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August 31, 2009

Charlene Frizzera, Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1413-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
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**RE: File code CMS-1413-P**

Dear Ms. Frizzera:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Center for Medicare and Medicaid Services (CMS) proposed rule entitled Medicare Program; Revisions to payment policies under the physician fee schedule and other revisions to Part B for CY 2010, published in the *Federal Register*, vol. 74, no. 132, pages 33520 to 33825. We appreciate your staff's ongoing efforts to administer and improve payment systems for physician and other services, particularly considering the agency's competing demands.

Our comments address provisions in the proposed rule on the physician fee schedule: the Physician Practice Information Survey (PPIS), valuing services under the fee schedule, the utilization rate for medical equipment, payment for consultation services, and updating the prices of high-cost supplies. We comment also on the following issues considered in the rule related to the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA): the Physician Quality Reporting Initiative (PQRI), the physician resource use measurement and reporting program, and accreditation standards for suppliers furnishing the technical component of advanced diagnostic imaging services. Finally, we comment on provisions concerning the competitive acquisition program (CAP) and payment for renal dialysis services.

**Physician Practice Information Survey**

For the 2010 fee schedule, CMS is proposing to use more current practice expense (PE) data for nearly all specialties from a new, privately-sponsored, voluntary survey—the Physician Practice Information Survey (PPIS). The American Medical Association (AMA) fielded the PPIS in 2007 and 2008 in conjunction with the national medical groups representing about 50 Medicare-recognized physician and nonphysician specialties.

Ensuring the accuracy of PE payments is important given that close to half of all payments under the physician fee schedule are associated with practice expense. The Commission has repeatedly raised concerns that the specialty-specific cost data that CMS uses to derive PE RVUs are not current for most specialties, which might lead to payments becoming inaccurate over time. Compared with the multiple data sources that CMS currently relies on for practice cost information, the PPIS is a step forward because: (1) it reflects current practice patterns and costs; (2) it measures costs of nearly all physician and nonphysician specialties; and (3) it uses a standard protocol for all specialty groups that was designed to derive PE RVUs. However, CMS should provide more information about the PPIS's response rate and representativeness. We are also concerned that CMS has not laid out options for ensuring the accuracy of PE RVUs in the long term. As a future step, CMS should consider alternatives for collecting specialty-specific cost data or options to decrease the reliance on such data.

The PPIS is more timely than the practice cost data that CMS currently relies on. For most specialties, CMS currently uses data from the Socioeconomic Monitoring System (SMS) survey (sponsored by the AMA) that reflects specialty-specific costs from 1995 to 1999. For 13 specialties, CMS uses more recent practice cost data from supplemental surveys conducted by those specialties between 2001 and 2006. The Commission has previously raised the concern that using more current practice cost information from some—but not all—specialties could cause significant distortions in the relative PE payments across services.

The PPIS is more comprehensive than the SMS and supplemental surveys: It includes nearly all Medicare-recognized specialties and was designed to be a nationally representative survey of physicians and nonphysicians. Only two specialties—clinical labs and independent diagnostic testing facilities—chose not to participate in the PPIS. (CMS is proposing to use practice cost data from their supplemental survey submissions.) By contrast, the SMS survey only distinguished among 26 major physician specialties and did not include nonphysician groups. Another advantage of the PPIS is that, unlike the SMS survey, it was designed to update the specialty-specific practice cost information that CMS uses to calculate indirect PE values. The AMA did not design the SMS survey with the goal of developing PE RVUs. In addition, the PPIS uses a consistent survey instrument for all participating specialties.

While the PPIS is a more current and comprehensive source of PE data than the SMS survey, the Commission believes that CMS should make more information available about the PPIS. In the proposed rule, CMS explained that (1) all of the survey responses were adjusted for nonresponse except for six nonphysician specialties because these groups lacked population data;<sup>1</sup> and (2) weighting for nonresponse had only a small impact on PE hourly values. We urge CMS to make information publicly available that would permit comparisons of the practice size, site of care, and other characteristics of the survey responders to the entire specialty and to nonresponders. CMS should also make each specialty's response rate publicly available. This would allow a fuller consideration of options for collecting PE data in the future.

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<sup>1</sup> The six specialties are chiropractors, clinical social workers, nuclear medicine, osteopathic manipulative therapy, physical therapy, and registered dietitians.

