MEDPAC Medicare Payment Advisory Commission

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Herb B. Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1385–P
Box 8018
Baltimore, Maryland 21244-8018

RE: File code CMS-1385-P

Dear Mr. Kuhn:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit these comments on CMS's proposed rule entitled: *Medicare program; Revisions to payment policies under the physician fee schedule, and other Part B payment policies for CY 2008* [CMS-1385-P] Federal Register, July 12, 2007. 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.

Resource-based PE RVUs

In estimating the per service price of medical equipment, CMS assumes that all equipment is operated 50 percent of the time that practices are open for business and that practices pay an interest rate of 11 percent when borrowing money to buy equipment. If these assumptions are inaccurate, then the RVUs of services that use costly equipment will also be inaccurate. In this proposed rule, CMS acknowledges that the 50 percent use rate applied to all equipment does not reflect the actual usage of all equipment, but states that there is not sufficient evidence to justify an alternative assumption. We believe there are two options for changing this assumption:

- collect data on equipment use through a survey of providers, or
- set a standard based on how frequently efficient providers are expected to use expensive equipment.

The American Medical Association's (AMA's) Physician Practice Information Survey, which is currently in the field, is collecting information on how many hours per week certain high-cost equipment, such as magnetic resonance imaging (MRI) and computed tomography (CT) machines, are used. This survey may produce estimates that CMS could use to update its assumption of how frequently expensive equipment is operated.

If there are not enough valid responses to the AMA's questions on equipment use, however, CMS could choose to field its own targeted survey to collect this information. In 2006, MedPAC conducted a survey of a representative sample of imaging providers in six markets that demonstrated that a short, targeted questionnaire can be used to collect information on how often providers use medical equipment and achieve a high response rate. Our survey results indicate that providers in those markets use MRI machines more than 90 percent of the time and CT machines more than 70 percent of the time (MedPAC, *Report to the Congress: Increasing the Value of Medicare*, 2006). This survey, which had a 72 percent response rate, raised questions about whether CMS underestimates how frequently providers use MRI and CT equipment. CMS could design and field a similar survey based on a nationally-representative sample of providers who use MRI machines, CT machines, and other expensive equipment. (Inexpensive equipment is a lower priority because it represents a small fraction of a service's practice expense.)

An alternative option is for CMS to base the assumption for expensive equipment on an expectation of how frequently efficient providers operate such equipment. CMS could retain the 50 percent assumption for less costly equipment. If providers buy expensive equipment and use it only half the time or less, this inflates the per service price of the equipment, which means that Medicare pays more for services performed with the equipment. Medicare should set its rates at a level that encourages providers to be efficient. For example, one could argue that a provider that purchases a $1 million machine should be expected to use it during all the hours it is open for business, with some allowance for down time due to maintenance and patient cancellations. Indeed, the MedPAC survey found that several MRI providers operate their machines more than 90 percent of the time. Because changes to practice expense RVUs are budget neutral, any savings from adopting a higher equipment use assumption would be redistributed to other physician services.

CMS's current assumption that providers pay an interest rate of 11 percent when purchasing equipment is based on 1997 data from the Small Business Administration (SBA) on prevailing loan rates for small businesses for equipment that costs over $25,000 with a useful life of over 7 years. Based on 2007 data from the SBA, CMS reports in the proposed rule that the interest rate for equipment at the same price and useful life ranges from 10.1 to 13 percent. CMS proposes to retain the current 11 percent interest rate.

The Commission appreciates that CMS has reviewed more current data on interest rates from the SBA. We encourage CMS to provide more information about the data. How were the SBA data collected (e.g., are they from a survey)? What methods did CMS use to analyze the data (e.g., how did CMS identify that the loans were used to purchase equipment)? Further, we encourage the agency to consider using an average of rates from multiple years. Using an average rate from multiple years would reflect the range of rates paid by providers who bought their equipment at different times. The number of years used to calculate the average rate could be based on the estimated useful life of equipment, such as five years for MRI and CT machines. Although changing the interest rate would have a very minimal effect on PE RVUs for services that use low-cost equipment, it would have a larger impact on services that use expensive equipment.

The Commission also suggests that CMS establish a reasonable time frame to periodically review and update the wage rates for clinical staff and the purchase prices of supplies and equipment, which are used in setting PE RVUs. CMS last updated nonphysician clinical staff wages for the 2002 fee schedule and has not indicated when wages will be reviewed again. CMS repriced supplies and equipment in the last few years but has not indicated when it will next perform a comprehensive review. Moreover, the prices of new, high-cost supplies and equipment should be reviewed more frequently than other items to ensure that price changes are reflected in the relative values. Prices for new items are likely to drop over time as they diffuse into the market and as other companies begin to produce them.

