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August 24, 2010

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Re: CMS – 1503-P
P.O. Box 8013
Baltimore, MD 21244

Submitted Electronically: http://regulations.gov

Re: Federal Register 40039-40718, 42 CFR 405, 409, et al. (July 13, 2010)

To whom it may concern:

The Medicare Rights Center (Medicare Rights) appreciates the opportunity to comment on the proposed rules concerning the payment policies under the physician fee schedule and other revisions to Part B for CY 2011. Medicare Rights is a national, nonprofit consumer service organization that works to ensure access to affordable, high-quality health care for older adults and people with disabilities through counseling and advocacy, educational programs and public policy initiatives. We have 21 years of experience providing education and counseling to Medicare consumers.

Should you have any questions or require additional information, please contact Ilene Stein, Policy Counsel, at 202-637-0961, ext. 5, or istein@medicarerights.org.

Comments

Section III. A. – Therapy Services (pgs 40095–40100)

The Centers for Medicare & Medicaid Services (CMS) should remove any reference to "improvement" as a condition for outpatient therapy. In discussing Option (1) in alternatives to outpatient therapy caps, the NPRM states on page 40098, "At a minimum, the new codes would allow contractors to more easily identify and limit the claims for beneficiaries that show no improvement over reasonable periods of time."

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The Medicare statute does not require improvement for coverage; the statute allows for coverage of services that are reasonable and necessary for the treatment or detection of an illness or injury.[1] For many Medicare consumers, outpatient therapy is necessary to maintain their current level of functioning or to prevent the deterioration of their condition. For example, for people who suffer from multiple sclerosis, Parkinson's disease, or Alzheimer's disease, outpatient therapy is crucial to prevent the progression of their condition.

In light of the statutory mandate, courts have rejected Medicare policies and practices that deny therapy services based upon arbitrary rules of thumb without consideration of the patient's individual condition.[2]

Language that refers to "improvement" included in the "Therapy Services" section of the NPRM conflicts with existing law, and all references to "improvement" should be removed in the final rule. Furthermore, removal of "improvement" as a factor for coverage may require CMS to reexamine their proposed models of outpatient therapy coverage to assure that therapy that helps to prevent disease progression is appropriately reflected in proposed alternatives to therapy caps.

Section VI. Q. – Section 4103: Medicare Coverage of Annual Wellness Visit Providing a Personalized Prevention Plan (pgs 40126–40129)

Medicare Rights fully supports the inclusion of screening for cognitive impairments in the annual wellness visit. Annual screening for cognitive impairments helps detect serious conditions, such as Alzheimer's disease, early, which can help slow their progression. Early interventions not only help decrease health costs and improve an individual's quality of life, but also provide an opportunity for patients to plan for the future with their families, and share in the decision making about their present and future treatment while they are still able.

Further, CMS should reconsider its exclusion of depression screening from the new annual wellness visit. Depression and similar disorders may develop over time and in any year of life—someone could show no signs of depression at age 65 and develop symptoms much later. The National Institute of Mental Health (NIMH) states that depression is underdiagnosed and undertreated among older Americans even though suicide rates are high among this population.[3] Specifically, "Although [people over 65] comprise only 12 percent of the U.S. population, people age 65 and older accounted for 16 percent of suicide deaths in 2004."[4]

Moreover, depression and mood changes can signal biological changes. Screening for symptoms related to depression may help in the detection and treatment of other diseases. According to NIMH, "[O]lder adults may have more medical conditions such as heart disease, stroke or cancer, which may cause depressive symptoms, or they may be taking medications with side effects that contribute to depression."[5] Also, medical evidence strongly supports links between depression and cognitive and progressive conditions such as Alzheimer's disease.[6]

In addition, the annual wellness visit should include screening for functional impairments. Like depression, functional impairments can be a symptom of other serious conditions and illnesses. Changes or deterioration in function may also be a sign of the progression of a condition, and their detection may allow for a more aggressive intervention or additional treatment that will allow individuals a higher quality of life and prolonged independence.