Looking further to the future, the Commission is concerned that CMS has not discussed a strategy to keep the specialty-specific practice cost data up to date and accurate for all specialties. The Commission has stated that, under the current method for calculating PE RVUs, Medicare needs a recurring source of practice cost data for all specialties to ensure the accuracy of PE payments. Practice costs could increase or decrease over time with changes in technology, personnel, and site of care. CMS should consider if Medicare or provider groups should sponsor future data collection efforts, if participation should be voluntary (such as surveys) or mandatory (such as cost reports), and whether a nationally representative sample of practitioners would be sufficient for either a survey or cost reports. As discussed in the proposed rule, surveys raise questions about both response rates and the precision of estimates.

In the long term, CMS could also consider alternative ways to set PE values that would decrease its reliance on specialty-specific cost data. One such option is to eliminate the use of specialty-specific cost pools from the method used to derive indirect PE RVUs. The Commission previously reported that such a change would reduce the complexity of the method.<sup>2</sup> In addition, the impact of such a change would be similar to the impact of using the PPIS. Eliminating specialty-specific cost pools would increase PE RVUs for evaluation and management (E&M) services and reduce PE RVUs for imaging, major procedures, other procedures, and tests. By comparison, we estimate that the changes in this proposed rule would increase PE RVUs for E&M services and other procedures and reduce PE RVUs for imaging, major procedures, and tests.<sup>3</sup>

### **Accuracy of prices under the physician fee schedule**

In the proposed rule, CMS raises questions about the need for a panel of experts—in addition to the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC)—that would advise the agency during reviews to determine whether the fee schedule's RVUs are accurate. The Commission recommended such a panel in March 2006 as an entity that could give the reviews more balance.

We comment also on three other issues that are examples of more specific concerns about the fee schedule's accuracy. First, CMS proposes to change an assumption that is important for calculating PE RVUs: expensive medical equipment is utilized only 25 hours per week. Second, CMS proposes to eliminate use of the fee schedule's billing codes for consultations. Documentation requirements for consultations have decreased, making valuation of the services an issue. Third, CMS discusses the issue of updating its data on the prices physicians pay for high-cost supplies.

#### *Valuing services under the physician fee schedule*

In discussing the need for an expert panel in addition to the RUC, CMS lists steps the agency has taken since the Commission recommended the panel in 2006:

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<sup>2</sup> For more discussion of alternative methods to calculate indirect PE RVUs, see MedPAC's June 2007 Report to the Congress (Medicare Payment Advisory Commission. 2007. *Report to the Congress: Promoting greater efficiency in Medicare*. Washington, DC: MedPAC.).

<sup>3</sup> Our estimates of the proposed rule's PE RVU changes include the use of PPIS data and increasing the equipment utilization rate.

- A five-year review of work RVUs was completed, with increases in the RVUs for primary care services.
- The methodology for determining PE RVUs was revised, also with increases in the RVUs for primary care services.
- Processes for identifying potentially misvalued services have improved and now include an ongoing review of rapidly growing services, services with substantial shifts in site of service, and other indicators. In addition, CMS has identified approaches for review of services often billed together and may expand the policy of a multiple procedure payment reduction.
- This proposed rule includes a number of policy changes aimed at improving the accuracy of RVUs, with a number of the changes leading to increases for primary care.

CMS believes these steps represent significant action and respond to Commission goals of improved RVU accuracy and increased payments for primary care services.

The Commission's position is that there are still reasons for CMS to establish the expert panel. First, rapid volume growth for specific services may signal that Medicare's payment for those services is too high. In consultation with the panel, CMS could determine whether there is evidence that RVUs should be adjusted downward, either through established review processes that include the RUC or—if those processes are not timely enough—an automatic adjustment of RVUs with RUC review to follow. Second, CMS needs a regular source of expertise available to assist with the highly complex process of valuing physician services, expertise that is not solely in the domain of the RUC. In addition to the RUC, the Commission recommends a panel comprised of representatives of CMS's network of contractor medical directors, experts in medical economics and technology diffusion, private plan representatives, and a mix of physicians, particularly ones that are not directly affected by changes to the fee schedule. Third, CMS must be an active and informed participant in the review process, especially in the current environment. The next five-year review starts this fall. With this review, the potential exists for specialty societies to come forward once again with proposals for increases in the RVUs for hundreds of billing codes. Depending on disposition of these requests, CMS may need to apply a budget neutrality adjustment that would reduce payment rates for all fee schedule services.

We understand that misvaluation of services in the physician fee schedule is a difficult problem and that CMS is operating under significant resource constraints. As the Commission recommended, the Congress must ensure that CMS has the administrative flexibility and resources necessary to collect and analyze data and to conduct other activities necessary for effective use of the expert panel.