Geographic practice cost indices (GPCIs): GPCI update

CMS has reviewed the geographic practice cost indices (GPCIs) and proposes new GPCIs for 2008. As you know, three separate GPCIs correspond to each of the three components of physician payment: physician work, PE, and professional liability insurance. The current PE GPCI does not recognize that individual services have different shares of inputs for which prices vary geographically (e.g., nonphysician staff and office space) and for which prices are uniform because they are purchased in national markets (e.g., equipment and supplies). Thus, for services with below average shares of equipment and supplies, the index does not adjust a large enough portion of the PE RVU; for services with above average shares of equipment and supplies, it adjusts too large a portion of the RVU. This distorts prices, which may alter the mix of services provided within a high- or low-cost area. We developed an alternative GPCI which better recognizes that services have different shares of inputs for which prices vary geographically (MedPAC, *Report to the Congress: Promoting Greater Efficiency in Medicare*, June 2007). This alternative—which excludes equipment and supplies—would be applied to the portion of the PE RVU related to indirect costs and nonphysician clinical labor but not to the portion related to equipment and supplies. It would produce more accurate prices for specific services among different markets, thus reducing financial incentives to provide one service over another. We encourage CMS to examine this alternative GPCI for its next proposed rule. We can offer technical assistance to CMS in considering this GPCI. We believe that the agency could implement this alternative within its current statutory authority.

Our alternative GPCI excludes equipment and supplies. Because staff wages and office rent vary geographically, the alternative is composed of nonphysician staff wages (50 percent of the index), office rent (33 percent), and other expenses (17 percent). The weights for each component are based on the relative size of each component in the MEI.
Although localities under the alternative GPCI have a wider range of values, this is balanced by not applying the alternative to the entire PE RVU. We apply the alternative GPCI to the portion of the RVU related to indirect costs and nonphysician clinical labor but not to the portion related to equipment and supplies. The reason is because the alternative GPCI includes inputs related to indirect costs and nonphysician clinical labor but not equipment and supplies. To determine the full PE RVU, the portion of the RVU adjusted by the GPCI is added to the unadjusted portion (representing equipment and supplies).

Our alternative GPCI would reduce PE payments for services with below-average shares of equipment and supplies (e.g., office/outpatient visit) in areas where input costs are low and increase them in areas where input costs are high. For example, the PE payment for office/outpatient visit (code 99213) would decline by 3.4 percent in the lowest-GPCI area (Puerto Rico) and increase by 3.0 percent in the highest-GPCI area (San Francisco). The total payment for this service would fall by 1.3 percent in Puerto Rico and increase by 1.6 percent in San Francisco. The alternative GPCI would have the reverse effect on services with above-average shares of equipment and supplies (e.g., MRI of the brain). For example, the PE payment for the technical component of MRI of the brain, with and without contrast (code 70553), would increase by 22.4 percent in Puerto Rico and decline by 18.8 percent in San Francisco. The total payment for this service would rise by 18.6 percent in Puerto Rico and fall by 16.7 percent in San Francisco.

Geographic practice cost indices: Reconfiguring payment localities

CMS has divided the country into 89 localities for applying geographic adjusters to physicians' payments. As described in the previous section, each locality has a set of three geographic practice cost indices that Medicare uses to adjust payment rates.

Some organizations that represent physicians have raised an issue that the structure of the payment localities often causes payments under the PFS to inaccurately reflect the local costs of providing care. This can cause physicians in some areas to be systematically underpaid while others are overpaid, creating payment equity issues. The underlying factor for the payment inaccuracies is that many localities encompass geographic areas with very different costs of providing care. This appears to occur for two reasons: many localities are too large to accurately track geographic differences in costs of care and many are based on geographic entities established in 1966 and have not been adjusted to reflect changes in economic and demographic conditions.

In this proposed rule, CMS expressed concern over variation in costs within existing payment localities. In response, CMS is soliciting comments on three possible locality reconfigurations:

- *Option 1:* Within each of the current localities, identify the counties where a measure of cost—the geographic adjustment factor (GAF)—is at least 5 percent higher than the GAF of the entire locality. Each of these high-cost counties would become a new payment locality.
- *Option 2:* The same as Option 1, except within each existing locality, combine the counties within the same state that are identified as high cost into a single new locality.
- *Option 3:* Within each state, order counties by GAF from highest to lowest. Combine into a new locality the county with the highest GAF and the other counties that have a GAF within 5 percent of the highest cost county. Then, find the highest cost county that remains. Combine that county and all the counties that have a GAF within 5 percent of the new highest-cost county. Continue this method until all counties are in a locality.

