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Cost-Based Stark Law Changes Under Consideration

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Major reforms to the Stark Law's "In-Office Ancillary Services" (IOAS) exception1 and the current Medicare payment system may be on the horizon.

On June 15, 2010, the Medicare Payment Advisory Commission (MedPac) issued a 267 page report to Congress (MedPac Report).2 MedPac is an independent congressional agency established by the Balanced Budget Act of 1997 to advise Congress on issues affecting the Medicare program.

Although MedPac is only authorized to study and analyze issues and make recommendations to Congress, its recommendations are typically given serious consideration by Congress and the Centers for Medicare and Medicaid Services (CMS) and are often incorporated into new laws and regulations.

The recent MedPac Report covered numerous issues relating to Medicare, including changes in payment policy, graduate medical education and a reformed healthcare delivery system. The focus of this article, however, is limited to the new strategies MedPac is considering regarding Medicare payments for expensive diagnostic tests, including MRIs, CT scans, PET scans, cardiac imaging stress tests and therapy services, such as radiation therapy and physical therapy.

While MedPac did not make specific recommendations in its June report regarding diagnostic tests or therapeutic services, the report discusses, in substantial detail, several possible options it is considering for further recommendations to Congress and CMS.

Attorneys who represent physicians, or businesses involved with imaging services, radiation therapy or outpatient physical, occupational or speech therapy (collectively, "outpatient therapy") should take note of the strategies MedPac is considering and seize the opportunity to submit comments to MedPac or Congress, because these strategies, as currently presented, could potentially change the landscape for many medical practices and business transactions for years to come.

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Why is MedPac even focusing on the way doctors perform imaging services, radiation therapy or outpatient therapy? Fundamentally, it is an economic issue.

MedPac is concerned that many physicians have expanded their practices over the years to include these services, even where they are not part of the physician's primary core practice. The rapid growth in these services has caused an increasing financial burden on Medicare.

To highlight this, MedPac points to studies showing that physicians tend to order more tests or therapeutic services when the physician is the provider of such services and is being paid on a fee-for-service basis, and that some of the diagnostic imaging and therapy services ordered by physicians are not clinically appropriate.

The Concern Behind Stark

It was this very concern about financial incentives motivating physicians to over-utilize services that drove Congress to enact the Ethics In Patient Referrals Act, known as the Stark Law.3

The Stark Law prohibits physicians from referring Medicare or Medicaid patients for certain "designated health services" (DHS), such as imaging, radiation therapy, clinical laboratory tests or physical therapy, to entities with which the physician has a financial relationship, unless the relationship fits within an exception. The IOAS exception allows physicians to perform most DHS in their offices or group practices if certain requirements are met.

Proponents of the IOAS exception argue that it is necessary to enable physicians to promptly diagnose and treat patients during an office visit, improve patient care coordination, improve their access and convenience, and encourage patients to comply with their physicians' diagnosis and treatment plan.

Indeed, these were among the reasons for enacting the IOAS exception in the first place. Congress tried to balance the need for maintaining clinical integrity, patient convenience and non-interference with the physician's practice with its belief that physician investment in ancillary services leads to increased utilization of services in a Medicare fee-for-service payment system.

MedPac would likely argue that the IOAS exception was enacted to allow a physician, such as a hematologist, to perform a blood test during a patient's office visit to determine if the patient is anemic, or a pulmonary physician to perform a chest x-ray to diagnose pneumonia so that an appropriate treatment plan could be prescribed promptly.

MedPac apparently does not believe that the IOAS exception was also intended to enable physicians to provide a host of other ancillary services that are not performed on the same day as an office visit. In fact, MedPac points to Medicare claims data to show that outpatient therapy, imaging, pathology, clinical laboratory, and nuclear medicine studies, as well as many other ancillary services, are frequently not provided on the same day as an office visit, but rather several days later, thereby undermining a key rationale for the IOAS exception.

In MedPac's view, the IOAS exception was not intended to enable physicians to add ancillary services to their practices that are not needed for the prompt diagnosis, treatment and convenience of the patient.

In light of the foregoing concerns, MedPac is exploring several strategies to rein in over-utilization of services and the concomitant increase in Medicare spending, with the goal of developing and presenting recommendations to Congress in the near future. These strategies are discussed below.

Excluding Therapies

MedPac is considering a recommendation to exclude from the IOAS exception all radiation therapy services and outpatient therapy services. Its rationale is that such therapeutic services are not typically ancillary to a patient's office visit and generally involve multiple sessions that are not provided or even initiated on the same day as an office visit.

If such a change were adopted, it would mean that a physician could not order or prescribe radiation therapy or outpatient therapy services that would be performed by another physician or therapist in the ordering physician's medical practice since the IOAS exception would no longer permit this "self-referral."

For example, an orthopedic surgeon would not be

able to refer a patient to a physical therapist employed by the surgeon's practice. If a physician currently provides either radiation therapy services or outpatient therapy services to his patients, he may be forced to restructure his practice, sell valuable equipment, terminate certain employees and cease providing such self-referred services to Medicare and Medicaid patients.