In the proposed rule, CMS also asks questions about how the agency would use an expert panel separate from the RUC:

- How could input from a panel of experts best be incorporated into existing processes of rulemaking and agency receipt of RUC recommendations?
- What specifically would be the roles of a panel of experts (for example, identify potentially misvalued services, provide recommendations on valuation of specified services, review RUC recommendations selected by the Secretary, etc.)?

- What should be the composition of a panel of experts? How could such a panel provide expertise on services that clinician group members do not furnish?
- How would such a panel relate to the RUC and existing Secretarial advisory panels such as the Practicing Physician Advisory Committee?

The Commission addressed these questions in detail on pages 142-145 of our March 2006 report. For example, on the question of incorporating input from the expert panel into existing processes, the panel should be involved at the outset of the five-year review to identify services that may be misvalued and that warrant consideration by the RUC. Later in the review process, CMS would use the panel to help evaluate RUC recommendations. We would be happy to discuss these questions with your staff and to provide additional clarifications if that would be helpful.

#### *Equipment utilization rate*

To calculate the per service cost of medical equipment, CMS multiplies the number of minutes the equipment is used for that service by its cost per minute. To derive a machine's cost per minute, CMS uses a formula to spread the machine's purchase price over the number of minutes it is projected to be used during its useful life, taking into account the cost of capital, maintenance costs, and other factors. To estimate the amount of time equipment is expected to be used, CMS multiplies the number of hours that providers are open for business by the percent of time the equipment is operated. CMS assumes that providers are open 50 hours per week, on average, and that all medical equipment is operated 50 percent of the time that practices are open, or 25 hours per week. However, if machines are used more frequently, their fixed costs are spread across more units of service, resulting in a lower cost per service. In this instance, such equipment would be overvalued by CMS.

CMS proposes to increase the equipment use rate for all equipment priced over \$1 million from 50 percent to 90 percent (equivalent to 45 hours per week). This change would affect expensive diagnostic imaging and radiation therapy machines. In support of this proposal, CMS cites evidence discussed in our March 2009 report that computed tomography (CT) and MRI machines are used much more than 25 hours per week.<sup>4</sup> According to a survey of imaging providers in 6 markets conducted by NORC in 2006 for the Commission, MRI scanners are used 52 hours per week, on average, and CT machines are used 42 hours per week, on average. According to data from a 2007 survey of CT providers by IMV, a market research firm, CT scanners are used 50 hours per week, on average. CMS states that this evidence suggests that providers only make large capital investments in equipment if that equipment is going to be used more than half the time.

The Commission supports CMS's proposal as it applies to diagnostic imaging machines that cost more than \$1 million, and we encourage CMS to explore increasing the equipment use factor for diagnostic imaging machines that cost less than \$1 million. MedPAC did not contemplate applying this policy to radiation therapy machines.

The Commission is concerned that the rapid volume growth of costly diagnostic imaging services in recent years may signal that they are mispriced. Setting the equipment use rate at 50 percent—rather than at a higher level—has led to higher practice expense RVUs for these services, thereby

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<sup>4</sup> Medicare Payment Advisory Commission. 2009. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

encouraging providers with low expected volume to purchase expensive imaging machines. Once providers purchase machines, they have an incentive to use them as frequently as possible. Thus, the Commission recommended in our March 2009 report that Medicare adopt a normative standard in which providers are assumed to use expensive diagnostic imaging machines at close to full capacity (45 hours per week, or 90 percent of the time that providers are assumed to be open). Such a standard would discourage providers from purchasing costly imaging equipment unless they had sufficient volume to justify the purchase.

We agree with CMS that decreasing practice expense RVUs for expensive diagnostic imaging services should not affect access to care in rural areas. As described in our March 2009 report, data from the American Hospital Association's 2006 annual survey of hospitals indicate that 95 percent of rural hospitals provide CT services in their community (either directly or through an affiliated provider) and 79 percent of rural hospitals provide MRI services in their community. Therefore, if rural areas do not have physician offices or freestanding centers with MRI and CT machines, most of these communities have access to such services through a hospital.

#### *Consultation services*

E&M services consist of different types of services, including office visits, visits to hospital and nursing facility inpatients, and emergency department visits. E&M services also include consultations. A consultation is a service furnished—usually by a specialist—at the request of another physician or appropriate source to evaluate and possibly treat a patient's problems. It can involve an opinion, advice, recommendation, suggestion, direction, or counsel.

For 2010, CMS proposes to eliminate use of the physician fee schedule's billing codes for consultations.<sup>5</sup> Instead of billing for services with these codes, physicians would use office visit codes and codes for hospital and nursing facility visits. The proposal is budget-neutral within E&M services and would increase the RVUs for office visits and hospital and nursing facility visits. On average, the work RVUs for office visits would go up by about 6 percent. Work RVUs for visits to hospital and nursing facility patients would go up by about 2 percent.