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[1] 42 U.S.C. §1395y(a)(1)(A).
[2] See, e.g., Fox v. Bowen, 646 F.Supp. 1236 (D.Conn. 1987).
[3] National Institute of Mental Health, "Older Adults: Depression and Suicide Facts" (2003), available at: http://www.nimh.nih.gov/health/publications/older-adults-depression-and-suicide-facts-fact-sheet/index.shtml.
[4] Ibid.
[5] National Institute of Mental Health, "Depression" (2007), available at http://www.nimh.nih.gov/health/publications/depression/complete-index.shtml#pub8.
[6] Robert C. Green et al., *Depression as a Risk Factor for Alzheimer Disease*, 60 *Arch Neurol* 753-759 (2003).

For these reasons, CMS should reconsider the exclusion of screening for depression and functional impairments from the annual wellness visit.

Currently the regulations require an update to a list of "current providers and suppliers" but make no mention of caregivers. CMS should require providers who conduct initial and annual exams to obtain information from patients about their current caregivers or other individuals who participate in their care who may not be medical professionals. Many people with Medicare have family members or other people who are responsible for their care. In order for preventive plans to be successful, caregivers must be engaged in the process to ensure patients are following their providers' recommendations. In addition, since caregivers often witnesses the day-to-day habits of the patient, speaking with caregivers may also help providers diagnose conditions or determine appropriate treatments and interventions. This is of particular important for those with Medicare who are very sick or suffer from cognitive or functional impairments.

Section V. R – Section 4104: Removal of Barriers to Preventive Services in Medicare (pgs 40129–40136)

Medicare Rights fully supports the elimination of cost-sharing for certain preventive services. It is important that the list of services, as well as simple explanations of the conditions and symptoms for which such preventive services are appropriate for consumers, be made available on the CMS website in consumer-friendly language. Materials developed for consumers should be updated regularly to reflect the most recent developments in available preventive services. While the list of preventive services covered free of charge is available in the Federal Register and on the U.S. Preventive Services Task Force's website, these sources are not easily accessible or understood by consumers and their caregivers. This is important because for some preventive services, cost-sharing is only eliminated for consumers with specific symptoms or qualifications-materials for consumers must reflect this information. To ensure consumers' appropriate use and understanding of preventive services, CMS must conduct consumer outreach and education.

Section U – Section 6404: Maximum Period for Submission of Medicare Claims Reduced to No more Htan 12 months (pgs. 40142-40144)

The Medicare Rights Center incorporates the following comments as provided by the Center for Medicare Advocacy.

This proposed change is designed to address statutory changes to §§ 1841(a)(1), 1835(a) and 1842(b)(3)(B) of the Social Security Act and applies to all claims for services furnished on or after January 1, 2010. We agree that services provided prior to October 1, 2009 should be subject to prior time limit requirements. However, we disagree that claims provided between October 1, 2009 through December 31, 2009 must be billed by December 31, 2010. The practical effect of applying this proposed time frame to filing claims for such services is to make the statutory change applicable to services provided *prior* to January 1, 2010, which is in contravention of explicit statutory language.

Section 6404 of the *Affordable Care Act* gives the Secretary authority to create exceptions to the one year timely filing period. We laud the Secretary for creating exceptions in this proposed rule. However, important exceptions are missing. Therefore, we suggest the following modifications and additions to the exceptions:

Proposed 42 CFR § 424.44(a)(2)(iii) establishes an exception to the one year time limit for filing claims when "a State Medicaid agency recovered the Medicaid payment for the furnished service from a provider 11 months or more after the service was furnished." We applaud the inclusion of this provision, but we believe that it needs to go further.