All three reconfigurations have the goal of revising payment localities so that payments more accurately reflect local costs of care. MedPAC agrees with this goal, and we have examined other methods of reconfiguration. Key results from our analysis include:

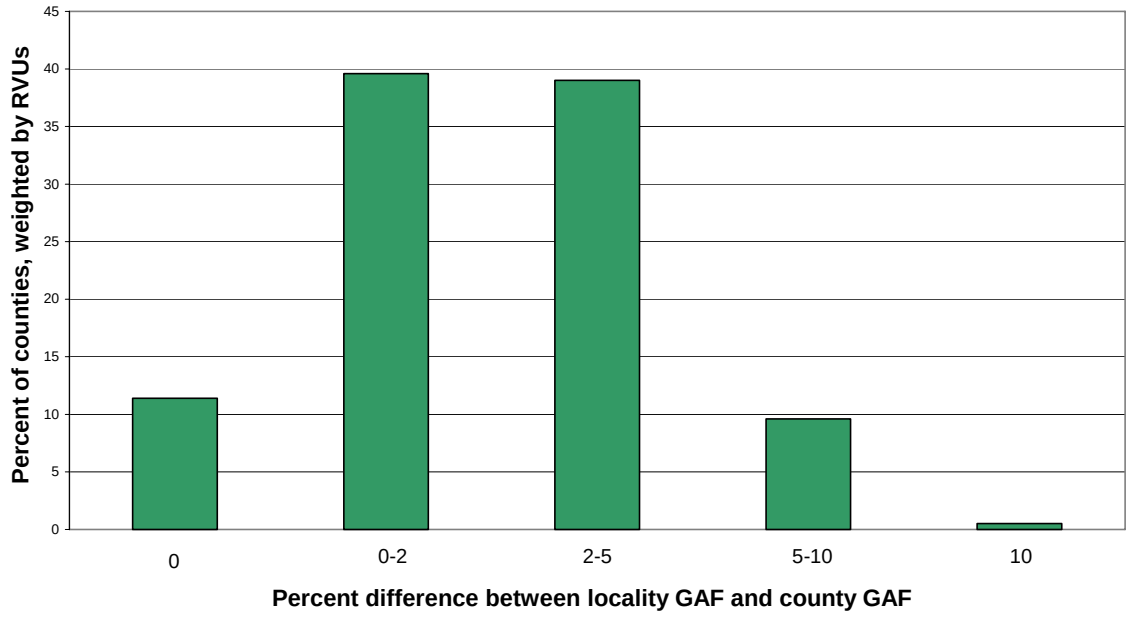
- Under existing localities, some areas have payments that differ substantially from local costs, creating some large payment inaccuracies.
- Large payment inaccuracies are not widespread. Most areas have fairly small differences between payments and local costs.
- Because most areas face small payment inaccuracies, improving payment accuracy requires calibrating payment changes so that they are small in most places.

Using the county as the definition of local markets for physician services, we started our analysis by investigating the extent of payment inaccuracies at the county level. We recognize that counties are largely an administrative geographic unit and do not perfectly represent local markets. However, counties are the smallest geographic unit for which data on physician costs are collected.

Our analysis of the data indicates that some large payment inaccuracies exist at the local level, with the largest differences between physician payments and local costs being close to 15 percent. However, large inaccuracies are relatively infrequent. Less than 1 percent of counties have payment rates that differ from local costs by more than 10 percent, and only 10 percent have differences of at least 5 percent (Figure 1).

As CMS considers alternatives to the existing payment localities, it should try to meet two goals: pay accurately for local input costs and avoid large differences in payments between adjacent counties. However, these two goals are typically in conflict with each other and a good definition of payment localities should balance them. On the one hand, relatively small localities typically promote more accurate payments because smaller localities tend to have less variation in costs of care than larger localities. Therefore, striving for accurate payments usually leads to many localities. For example, making all 3,200 counties individual payment localities would result in more accurate payments than using states. However, this could be cumbersome and GAFs could be unstable over time in areas with little data. On the other hand, large payment localities typically have smaller differences among adjacent counties within a state. An extreme example is using the nation as a payment locality, which would result in no differences in payments between adjacent counties.

Figure 1. Difference between locality GAF and county GAF



Note: GAF (geographic adjustment factor); RVU (relative value unit).
Source: MedPAC analysis of data on geographic adjustment factors from CMS.

Because the organizations that advocate a reconfiguration of the payment localities are arguing for more accurate payments at the local level, we investigated two methods that would improve payment accuracy. Improving payment accuracy at the local level requires smaller payment localities, which leads us in the direction of more localities than currently exist.

One of these methods uses the existing localities as the starting point, and we refer to it as the "locality" option. This method goes through an iterative process for each locality. In the first iteration, we compare the GAF for the highest-cost county in a locality to the average GAF among the lower-cost counties in the locality. If the GAF of the highest-cost county exceeds the average of the other counties by more than a pre-set threshold (5 percent), the highest-cost county becomes a separate locality. In the next iteration, we compare the GAF of the second-highest county to the average GAF of the remaining lower-cost counties. If the GAF of the second-highest county exceeds the average of the lower-cost counties by the pre-set threshold, it becomes a separate locality. The process stops when the GAF of the highest-cost remaining county does not exceed the average of the lower-cost counties by the pre-set threshold, and the remaining counties form a single locality.