CMS makes a case that consultations are misvalued. To document a consultation, a physician must give the requesting professional a written report. At least partly because of this requirement, fees for consultations were initially set in 1992 at a level higher than the fees for most other E&M services, and such differentials have continued to the present. For example, in 2009, the average fee for mid-level office consultation in a non-facility setting is \$125. By comparison, the average fee for a mid-level office visit by a new patient in a non-facility setting is \$92. The average fee for a mid-level office visit by an established patient in a non-facility setting is \$61.

Misvaluation of consultations has become an issue because—as explained in the proposed rule—the documentation requirements for the services have diminished and are now similar across all E&M services. While the physician furnishing a consultation must still give the requesting professional a written report, CMS has eased this reporting requirement by reducing the required level of formality and permitting the report to be made in any written form, including submission of a copy of documentation taken directly from the medical record and without a letter from the consulting physician.

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<sup>5</sup> CMS would exempt telehealth consultations from the change in policy.

The Commission's view is that the valuation of a service under the physician fee schedule should reflect the resources used to provide it. CMS indicates that the relaxation of consultation documentation requirements over time has brought the effort involved in consultations to levels comparable to those of visits. If so, CMS's proposed change seems an appropriate policy response. However, we note that reduced consultation documentation may not sufficiently meet the needs of the requesting physician, and thus not help achieve the goals and benefits of well-coordinated care. While CMS' proposed payment policy for consultations may be appropriate in light of current practice, in the future, the agency may wish to consider whether to increase the requirements for consultations in order to better coordinate care among physicians treating a patient, and increase consultation payments commensurately.

#### *High cost supplies*

In the proposed rule for the 2009 physician fee schedule, CMS proposed a process to update the prices of high cost supply items every 2 years. In the final rule, however, CMS did not adopt a method for updating the prices of these items. Instead, the agency stated that it would continue to examine ways to obtain accurate pricing information and that it would revisit this issue in the future. The proposed rule for the 2010 physician fee schedule does not propose a method for updating supply prices.

The Commission believes that it is important for CMS to update the prices of higher-priced supplies (e.g., renal cryoablation probes) on a regular basis, such as every two years. Inaccurate prices of high-cost medical supplies could result in distortions in practice expense RVUs for different services over time. Likewise, inaccurate prices of higher-cost medical equipment (e.g., MRI machines) could also distort RVUs. Prices for both new supplies and equipment are likely to drop over time as they diffuse into the market and as other companies begin to produce them. Consequently, the Commission encourages CMS to regularly update the price information of high-cost supplies *and* medical equipment, as we suggested in our June 2006 Report to the Congress.<sup>6</sup>

As we noted in our comment letter on last year's proposed rule, obtaining price information from specialty societies might not result in objective and accurate prices of medical supplies and equipment because specialty groups have a financial stake in the process. Ideally, prices of supplies and equipment should be based on an independent source that captures average transaction prices net of discounts and rebates that manufacturers give to providers, rather than manufacturers' suggested list prices.

### **Issues related to the Medicare Improvements for Patients and Providers Act of 2008**

#### *Physician payment, efficiency, and quality improvements—PQRI*

The Physician Quality Reporting Initiative (PQRI) is a voluntary quality data reporting program that provides an incentive payment to eligible professionals (defined as physicians and the other types of providers allowed to bill for services under the physician fee schedule) who satisfactorily report data on quality measures for covered professional services during a specified reporting

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<sup>6</sup> Medicare Payment Advisory Commission. *Report to the Congress: Increasing the value of Medicare*. Washington, DC: MedPAC.

period. In 2009 and 2010, the incentive payment for an eligible professional who meets the program's reporting requirements will equal 2 percent of the estimated total allowed charges for all covered professional services furnished during the calendar year. The PQRI included 153 quality measures in 2009 and CMS proposes to include 168 measures on which individual eligible professionals can report for the 2010 PQRI.

In 2009, there are two methods by which eligible professionals can report data on the PQRI measures and measure sets: report the appropriate quality data codes on their Medicare Part B claims (claims-based reporting), or submit data on PQRI quality measures to a qualified clinical registry and request that the registry submit PQRI quality measure data to CMS on their behalf (registry-based reporting). For 2010, CMS proposes to add an EHR-based reporting mechanism for the PQRI. CMS also notes that it is considering significantly limiting the claims-based mechanism of reporting clinical quality measures for the PQRI after 2010, contingent upon there being an adequate number and variety of registries available and EHR reporting options. CMS invites comments on its intent to decrease reliance on the PQRI claims-based reporting mechanism beyond 2010.

