that way benefit indigent patients. Finally, to make sure that dollars in the uncompensated care pool actually go to the hospitals

¹ Medicare Payment Advisory Commission. 2015. *Report to the Congress: Overview of the 340B Drug Pricing Program*. Washington, DC: MedPAC.

² Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

providing the most uncompensated care, the Commission recommended that payments be distributed in proportion to the amount of uncompensated care that hospitals provide.

The benefits of our March 2016 recommendation are threefold:

- Beneficiaries would share in the savings from the 340B program.
- Resources would be better targeted to hospitals that provide the most uncompensated care. Currently, the 340B program is not well targeted to hospitals that provide high levels of uncompensated care. For example, we found that 40 percent of 340B hospitals provide less than the median level of uncompensated care.
- 340B hospitals would still be able to make a profit on the covered drugs.

We emphasize that one of the intents of this recommendation is to better target the resources of the 340B program while still allowing the hospitals to continue to earn a profit on covered drugs. We note that CMS's proposal of ASP – 28.7 percent would reduce the financial benefits of the 340B program. To make this proposed policy budget neutral, CMS would have to make an upward adjustment to the OPSS payment rates for the services covered under the OPSS. Therefore, this policy would result in a shift of resources from the hospitals that participate in the 340B program to the hospitals that do not participate.

As a general principal, we agree that Medicare's payments for goods and services should reflect providers' costs, inducing strong incentives for efficiency where possible. Therefore, we understand CMS's rationale for this proposal. In this instance, however, we believe the Commission's March 2016 recommendation described above would better accommodate the broader intent of the 340B program. Legislation would likely be needed to implement the part of our recommendation that directs the savings to the uncompensated care pool because current law would require that the savings be retained within the OPSS to make it budget neutral. In summary, if CMS is unable to implement our recommendation administratively, we encourage CMS to request that the Congress enact the legislation necessary to allow CMS to implement the Commission's recommendation.

Phase out the inpatient-only list

The inpatient-only (IPO) list is a list of Healthcare Common Procedure Coding System (HCPCS) codes that are typically provided in an inpatient setting and cannot be paid under the OPSS. The IPO list currently comprises 1,740 HCPCS codes. In previous years, CMS has received comments from stakeholders recommending that CMS eliminate the IPO list, while other stakeholders have recommended that CMS should maintain the list. Those who advocate for the elimination of the IPO list argue that regulations should not supersede physicians' knowledge and assessments of their patients' conditions and that physicians can appropriately determine whether a procedure can be performed safely in the hospital outpatient setting. In addition, excluding services from coverage under the OPSS could have an adverse effect on advances in surgical care. Stakeholders who advocate for the continuation of the IPO list consider it an important tool to determine which services are appropriate to furnish in the

outpatient setting and to ensure that Medicare beneficiaries receive care in clinically appropriate settings. In addition, services included on the IPO list are excepted from the two-midnight rule and, therefore, are considered appropriate for inpatient admission and payment under Part A regardless of the expected length of stay.

In this proposed rule, CMS asserts that the IPO list is no longer needed to distinguish the services that require inpatient care from those that can be provided safely in the outpatient setting. Physicians should use their clinical knowledge and judgment, together with the patient's specific needs, to determine the appropriate site of service. CMS also argues that there have been significant developments in the practice of medicine that have allowed numerous services to be safely and effectively provided in the outpatient setting. Finally, CMS argues that the combination of physician judgment, state and local licensure requirements, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and CMS quality and monitoring initiatives and programs will continue to ensure the safety of patients in both the inpatient and outpatient settings, even in the absence of the IPO list. Therefore, CMS proposes to eliminate the IPO list.

CMS also proposes to phase out the IPO list over a three-year period, beginning January 1, 2021, and ending January 1, 2024. For 2021, CMS proposes to eliminate all 266 musculoskeletal HCPCS codes from the IPO list. CMS chose musculoskeletal procedures as the first group to eliminate from the IPO list because many musculoskeletal procedures have been removed from the IPO list in recent years, such as total knee arthroplasty (TKA) and total hip arthroplasty (THA). In addition, stakeholders have requested that CMS remove other musculoskeletal procedures from the IPO list. CMS is requesting comment on whether three years is an appropriate time frame for the phaseout of the IPO list.