Our locality option is similar to CMS's Option 1 discussed above, with one key difference: Our method is iterative, but CMS's is not. CMS compares the GAF of each county in a locality to the average GAF for all counties in the locality. We start by comparing the GAF of the highest-cost county in a locality to the average GAF for all lower-cost counties. Then we go through

iterations, comparing the GAF of the highest-cost remaining county to the average GAF of the remaining lower-cost counties.

The difference in practice between these two methods is that iterative methods tend to result in more payment localities. We prefer the iterative method over a method that compares the GAF of the highest-cost entity to the overall average GAF because the most costly entities are often very large and have a strong influence on the overall average GAF. In cases where the difference in GAFs is large between the highest-cost entity and all other entities, using the overall average reduces the likelihood that the highest-cost entity would become a separate locality.

The other method we developed, which we refer to as the metropolitan statistical area (MSA) option, starts at the state level. We collect the urban counties in each state into MSAs and the nonurban counties into a nonurban area. An iterative process follows. In the first iteration, we compare the GAF of the highest-cost MSA in a state to the average GAF of the other areas in the state. If the GAF of the highest-cost MSA exceeds the average of the lower-cost areas by a pre-set threshold (5 percent) the highest-cost MSA becomes a separate locality. In the next iteration, we compare the MSA with the second-highest GAF to the average GAF of the remaining lower-cost areas. If the second-highest GAF exceeds the average of the lower-cost areas by more than the pre-set threshold, the second-highest MSA becomes a separate locality. The process stops when the GAF of the highest-cost remaining MSA does not exceed the average of the lower-cost areas by the pre-set threshold, and the remaining areas form a single locality.

Both the locality and MSA options would shift spending within a state. However, neither would affect aggregate spending within a state, and, therefore, neither would affect national aggregate spending. In other words, both options are budget neutral.

We evaluated both the locality and MSA options using a 5 percent threshold for identifying new payment localities. We found that both options would increase the number of localities from the current number of 89 (Table 1). Because both options increase the number of localities, the size of localities is smaller relative to existing localities. The result is more accurate payments. The average difference between county and locality GAFs is 2.2 percent under current localities. That would decrease to 1.5 percent under the locality option and 2.0 percent under the MSA option (Table 1). However, the average difference in GAFs among adjacent counties would be higher under the locality option (2.0 percent) than under the current localities (1.8 percent) because the locality option breaks down existing localities into smaller units. In contrast, the average difference among adjacent counties would decline under the MSA option (to 1.4 percent) because more counties under the MSA option would have no difference between its GAF and the GAF of its adjacent counties.

Table 1. Locality and MSA options have similar effect on geographic adjustment factors

Locality definition method	Number of localities	Avg diff betwen county and locality GAFs	Avg difference in GAFs among adjacent counties	Avg change in GAFs from current levels
Locality option	186	1.5%	2.0%	1.0%
MSA option	119	2.0	1.4	1.6
Current method	89	2.2	1.8	NA

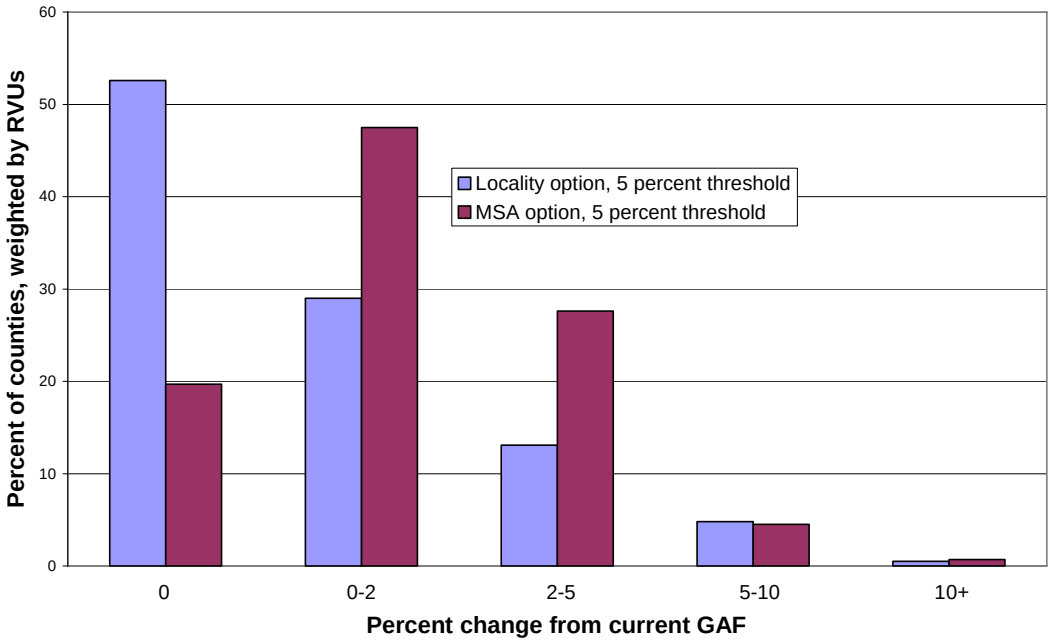
Note: MSA (metropolitan statistical area), GAF (geographic adjustment factor). All averages are means among counties, weighted by number of relative value units. The average changes in GAFs in the final column are averages of absolute value changes. The average of the actual change in GAFs is zero under both the locality and MSA options because both options are budget neutral to the existing localities.