In our March 2005 Report to the Congress, we recommended that the Congress grant CMS the authority to base payments on pay-for-performance (also referred to as value-based purchasing or VBP). The Commission recommends that a portion of Medicare payments should depend on providers' performance on the selected quality measures, not simply on whether they report the specified data to CMS. We commend CMS for moving forward with the development of a plan to implement physician VBP, and we submitted a detailed comment letter on the agency's Physician VBP Program Issues Paper in December 2008.

Pending authorization from the Congress to allow CMS to transition from the PQRI "pay-for-reporting" program to VBP for physician services, we emphasize two overarching points on the PQRI:

- CMS should strategically select PQRI measures to address significant existing gaps in quality, focusing on services with the potential to deliver high value to Medicare patients and avoiding services—particularly high-cost or high-volume services—that may yield little or no value to beneficiaries. Ideally, the program should only use measures where, on the basis of clinical evidence, the benefit of the service being measured is high relative to the resources used to furnish it. CMS has already included measures like this in the 2009 PQRI, such as reporting the percentage of a physician's patients with chronic kidney disease who meet specified clinical criteria to be referred for placement of an arteriovenous (AV) fistula (PQRI measure #153). The list of all the measures used in the program should evolve as we develop a better clinical evidence base and greater understanding of the benefit-cost trade-offs of particular services and treatments.
- The measures selected for PQRI should not reward physicians for providing marginally effective care or care that is already routinely furnished. Measures based on this type of care would work at cross-purposes to the goal of increasing the efficiency, as well as the quality, of physician services delivered to beneficiaries.

Increasing the use of registry-based and EHR-based physician quality reporting mechanisms

The Commission has found that claims-based process measures provide important information about quality and are the least burdensome approach to collecting specific quality information for a broad and growing array of clinical conditions and types of physicians. In addition, we have discussed the value of patient registries and other tools that can aggregate and report data from a provider's patient population. The Commission has recommended that providers should be able to generate lists of patients with specific clinical conditions, such as diabetes or congestive heart failure, to proactively manage the care for patients with these chronic conditions. Registries also can be used to analyze a provider's adherence to evidence-based process measures and to track patients' health outcomes over time. Providers can use registries to track patients who are prescribed a particular drug, information that could be used for post-market surveillance of clinical outcomes associated with the use of that product. The latter function will be increasingly important if and when a pathway is created for the approval and use of follow-on biologics.

The Commission strongly supports the use of EHRs and other health information technology (such as computerized provider order entry and clinical decision support) as tools to improve the quality and reduce the cost of care for Medicare beneficiaries. We have specifically recommended that CMS should include measures of functions supported by the use of information technology (as opposed to simply having the technology) in Medicare initiatives to financially reward providers on the basis of quality. Examples of such uses include a physician who uses an EHR to track patients with chronic conditions to send reminders about using preventive services, or who checks for drug allergies or drug-to-drug interactions when prescribing a medication. EHR-based quality measurement should focus on how the technology is used to improve quality of care for patients, not simply that it is being used.

EHRs may also reduce the administrative burden of collecting, and reporting types of clinical data that are not readily available from claims data, such as diagnostic laboratory test results and prescription drug dispensing data, although these two types of data are available and could be reported now, prior to widespread EHR use. In our March 2005 Report to the Congress, we specifically recommended that Medicare should start using quality measures that rely on clinical laboratory test results and prescription drug dispensing data. To the extent EHRs enable providers to easily access these types of data for quality measurement, we support CMS's proposal to allow providers to use EHRs to report quality measurement data. As noted above, however, the Commission recommends that Medicare should move away from pay-for-reporting to pay-for-performance for physician services as soon as possible.

*Physician resource use measurement and reporting program*

As CMS continues to develop its Physician Resource Use Measurement and Reporting Program and Resource Use Reports, it solicits comments on several aspects of the program, including the way the agency provides resource use reports to physicians. We comment specifically on the use of proprietary episode grouper software, the use of paper versus electronic reports, the design of these reports, reporting to individual physicians versus group practices or other aggregations of physicians, and integrating quality measures with resource use measures.

### Proprietary products

The software CMS selects for its Physician Resource Use Measurement and Reporting Program should use a Medicare-specific, transparent, publicly available episode grouper. Currently, CMS's program relies on commercially available episode grouper software packages, which allows the agency to evaluate the software packages' features that can be included in a Medicare-specific, open source software package. The episode grouper CMS selects could be developed by one of the existing episode grouper software companies, tailored to suit Medicare's needs. Existing episode grouper software has been used by private payers. Since Medicare was not a customer until recently, the software was not developed with the program's unique characteristics in mind. Therefore, existing software will likely need to be modified to suit the Medicare program. When Medicare adopts a final episode grouper, it should make publicly available the Medicare-specific, open source software package, an explanation of its measurement methodology, and a description of the data sources used.