Patients who require such services would have to be referred to other physicians, independent therapists, or hospitals with which the referring physician has no financial relationship.

Limiting IOAS Exception

A second approach being considered by MedPac is to limit the IOAS exception to only those medical practices that meet new and more demanding clinical integration requirements. This approach would require CMS to define "clinical integration" in a way that could be measured.

One option MedPac is considering would require each physician who is an employee or independent contractor in a group practice to provide a "substantial share," such as 90 percent, of his services through the group. MedPac believes this would promote a sharing of patient information, greater physician interaction, and uniformity of clinical pathways.

This approach, however, would result in the elimination of part-time physicians in group practices that perform self-referred ancillary services. This could profoundly affect the operations of many medical practices that utilize part-time physicians in their core practice.

In addition, there are many group practices such as urology, cardiology and oncology groups that hire part-time physicians to supervise or perform imaging or radiation therapy services for the group's patients. These groups and their patients would be directly affected if this option were adopted.

Excluding Tests From IOAS

A third limitation to the IOAS exception under consideration is excluding from it those diagnostic tests that CMS determines are not typically provided on the same day as a patient office visit. The rationale for this limitation is that the test is not being used to make an immediate diagnosis at the time of the patient's visit and therefore lacks a major underlying justification for the IOAS exception.

MedPac acknowledges that this approach may involve setting an arbitrary threshold for determining which diagnostic tests are usually provided on the same day as an office visit, and that many factors may affect the timing of a diagnostic test such as the type and severity of a patient's condition. If adopted, the elimination of specific diagnostic tests from the IOAS exception would undoubtedly have a severe economic impact on many physician practices. Nevertheless MedPac views this approach as a viable option.

Reducing Reimbursement

MedPac is also considering an option that focuses on Medicare payment reductions for self referred ancillary services.

This option would reduce the Medicare payment rate for diagnostic tests performed by self-referring physicians or other physicians within their group. This would mean that tests that are self-referred by a physician under the IOAS exception would be reimbursed at a lower rate than the same tests performed by outside practitioners.

MedPac advances a theoretical justification for this, claiming that certain pre-service and post-service activities, such as reviewing the patient's history, prior studies and medical records, and discussing findings with the referring physician become unnecessary if the referring physician is the same person who performs and interprets the test. Therefore, MedPac argues, self-referring physicians should not be paid the same rate for such services.

MedPac fails to recognize, however, that self-referring physicians often refer their patients for tests performed by, or interpreted by, another physician within the ordering physician's practice and that the physician must therefore perform the same pre-service and post-service patient review activities as an outside provider.

Other Payment Changes

A fifth option being considered includes two other potential payment changes:

(i) re-evaluating payment rates for various ancillary services to improve payment accuracy, based on the time and intensity of effort required to perform the service in light of advances in technology, the rate of equipment use by physicians, and other factors, and

(ii) combining discrete services into larger units of payment. This second approach would involve "packaging" multiple services typically furnished during the same patient encounter into a single payment rate (for example, the payment for an office visit for a knee injury would also cover the cost of all lab tests and X-rays of the knee during the visit), or "bundling" all services in multiple encounters into a single payment.

This is similar to the approach already used for many surgical procedures, where one global payment covers the pre-operative care, the surgery and post-operative visits in the hospital and doctor's office. MedPac believes such payment changes would encourage physicians to use tests and other ancillary services more prudently.

Prior Authorization Program

A sixth option being considered by MedPac would require self-referring physicians who order high volumes of advanced imaging tests like MRIs, CT scans, PET scans and nuclear medicine studies, to obtain prior authorization from a Medicare administrative contractor before such tests could be performed by, or within the group of, the self-referring physician.

This approach would target outlier physicians who order frequent, advanced imaging tests without burdening physicians who appear to follow the "norms" set by CMS, and would, at the same time, not globally prohibit the self-referral of advanced imaging services by physicians. The downside of this approach is the high administrative costs for such a program, the increased wait time for patient tests, and the administrative burden on physicians. Nevertheless, MedPac believes this approach has merit.

Conclusion

While MedPac continues to explore all of the above options as interim approaches to address concerns about the rapid increase in ancillary services in physician practices, physicians and their counsel would be wise to carefully track developments over the next several months as they unfold.

It is clear that MedPac intends to consider these strategies individually, or in combination, in an attempt to craft policy recommendations to Congress in order to constrain the volume of medical services while maintaining quality of care. Physicians and their counsel would be well advised to take note of these potential policy changes in formulating future plans. The impact may be both significant and long-lasting.

1. 42 U.S.C. §1395 nn(b)(2); and the regulations pursuant thereto at 42 C.F.R. §411.355 (b).

2. www.medpac.gov/documents/Jun10_EntireReport.pdf, Report to the Congress: Aligning Incentives in Medicare, June 2010.

3. 42 U.S.C. §1395 nn.

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