Source: MedPAC analysis of data on geographic practice cost indexes from CMS.

Although both options would increase payment accuracy and would affect differences in payments between existing localities, these two options would have small effects on both measures (Table 1). For example, a move from current localities to the locality option would change payments by less than 2 percent in 82 percent of all counties; a move to the MSA option would change payments by less than 2 percent in 67 percent of all counties (Figure 2).

Finally, under the current localities, thirty-four states are statewide localities, meaning there is a single payment rate for all physicians in those states. Six of those states—Minnesota, Nebraska, Oklahoma, North Carolina, Ohio, and Iowa—opted for statewide configuration because of widespread agreement among physicians in those states. It is plausible that widespread preferences for statewide localities are still present in these six states and may be present in other statewide localities. Therefore, if CMS reconfigures the payment localities, it may be prudent to determine which statewide localities would like to maintain that status and exclude them from reconfiguration.

Figure 2. Change in GAFs from current level under locality and MSA options



Note: GAF (geographic adjustment facor), RVU (relative value unit), MSA (metropolitan statistical area).
Source: MedPAC analysis of geographic practice cost indexes from CMS.

Coding—additional codes from 5-year review

In addition to proposals on practice expense RVUs, the proposed rule addresses the fee schedule's RVUs for physician work. During the most recent 5-year review of work RVUs, CMS deferred action on 58 codes because either the agency had not received a recommendation from the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC) or because CMS had asked the RUC to reevaluate its original recommendation. Now that the RUC has completed its work, CMS is proposing to accept all but one of the RUC recommendations and complete the 5-year review.

As we have seen with previous work on the 5-year review for 2007 and indeed with work on both of the earlier reviews—for 1997 and 2002, the proposed action on the additional 58 codes is tipped in favor of higher RVUs: RVUs would go up for 33 codes, down for 10 codes, and not change for 15 codes. In addition, CMS is proposing to adopt a RUC recommendation that would increase the valuation of physician work for anesthesia services by 32 percent. To maintain the required budget neutrality of these changes, the proposal is to increase the budget neutrality adjustment that applies to the fee schedule's work RVUs. The adjustment would increase from the current 10.1 percent to 11.8 percent.

The Commission remains concerned about what appears to be a bias in the 5-year review in favor of undervalued codes as compared to overvalued codes. Services that are overvalued may

be overprovided because they are more profitable than other services. In addition, because so many more codes would have their values increased than decreased, CMS would passively devalue all work RVUs with a budget neutrality adjustment of almost 12 percent.

In our March 2006 Report to the Congress, MedPAC evaluated the five-year-review process and concluded that CMS itself must take a more central role in identifying potentially misvalued services, especially overvalued ones. We recommended that CMS reduce its reliance on physician specialty societies by establishing a standing panel that would provide expertise in addition to that provided by the RUC. This new panel would help CMS identify misvalued services and collect data to establish supporting evidence for the RUC to consider. The panel would also be useful in evaluating codes when no specialties express an interest in collecting the necessary data, as happened with the case of one code.

The Commission has also identified ways to identify services in need of review. First, the Secretary could implement reviews of services based on analyses of Medicare data. For example, high volume growth may be an indicator that the price of a service is set too high. Second, the Commission suggested instituting automatic reviews of work RVUs for selected recently introduced services. The time and intensity may decline as they are disseminated, and there is evidence that the current review process is not timely enough to detect such changes. Third, the Secretary should establish a process by which all services are reviewed periodically.

We recognized that the recommendations would increase demands on CMS and—since the goal was to improve the accuracy of Medicare's payments and achieve better value for Medicare spending—encouraged the Congress to provide the agency with the financial resources and administrative flexibility to undertake them. Our recommendations were not intended to supplant the RUC but rather to augment it. The RUC and the specialty societies play an important role, which should continue.