### Paper versus electronic feedback

Merely mailing physicians a paper feedback report is not enough. At a minimum, physicians need to be able to contact someone for answers to their questions. Recognizing this, MIPPA requires that Medicare conduct education and outreach activities as part of the physician feedback program. While paper feedback reports with additional education and outreach activities may be sufficient, web-based or other electronic feedback is ideally suited to the program; it would allow physicians to instantly explore the drill downs (e.g., type of service, provider, and condition) of greatest interest in more detail. Regardless of whether CMS opts for paper or electronic feedback, given CMS's limited resources and numerous responsibilities, these new efforts will be challenging. CMS could partner with other entities, including physician organizations and specialty societies, to support physicians in interpreting feedback reports and using them to improve practice patterns. Another possible approach is to include such activities as a specific task in the next scope of work for the Quality Improvement Organizations.

### Design of Resource Use Report

CMS's physician Resource Use Report provides richly detailed drill-down information that makes feedback more actionable for physicians. Feedback should continue to include detailed breakouts—such as by type of service, provider, and condition—in addition to overall scores in such a way that it is clear to physicians which aspects of their practice patterns they should act on. For example, some physicians treat diabetic patients in a more resource-intensive manner or use more intensive imaging services than their peers. Providing detailed information in addition to aggregate measures makes physician feedback more actionable by identifying differences in practice patterns that influence physicians' overall feedback results.

Specifically in the report, the information on per episode utilization of hospital services for specific conditions provides useful drill down details for emergency room visits, hospital admissions, and average length of stay for hospital admissions. In addition, the feedback should also include details on hospital readmissions and post acute care.

In addition, the information on costs of service per capita—and per episode for specific conditions—provides a wide range of drill-down details for E&M, hospital, procedures, ambulatory care, and post acute care services provided by the physician receiving the feedback as

well as other physicians in the episode. This level of detail should continue to be part of the feedback program.

We want to be clear that the feedback will not answer all questions about how to improve practice patterns for greater efficiency. The success or failure of the feedback program will depend on Medicare's ability to forge a collaborative partnership with physicians and on the physician community's willingness to embrace thoughtful examination of their practice patterns. Physicians will have to come together in professional societies and other organizations to learn from feedback and discuss how best to improve efficiency and then act on these decisions.

#### Report to individuals and groups

The physician feedback program should use individual physicians as the basic building block of resource use measurement methodology but be capable of aggregating these measures in multiple ways—such as by physician group practice or by accountable care entities—for confidential feedback. This capacity will allow the program maximum flexibility in applying the measurement results in multiple ways to tailor feedback reports to best suit physicians' preferences. It also will allow the program to measure the nearly 40 percent of physicians who continue to work as solo practitioners.

The program's methodology should be designed to anticipate the potential to publicly report physician efficiency and quality measures by building in the flexibility to be able to provide feedback to individual physicians or groups to parallel the way that beneficiaries select their physicians. For example, a beneficiary who receives his primary care at a small family medicine practice where his appointments might be with any of the physicians in the practice would most likely want to consider the performance of the group as a whole. On the other hand, the same beneficiary could seek cardiology care at a large multispecialty group practice with numerous satellite offices. If the beneficiary planned to visit only one of those offices and use only cardiology care, more aggregated performance measures would not be as helpful for him.

#### Integrate quality measures

CMS should not wait until the quality and efficiency measurement methodology is perfected to implement the program. Since the program relies on confidential feedback to educate physicians, it should begin as soon as possible with as many measures as are ready. Measures can be refined and new ones added over time. It may be reasonable to begin by incorporating the measures used by PQRI and the Generating Medicare Physician Quality Performance Measurement Results (referred to as GEM) Project. However, MedPAC defines efficiency using both resource use and quality. While we understand the need to begin the program by dealing with these aspects separately, we urge CMS to move quickly to measuring, reporting, and rewarding efficiency as a whole. In addition, we encourage CMS to advance physician quality efforts from reporting to measurement of structure, process, and outcome indicators as quickly as possible. Therefore, we urge CMS—as the agency develops a Medicare-specific, transparent software package to measure physician resource use—to integrate measurement of physicians' efficiency in terms of both resource use and quality. Both types of measures should be vetted and periodically re-evaluated. While many physician quality measures are available and are already being used in private purchasers' pay-for-performance programs, they are not yet available for every type of patient or physician. To encourage specialty societies and other measure developers to speed development of these types of

measures, Medicare should establish a date certain when all physicians will be measured on their performance on processes of care relevant to their patients.