Comment

The Commission understands CMS's motivation for this proposal to eliminate the IPO list, but we believe CMS should proceed cautiously. In the absence of the IPO list, the Commission believes that, in general, clinicians will use their knowledge and judgment to provide patient care in the most appropriate setting. However, there is no guarantee that physicians will always select the most appropriate setting. Factors other than clinical knowledge and judgment, such as financial considerations, can affect these decisions. In addition, errors in judgment can occur. Therefore, CMS should proceed more slowly than a three-year phase out of the IPO list. The Commission's preferred approach is for CMS to remove musculoskeletal services from the IPO list, then allow enough time to determine the share of cases transitioning to an outpatient setting and the effect on beneficiary outcomes (perhaps three years) before making any more substantial changes to the list. We urge similar caution in modifying the ASC covered procedure list in comments later in this letter.

Change minimum level of physician supervision required for nonsurgical extended duration therapeutic services from direct supervision to general supervision

Nonsurgical extended duration therapeutic services (NSEDTS) are services that can last a significant period of time, have a somewhat complicated initiation phase followed by a substantial

monitoring component that is typically performed by auxiliary personnel, have a low risk of requiring the physician's immediate availability after the initiation of the service and are not primarily surgical in nature. Initiation means the beginning portion of the NSEDTS, which ends when the patient is stable and the supervising physician determines that the remainder of the service can be delivered safely under general supervision. The required minimum level of supervision of NSEDTS is direct supervision³ during the initiation phase, followed by general supervision⁴ at the discretion of the supervising physician or appropriate nonphysician practitioner.

On March 31, 2020, in response to the coronavirus pandemic, CMS issued an interim final rule with comment period (IFC) that included a change in the minimum supervision requirements for the initiation phase of NSEDTS from direct to general for the duration of the PHE. The purpose of this change is to give providers additional flexibility to handle the burdens created by the PHE.

CMS proposes to make permanent the change in the minimum level of supervision of NSEDTS created under the IFC released on March 31, 2020. CMS believes making this change permanent would be beneficial to patients and hospital outpatient providers because it would allow greater flexibility in providing these services and reduce provider burden, which would improve access to NSEDTS. In addition, hospitals continue to be subject to CoPs that complement the general supervision requirements for hospital outpatient therapeutic services, including NSEDTS, to ensure that Medicare patients receive services that are properly supervised.

Comment

The Commission believes that CMS should use clinical judgement regarding the patient's safety when deciding the most appropriate supervision level for outpatient therapeutic services, including NSEDTS, and that its clinical determination should apply to all hospitals. In general, we support CMS's proposal to make general supervision the minimum required level of supervision for all phases of NSEDTS provided in the hospital outpatient setting, as it would reduce provider burden and would likely reduce the payment rates for these services. However, we believe that CMS should perform due diligence in monitoring the quality of NSEDTS under general supervision, particularly for those services most likely to involve the risk of life-threatening complications.

Allow direct supervision of pulmonary rehabilitation services, cardiac rehabilitation services, and intensive cardiac rehabilitation services using interactive telecommunications technology

Section 1861(eee)(2)(B) of the Social Security Act establishes that for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation programs that are furnished in a physician's office or an HOPD, a physician must be immediately available and accessible for

³ *Direct supervision* means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed.

⁴ *General supervision* means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually perform the procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.

consultation and medical emergencies at all times. This requirement for immediate availability of a physician indicates that direct physician supervision is required for these services.⁵ In the IFC issued March 31, 2020, CMS implemented a policy for the duration of the COVID-19 PHE that allows the direct supervision requirement for these services to be met by the virtual presence of the supervising physician through audio/visual real-time telecommunications technology when use of that technology is indicated to reduce exposure risks to COVID-19 for the beneficiary or health care providers.

CMS asserts that the use of the virtual presence of physicians through the use of audio and visual telecommunications technology could improve access for patients and reduce provider burden after the end of the PHE. Therefore, CMS proposes to change regulations so that beginning January 1, 2021, direct supervision of these rehabilitation services can include the virtual presence of the physician through audio/visual real-time telecommunications technology, subject to the clinical judgment of the supervising physician.