To date, CMS has not implemented the Commission's recommendations. Last year, in the final rule for 2007, the agency acknowledged the recommendations and stated that it is continuing to examine how best to identify misvalued services. There was also a reference to a new RUC subcommittee that will suggest approaches to identifying overvalued services. While the Commission is hopeful that this subcommittee will have some success, the history of a review process dominated by specialty societies suggests that more effort is necessary. We encourage you to revisit our recommendations.

ASP Issues

The ASP payment method ties Medicare payment rates for Part B drugs to average transaction prices. It has resulted in substantial savings for the Medicare program and its beneficiaries. Sometimes manufacturers offer provider discounts for one of their products contingent on purchases of one or more other products. We have recommended that CMS clarify how these bundled discounts should be allocated when manufacturers calculate ASP. In the proposed rule, CMS requires that manufacturers allocate the total value of all price concession proportionately according to the dollar value of the units of each drug sold under a bundled arrangement. This

method is similar to the method proposed for allocating bundled discounts under Medicaid. We are generally supportive of this methodology and believe it would result in more accurate ASPs in most cases.

We congratulate CMS for tackling this difficult issue and providing guidance to manufacturers. Bundled discounts can take many forms. For example, some bundling arrangements may include only Part B drugs while others may include both Part B drugs and other products. Similarly, price concessions may be structured in different ways. We have found that the way manufacturers allocate the bundled discount can affect the accuracy of reported ASPs. In our 2007 report to the Congress on the impact of changes in Medicare payments for Part B drugs, we suggested a number of different ways in which bundled discounts might be allocated to preserve the integrity of the payment system.

Although we believe the method proposed by the agency will increase the accuracy of the payment system, we do not believe that the method is sufficient to cover all cases where bundled price concessions result in inaccurate ASPs. Contract terms between manufacturers and the providers who purchase their products change frequently. These terms may still create contingencies that distort the accuracy of payment rates. If the Medicare payment rate does not reflect the average purchase price, physicians may find that financial rather than clinical factors drive their choice of products. The Commission believes that the link between ASP and transaction prices must be maintained.

One commenter has suggested that CMS establish an exceptions process. Under this proposal, providers could supply evidence of contractual arrangements that included bundled price concession with drugs for which there are no clinical alternatives. The provider would have to show how the contract affected the accuracy of the payment rate and limited its ability to purchase needed products at the Medicare rate. CMS would evaluate the evidence and allow for a suitable comment period. If the agency determined that allocation of discounts in the bundled arrangement resulted in the distortion of ASP, it could require the manufacturer to reallocate bundled discounts according to the contingencies in the contract terms. We believe this proposal is worth considering in terms of feasibility, including determining which products would fall into the exceptions process.

ESRD provisions

Using the method the agency developed last year, CMS proposes to update the add-on payment to the composite rate (as mandated by the MMA) by 0.5 percent, thus increasing the total add-on payment from 14.9 percent in 2007 to 15.5 percent in 2008. This update would result in increasing the add-on payment from $19.64 to $20.36 per session, or an increase in total add-on payments of about $22.6 million in 2008.

In our June 2005 report, the Commission recommended to the Congress that these two payments should be combined. The add-on payment is complex and administratively burdensome for the agency to maintain. In addition, an increase in the add-on payment for dialysis drugs risks

overpayment for use of the drugs. For these reasons, the Secretary should seek Congressional authority to combine the composite rate and the add-on payment.

IDTF issues

We support CMS's proposal to prohibit fixed-site independent diagnostic testing facilities (IDTFs) from sharing their space, equipment, or staff, or subleasing their operations, to another individual or organization. CMS says that this change would make it easier to ensure that each IDTF establishes Medicare billing privileges and meets Medicare's performance standards. CMS also claims that this policy would prevent subleasing agreements that could violate physician self-referral and anti-kickback prohibitions.

We are concerned about the emergence of arrangements in which a physician practice leases a block of time from an imaging provider (such as an IDTF) or agrees to pay the provider a per service fee to use its facility. The group practice then refers its patients to the imaging provider for imaging tests and bills the insurer for the services, usually profiting from the difference between the insurer's payment rates and the fees the practice pays to the imaging provider. A recent study found that these types of arrangements are common among physicians who billed a large California plan for advanced imaging studies.[a] The Department of Justice is investigating whether a chain of imaging centers in Florida violated the federal anti-kickback statute by offering leasing deals to physicians that allowed the physicians to profit from referring patients for MRI and CT studies.[b] These arrangements create financial incentives that may influence physicians' clinical judgment and may lead to unnecessary services. Several studies have found that physicians who benefit financially from diagnostic imaging refer their patients more frequently for imaging studies than those who don't.[c] CMS's proposed change to the IDTF rules would prevent at least some of these leasing arrangements by prohibiting IDTFs from leasing their space, equipment, or staff to physicians who are able to refer patients to the facility and bill Medicare for the services.