*Implementation of accreditation standards for suppliers furnishing the technical component (TC) of advanced diagnostic imaging services*

Section 135(a) of MIPPA requires that, starting in 2012, providers who bill Medicare under the physician fee schedule for the TC of advanced diagnostic imaging services must be accredited by an accreditation organization designated by the Secretary. However, MIPPA did not mandate standards for physicians who interpret imaging studies and bill for the professional component. In addition, MIPPA specifically excluded X-ray, ultrasound, and fluoroscopy services from the accreditation requirement. In this proposed rule, CMS lays out the criteria for the Secretary to designate accreditation organizations.

In our March 2005 Report to the Congress, the Commission recommended that the Congress direct the Secretary to set quality standards for providers who bill Medicare for performing and interpreting all types of diagnostic imaging studies.<sup>7</sup> We also recommended that, to reduce the burden on CMS, the Secretary should select private sector organizations to administer the standards.

Therefore, we support CMS's proposal to implement mandatory accreditation of providers of advanced diagnostic imaging, but encourage CMS to strengthen this quality program in the following ways:

- Consistent with MIPPA, CMS should require that accreditation groups have standards for providers' imaging equipment.
- Data received from accreditation organizations on their accreditation activities and their list of accredited providers should be made public.
- The accreditation program should be expanded to include all types of diagnostic imaging services (although standards for advanced imaging should be implemented first).

Further, Medicare should also establish quality standards for physicians who bill for the professional component of imaging studies, although this would probably require statutory authority.

In proposed Section 414.68, an accreditation organization applying for approval by the Secretary would have to describe how it evaluates imaging providers in the following four areas: the qualifications of non-physician personnel; the qualifications of medical directors and supervising physicians; procedures to ensure the reliability, clarity, and accuracy of diagnostic images; and procedures to ensure the safety of patients and staff. Although MIPPA mandates that accreditation organizations also evaluate providers' imaging equipment, CMS does not include this standard in the proposed regulatory language. It appears that "procedures to ensure the reliability, clarity, and accuracy" of images refers to a quality assurance program, which is distinct from equipment specifications. As described in the Commission's March 2005 report, we believe that imaging equipment should meet quality standards. Existing accreditation programs establish standards for

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<sup>7</sup> Medicare Payment Advisory Commission. 2005. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

imaging machines that are separate from the requirements for a quality assurance program. For example, the Intersocietal Commission for the Accreditation of CT Laboratories specifies hardware and software standards for different types of CT studies.

According to proposed Section 414.68, accreditation organizations would have to provide CMS with summary data on the prior year's accreditations and trends, as well as a list of all currently accredited suppliers. We encourage CMS to post this information on its public website so that congressional support agencies and the general public can evaluate the accreditation program and identify accredited providers.

Although MIPPA excluded certain types of imaging from the accreditation requirement, CMS should expand the program to include all types of diagnostic imaging services. The Commission has recommended that Medicare develop standards for all types of diagnostic imaging, not only advanced imaging. About half of physician fee schedule spending for imaging in 2007 was for modalities not covered by the proposed accreditation program, such as echocardiography, other ultrasound, and standard imaging (e.g., X-rays). Moreover, studies have found evidence of quality problems among some providers of vascular ultrasound and standard imaging.<sup>8</sup> Because advanced imaging is growing more rapidly than other types of imaging, standards for advanced imaging should be implemented first. We believe that the Congress should provide CMS with adequate resources to expand the imaging accreditation program.

The Commission has also recommended that CMS implement quality standards for physicians who interpret imaging studies and bill for the professional component. When studies are read by physicians who lack the proper training and experience, the interpretations may be inaccurate and may lead to repeat tests and inappropriate treatment. There is a precedent for setting standards in this area: Under the Mammography Quality Standards Act, the Secretary established qualifications for physicians who interpret mammograms. We encourage CMS to seek the statutory authority to set standards for physicians who interpret other types of imaging studies.

### **Issues related to Part B Drug Payment**

Medicare pays for drugs under Part B using a method known as the average sales price (ASP). The ASP payment method ties the Medicare payment rate for Part B drugs to average transaction prices for all purchasers, with some exceptions. Typically, physicians who purchase Part B drugs are paid ASP+6 percent when they administer these drugs to Medicare beneficiaries. This payment method has resulted in substantial savings for the Medicare program and its beneficiaries.