Comment

The Commission understands that use of audio/visual telecommunications technology to provide direct supervision of these rehabilitation services has the potential to improve patient access and reduce provider burden. However, the literature the Commission reviewed in our March 2018 report to the Congress indicates that use of telehealth services offers a mixed picture. Some studies found that telehealth services can improve access to care, reduce costs, and improve quality. Other studies caution that expanded use of telehealth could harm quality or increase spending.⁶ Moreover, it is not clear that the technology will always perform as needed, as malfunctions of the equipment can occur, raising the possibility of increased frequency of adverse events for patients receiving these services. Therefore, the Commission believes that CMS should delay making this change in direct supervision policy permanent. CMS could use information about the performance of the telecommunications technology during the COVID-19 PHE to determine whether use of telecommunications technology during these services consistently performs when needed and does not increase the rate of adverse events. If CMS finds that the direct supervision of these services using the telecommunications technology produces satisfactory clinical results and maintains program integrity without increasing Medicare program spending, the Commission would support making this policy permanent.

Options for modifying the approach to adding surgical procedures to the list of covered surgical procedures under the ASC payment system

CMS maintains the ASC covered procedures list (CPL) as a formal indicator of the surgical procedures that are covered under the ASC payment system. Under regulations at 42 CFR 416.166, surgical

⁵ *Direct supervision* means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed.

⁶ Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

procedures in the ASC CPL are those that meet the general standards specified in 42 CFR 416.166(b) and are not excluded under the eight general exclusion criteria in 42 CFR 416.166(c).

Since CMS implemented the current ASC payment system in 2008, the agency has excluded procedures that would pose a significant safety risk to the typical Medicare beneficiary if performed in the ASC setting. Since then, advances in medical technology have expanded the list of services that can be safely provided in the ASC setting. In response, CMS has steadily added to the services in the ASC CPL. CMS now believes that medical technology and the level of safety in ASCs have advanced to the point that the regulations in 42 CFR 416.166 that guide its decisions about which procedures to include in the ASC CPL can be modified to substantially increase the procedures included in the ASC CPL. In particular, CMS proposes two options for modifying its approach to adding surgical procedures to the ASC CPL: (1) A nomination process and (2) a broader approach under which CMS would revise the regulations in 42 CFR 416.166.

The nomination approach would involve soliciting recommendations from external stakeholders, such as medical specialty societies, for procedures that may be suitable additions to the ASC CPL. CMS proposes that stakeholders would have to submit nominations by March 1 of each year to be considered for inclusion in the ASC CPL the following year. CMS would evaluate the nominated procedures based on the applicable statutory and regulatory requirements. CMS would present the decisions about the nominated procedures in the next final rule.

Under the nomination approach, CMS would consider whether the nominated procedures meet the requirements for covered surgical procedures under 42 CFR 416.166. However, CMS proposes to make two modifications to those regulations. One modification would eliminate the general exclusion requirements in 42 CFR 416.166(c)(1) through (c)(5). These regulations exclude from the ASC CPL procedures that have any of these five characteristics:

- generally result in extensive blood loss,
- require major or prolonged invasion of body cavities,
- directly involve major blood vessels,
- are generally emergent or life-threatening,
- commonly require systemic thrombolytic therapy.

The other modification results from the proposed elimination of the IPO list, which we discussed earlier in this letter. Regulation 42 CFR 416.166(c)(6) prevents procedures that are on the IPO list from being on the ASC CPL. In response to the proposed elimination of the IPO list beginning January 1, 2021, CMS proposes to modify 42 CFR 416.166(c)(6) so that procedures that require inpatient care as of December 31, 2020, would not be allowed to be on the ASC CPL. CMS argues that eliminating the five general exclusions in 42 CFR 416.166(c)(1) through (c)(5) is appropriate because the general standards in 42 CFR 416.166(b) combined with appropriate patient selection

and medical judgment by physicians would provide sufficient guardrails to ensure safe provision of these services in an ambulatory setting.⁷