Physician self-referral provisions

Changes to reassignment and physician self-referrals rules relating to diagnostic tests (anti-markup provision)

CMS proposes to prohibit physicians from marking up the technical or professional component of a diagnostic test when billing Medicare for a test that is performed by another provider. In other words, the billing physician could not charge Medicare more than the amount he or she paid to the provider that actually performed the test. This rule would apply when the billing physician purchased the test from the provider who performed it, and when the provider that

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[a] Mitchell, JM. 2007. "The prevalence of physician self-referral arrangements after Stark II: Evidence from advanced diagnostic imaging." *Health Affairs* web exclusive, p. w415-w424. April 17.
[b] Armstrong, D. 2005. "Prosecutors investigate medical scan deals at Florida center." *Wall Street Journal.* July 28.
[c] Government Accountability Office. 1994. *Medicare: Referrals to physician-owned imaging facilities warrant HCFA's scrutiny*, no. GAO/HES-95-2. Washington, DC: GAO. October.

performed the test reassigned their right to bill to the billing physician. The Commission agrees with CMS that allowing physicians to purchase or contract for the provision of diagnostic tests and to realize a profit when billing Medicare could lead to overuse of services and higher program costs. Therefore, we support this proposed change.

In-office ancillary services exception

CMS seeks comments on which in-office ancillary services should continue to be considered designated health services and excluded from self-referral rules, specifically mentioning therapy services that are not furnished as incident to a physician service, pathology services, and expensive imaging services. At this point in time, MedPAC is not ready to identify which services should continue to be excluded from the self-referral rules but we plan to examine this issue this year. For example, we will consider whether therapy services fit the logic and original intent of the exceptions given the amount of physician involvement in some therapy services furnished as part of physician practices.

Unit-of-service (per click) payments in space and equipment leases

In the phase I final rule to the Stark self-referral law, CMS permitted physicians to own entities that provide services and equipment to providers of designated health services (DHS), such as a hospital or imaging center, and to refer Medicare or Medicaid patients to the providers, as long as the physicians do not own the actual entity submitting claims to Medicare or Medicaid. For example, physicians could lease an MRI machine to an imaging center for an amount that is fair market value. Further, CMS allowed physicians to lease equipment or space to providers on a per-use (or per-click) basis; the physician could receive additional payments each time he or she referred a patient to the provider for a service that involved the use of the equipment.

The Commission believes that the financial incentives created by these arrangements could lead to overuse of imaging services (MedPAC, *Report to the Congress: Medicare payment policy*, March 2005). We recommended that the Secretary prohibit these arrangements by expanding the definition of physician ownership to include interests in an entity that derives a substantial proportion of its revenue from a provider of designated health services (MedPAC, March 2005). This recommendation would prevent physicians from referring patients to a hospital, imaging center, or other provider if they also owned equipment or space that was leased primarily to the provider.

CMS now proposes to prohibit space and equipment leases between physicians and providers of DHS that include per-click payments when the physician refers patients to the provider. CMS believes that such arrangements are susceptible to abuse because the physician who owns the space or equipment has a financial incentive to refer more patients to the provider. Under CMS's proposal, however, physicians would still be allowed to lease equipment or space primarily to a separate provider for a fixed amount set in advance (e.g., a fixed amount per day or per week). Even though the physician's revenue would not increase directly through the referral of additional patients to the provider (as it would under a per-click agreement), the physician still has a financial incentive to refer patients to the provider in exchange for the fixed payment. For

example, a physician could agree to lease an imaging machine to a hospital for an amount at the high end of the range of fair market value, with an implicit understanding that the physician will refer patients to the hospital for services that require the machine.

The Commission's March 2005 recommendation (described above) would prohibit all types of leasing arrangements (including on a per-click and fixed amount basis) when the physician-owner refers patients to the provider *and* a substantial portion of the revenue for the equipment or space is received from the provider to which the physician refers patients. We emphasize that our concern relates to physician ownership of entities that derive most of their revenue from leasing space or equipment or furnishing other services to providers of DHS, rather than ownership of entities that primarily provide such services to non-DHS providers. Thus, the Commission urges CMS to substitute our March 2005 recommendation for its proposal in this section.

Services furnished "under arrangements"

CMS allows providers, such as hospitals and skilled nursing facilities, to contract with other entities to serve the provider's patients. For example, a hospital may contract with a physician practice to furnish imaging services "under arrangements" to the hospital's patients; the hospital bills Medicare and pays the practice a fee. This model was originally used by hospitals to provide certain services to their patients that were not available at the hospital because they were required infrequently.

In this proposed rule, CMS explains that "under arrangements" deals between referring physicians and hospitals have proliferated. The agency cites anecdotal reports of hospital and physician joint ventures that provide imaging services to the hospital's patients; previously, these services were provided directly by the hospital. The sole purpose of these arrangements appears to be to allow physicians to profit from referring patients to the hospital, which may lead to overuse of services. A hospital may engage in these arrangements to secure physician loyalty to the hospital.