The Congress also mandated the establishment of a competitive acquisition program (CAP) as an alternative way for providers to acquire physician-administered drugs. Under CAP, designated vendors purchase and dispense drugs to physicians who elect to participate in the program. Medicare pays the vendors directly and the vendors bill patients for required copayments. The goal

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<sup>8</sup> Brown, O., P. Bendick, P. Bove, et al. 2004. Reliability of extracranial carotid artery duplex ultrasound scanning: Value of vascular laboratory accreditation. *Journal of Vascular Surgery* 39, no. 2 (February): 366–371; Moskowitz, H., J. Sunshine, D. Grossman, et al. 2000. The effect of imaging guidelines on the number and quality of outpatient radiographic examinations. *American Journal of Roentgenology* 175, no. 1 (July): 9–15.

of the program was to increase competition for Part B drugs. The program was also designed to eliminate financial incentives for physicians to prefer one drug over another since they would no longer be purchasing drugs directly. Additionally, small practices unable to purchase drugs at the Medicare payment rate would have an alternative way of acquiring drugs. In this sense, CAP functions as a safety net for providers.

The CAP program operated with a single designated vendor from July 1, 2006 through December 31, 2008. The program achieved limited success. Only one vendor chose to participate and physician enrollment was low. In 2009, CMS suspended the program and sought public comment on ways to increase the flexibility and efficiency of the program.

In this proposed rule, CMS makes significant changes to the way CAP would operate.

- The Agency would update drug prices quarterly based on vendors reported reasonable acquisition costs. In no case would the CAP payment amount exceed ASP+6 percent. Quarterly price updates will eliminate automatic increases that currently take place. These updates have resulted in cases where Medicare pays well above the average sales price for some products.
- The Agency would ease restrictions on physicians transporting CAP drugs subject to voluntary agreements between vendors and physicians. This proposal accords with a previous Commission recommendation. In 2006, we recommended that the Secretary allow an exception to the CAP delivery rules for rural satellite offices which often have limited hours and few storage facilities. The goal was to permit physicians with multiple offices to receive drug shipments at their main office and transport them as needed to other sites.
- The Agency would allow CAP vendors to maintain ownership of a quantity of drugs stored at physicians' offices. When a physician administers a drug from this stock, they would notify the vendor electronically and the vendor would bill Medicare and the beneficiary. Under current rules, physicians have to order drugs for each patient as needed and store them separately from the rest of their drug inventory. In our discussions with physicians, many cited these rules as burdensome and a barrier to CAP enrollment. Allowing vendors to track drugs electronically and bill Medicare as they are used should make the program more efficient.
- The Agency would limit CAP-provided drugs to high cost, high volume products. This should further ease the administrative burden of tracking and billing for all drugs.

We commend CMS for their work on this difficult issue. In the past, the Commission has discussed how to make the CAP program more workable for physicians. The goal has been to lessen the administrative burden on physicians and vendors. To that end, we are encouraged by the modifications CMS has proposed.

### **Provisions related to payment for renal dialysis services furnished by ESRD facilities**

CMS proposes to not update the add-on payment to the composite rate, which would maintain the 2009 add-on payment of \$20.33 in 2010. CMS based this proposal on a projected 3.5 percent decrease in per patient growth in drug expenditures between 2009 and 2010. The agency did not propose to reduce the add-on payment because the statutory language instructs the Secretary to

annually *increase* the add-on payment based on the growth in expenditures for separately billable ESRD drugs.

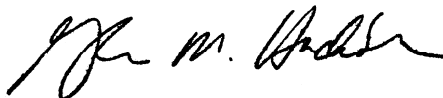
While we have recommended eliminating the add-on payment (and thus the need to update it), the Commission recognizes that CMS is required to do so until calendar year 2011, when MIPPA mandates a broader dialysis payment bundle. As we recommended in our June 2005 Report to the Congress, the Commission believes that the composite rate and the add-on payment should be combined. The add-on payment is complex and may not be the most appropriate way to pay for dialysis services. MedPAC and other researchers have noted that the pre-MMA drug payment policy promoted a less-than-efficient use of drugs by certain providers. The add-on adjustment continues to base payment on this policy. In addition, an increase in the add-on payment for dialysis drugs risks overpayment for use of the drugs.

***Conclusion***

MedPAC appreciates the opportunity to comment on the important policy proposals crafted by the Secretary and 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 Mark Miller, MedPAC's Executive Director.

Sincerely,

A handwritten signature in black ink, appearing to read "Glenn M. Hackbarth". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Glenn M. Hackbarth, J.D.  
Chairman

GMH/kh/aj