The other alternative that CMS proposes is similar to the nomination approach, except CMS would only modify the exclusion requirements in 42 CFR 416.166(c)(1) through c(6) and would not have any nomination process. Specifically, CMS would eliminate the requirements in 42 CFR 416.166(c)(1) through (c)(5) and modify 42 CFR 416.166(c)(6) so that procedures that require inpatient care as of December 31, 2020, would not be allowed to be on the ASC CPL. CMS believes it is appropriate to soften the exclusion requirements because the general standards combined with appropriate patient selection and medical judgment are sufficient to ensure that the procedures can be performed safely in an ambulatory setting. This change to the exclusion requirements would substantially increase the number of procedures on the ASC CPL, as CMS estimates that 270 procedures would be added to the ASC CPL in 2021.

Comment

The Commission generally supports giving providers more autonomy in the decisions about the appropriate setting for providing surgical procedures. However, consistent with our comments above in which we urge CMS to proceed cautiously in paring back the IPO list, here we implore CMS to proceed carefully to ensure patient safety. Because of concerns over patient safety, the Commission prefers the nomination alternative, which includes a system of formal public assessment and comment that would not be part of the alternative that only changes the regulations. In addition, the nomination alternative should include a requirement that any individual or group that nominates a procedure or procedures for inclusion in the ASC CPL should not be involved in the process of approving the nominated procedure or procedures to the list.

Require prior authorization for some hospital outpatient services to control unnecessary increases in volume in the hospital outpatient setting

As part of its responsibility to protect the Medicare Trust Funds, CMS analyzes hospital outpatient claims to assess whether the volume of any service is increasing at a rate that the agency believes is unnecessarily high. CMS previously identified four categories of largely cosmetic services that CMS believed had unnecessarily high volume growth. CMS now requires providers to submit prior authorization requests to CMS before furnishing the services in question and submitting claims. In this proposed rule, CMS identifies two additional service categories that CMS believes have had unnecessarily large volume increases: (1) cervical fusion with disc removal and (2) implant of spinal neurostimulators. CMS considers the growth in volume for these services to be unnecessarily high and consequently proposes to require that providers submit prior authorization requests before providing services represented by five HCPCS codes (22551, 22552, 63650, 63685, and 63688).

⁷ The general standards in 42 CFR 416.166(b) indicate that services on the ASC CPL must be services that are separately paid under the OPPI that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

The services proposed for prior authorization are not largely cosmetic procedures like those specified for prior authorization in 2020. It is possible that CMS considers these services as generally having low value to most patients, but CMS does not indicate that issue in this proposed rule.

Comment

The Commission shares CMS's concern about the rapid growth of some services covered under the OPPS. Moreover, the five services cited by CMS have relatively high OPPS payment rates, so the Commission understands why CMS is concerned about rapid growth in these services. In response to advanced imaging services that had high payment rates and high volume growth, the Commission recommended the use of prior authorization to ensure appropriate use of those services.⁸ Rapid volume growth could also indicate the need to adjust payments to better align payments with provider costs. However, the Commission has a number of concerns about CMS's proposal for requiring prior authorization for more complex services such as cervical fusion with disc removal and implant of spinal neurostimulators: a lack of experience in using prior authorization for such services in fee-for-service Medicare, a lack of administrative structure for implementing this proposed policy, and a lack of guidelines through which providers would obtain prior authorization. The Commission is concerned that access to necessary care could be adversely affected if this prior authorization proposal is not implemented effectively. Therefore, CMS should proceed carefully in using prior authorization, taking care to develop policies that align with best practices used by other payers and considering the potential burden on beneficiaries, providers, and the agency's resources.

Conclusion

MedPAC appreciates the opportunity to comment on the important policy proposals from CMS. The Commission also values the ongoing cooperation and collaboration between CMS and MedPAC staff on technical policy issues. We look forward to continuing this productive relationship.

If you have any questions, or require clarification of our comments, please feel free to contact James E. Mathews, MedPAC's Executive Director.

Sincerely,



Michael E. Chernew, Ph.D.
Chair

⁸ Medicare Payment Advisory Commission. 2011. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.