CMS proposes to prohibit physician investment in entities (e.g., an imaging center) that provide services under arrangements with a hospital when they refer patients for the services provided by the entity. The agency would accomplish this by expanding the definition of an entity that provides designated health services to include entities that actually perform the services as well as entities that bill Medicare (currently, the definition only includes entities that bill Medicare). Thus, a physician would no longer be allowed to refer patients to a hospital for imaging services if the physician also invested in the entity that provided imaging services under arrangements to the hospital's patients.

We share CMS's concern with the growth of services provided under arrangements to hospitals by physician-owned entities, and their proposal is an effective way to address this issue. In our March 2005 Report to the Congress, the Commission recommended an alternative path to restrict these arrangements. We recommended that the Secretary expand the definition of physician ownership to include interests in an entity that derives a substantial proportion of its revenue

from a provider of designated health services. This change would prohibit an "under arrangements" model in which the physician-owned entity received most of its revenue from the hospital or other DHS entities. For example, it would prohibit physicians from referring patients to a hospital if they also owned an entity that provided outpatient surgery, imaging, or other services primarily to the hospital's patients. In contrast to CMS's proposal, however, the Commission's recommendation would permit physician referrals to the hospital if the physician-owned entity received less than a substantial share of its revenue from the hospital.

TRHCA—Section 101(d): PAQI and Section 101(b): PQRI

The Tax Relief and Health Care Act of 2006 (TRHCA) establishes the Physician Assistance and Quality Initiative Fund—totaling $1.35 billion. By statute, the Secretary may use the fund for "physician payment and quality improvement initiatives, which may include application of an adjustment to the update of the conversion factor." The statute further specifies that the fund be used for payment of physician services furnished during 2008.

In our March 2007 report to Congress, MedPAC recommended a payment rate increase for physician services in 2008. Thus, the Commission reasons that this fund should be used towards financing the 2008 physician update, which, under current law, will be substantially negative. Although TRHCA explicitly allows for the fund to be used towards the 2008 physician update, CMS notes legal and operational problems with doing so. While we are aware of CMS's concerns, MedPAC urges CMS to re-examine ways that the fund could be directed toward the 2008 update for physician services.

The Commission has recommended that the Congress begin implementing P4P programs across many provider sectors, including physician services. An essential component of P4P programs is that they include rewards and penalties that are based on the *content* of the data reported—and thus the provider's performance. Medicare should reward providers who improve care and meet or exceed specified benchmarks.

The process of selecting an appropriate set of measures is a critical element of any P4P initiative. The measure set should be vetted by a credible, independent entity. In addition to examining measures for statistical validity and reliability, this entity could also consider each measure's relative usefulness toward improving beneficiary care (i.e., the impact of potential improvement on beneficiary care, relative to other measures). This consideration will encourage specialty societies to devote resources toward bringing the most meaningful and effective measures to the table for review.

Constructing this measure set must also balance the need for validity and accuracy with speed and comprehensiveness. In our March 2007 Report to the Congress, we stated that P4P programs might, in the short-term, prioritize some P4P measures over others. Initial focus on high-cost, widespread, chronic conditions may be a prudent short-term goal. Although some specialties may have more P4P measures than others, a targeted approach for measure selection would maximize benefits to the Medicare program and to beneficiaries. Ultimately, as measures for less

prevalent or less costly conditions become well-established, they can be incorporated into P4P programs in the long-term.

Finally, the ideal measure set would include process measures that focus on services that are both highly-valued and under-provided. To *improve* care, the Commission does not find it a worthy effort to reward physicians for providing marginally effective care or care that is already routinely furnished. Indeed, such measures could diminish the overall effectiveness of quality initiatives, especially in their early stages.

Therapy standards and requirements

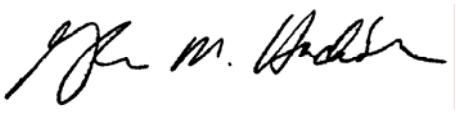
The Commission is concerned that therapy services continue to be one of the key drivers of spending growth for part B services. We have not examined whether the current controls—the physician review requirements, the therapy caps and exceptions process, the local medical review and systems edits, and educational materials—have controlled volume. That said, this proposal would result in less review of therapy that lasts beyond 30 days, and we would generally support greater rather than less review. We believe that CMS needs effective mechanisms in place to help ensure that beneficiaries get appropriate services and the program does not pay for medically unnecessary services. We encourage CMS to develop approaches to paying for therapy services that creates financial incentives for providers to furnish medically necessary care efficiently, such as paying for bundles or episodes of services.

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,



Glenn M. Hackbarth, J.D.
Chairman

GMH/kh/cw