State Medicaid agencies are required to assure that Medicaid is the payer of last resort, and that all other payments (including Medicare) have been exhausted. This means that providers may be required to submit claims for services *prior to* a State Medicaid agency's recovery of a Medicaid payment, as a decision from a Medicare contractor may be necessary prior to the State's ability to recover a Medicaid payment. For a number of states, in order to avoid multiple Medicare claims and appeals which can tax the Medicare appeals system

and the provider community, it is far more efficacious to request that providers submit multiple claims for extended periods of time (for example, a year's services) to Medicare at the same time. This approach also provides a more accurate picture of the consumer's medical condition and a better opportunity to make an accurate Medicare coverage determination. Under the proposed time limit, however, a review of such extended periods will be difficult to accomplish because of the practical need for state Medicaid agencies to identify services for which submission to Medicare is required, and for providers to have the necessary lead time to prepare and submit claims for these identified services in a timely fashion.

Thus, we urge CMS to create an additional exception should be created to permit providers to submit claims for services *at the request of a Medicaid state agency or its agent* under the terms of the old regulation; that is, by the end of the calendar year following the year in which the services were delivered (with services delivered in the last quarter of a calendar year being treated as though they were delivered in the next calendar year). In this way, Medicaid state agencies can assure proper billing of services to Medicare, as an appropriate third party payer, without overtaxing providers or Medicare contractors by requiring them to submit multiple claims at varying times.

An exception also should be created for claims for Medicare consumers who are retroactively disenrolled from a Medicare Advantage plan, so that all claims for services provided to the consumer while enrolled in the Medicare Advantage plan can be submitted for coverage and payment to original Medicare.

Under applicable regulations and CMS policy provisions, a consumer enrolled in a Medicare Advantage plan may be retroactively disenrolled from that plan under a variety of circumstances.[7] The effect of this retroactive disenrollment is that the consumer is deemed never to have been enrolled in the Medicare Advantage plan for coverage and payment purposes. *Id.* However, if a retroactively disenrolled consumer is unable to have claims for services submitted to original Medicare because some of those services were delivered more than a year prior to the date of actual disenrollment, then the consumer will be unable to be made whole, and the ability to disenroll retroactively will be rendered pyrrhic at best. While proposed 42 CFR § 424.44(2)(ii) recognizes beneficiaries who receive notice of "Medicare entitlement effective retroactively", the scenario in question does not involve simple "Medicare entitlement," as the consumer is already entitled to Medicare. For this reason, an additional exception should be created for a consumer who is retroactively disenrolled from a Medicare Advantage plan.

In addition, Medicare Rights believes an exception should be created for claims for consumers who retroactively enroll in original Medicare Part B, such as consumers who successfully apply for equitable relief. For example, a person may choose to take Part A (because it is premium free) but may mistakenly choose not to enroll in Medicare Part B due to cost or because they believe that other insurance for which they already pay a premium, such as retiree coverage or coverage through a group health plan provided by a small employer, will pay medical costs. As a result, insurance that is supposed to pay secondary to Medicare incorrectly pays primary. If the insurance plan discovers that a person was eligible for Medicare Part B but did not enroll and therefore the plan was supposed to pay secondary, the insurer can recoup payments made back to the date the enrollee became Medicare Part B eligible. In some instances, a person may obtain a retroactive Medicare Part B start date back to the original date of Medicare eligibility. This retroactive start date can be a few months to a few years and is not limited by statute. As a result, providers from which secondary insurers recouped payment, would need the ability to submit claims to Medicare for services provided over one year in the past. In these cases, because the consumer is already enrolled in Medicare Part A and not Part B, Medicare Rights is concerned that claims would not fall under the language of CFR § 424.44(2)(ii) as the consumer is already entitled to Medicare.

General Comments – Misuse of Allowable Extra Fees

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[7] See, 42 CFR §422.66(a)(5) and Medicare Managed Care Manual (CMS Pub. 100-16), Ch. 2, §60.5.

Medicare Rights is concerned that the rules do not address the appropriate use of "extra fees" charged by Medicare-participating providers to consumers for services assumed not to be covered by Medicare. The current guidance, including the alert issued by the Office of the Inspector General (OIG) on March 31, 2004, on this topic is inadequate.[8] The Centers for Medicare & Medicaid Services (CMS) should promulgate clear rules and guidance on allowable "extra fees" for non-Medicare covered services, including a clearer definition and examples of what is considered a non-Medicare covered service.

The form of these fees vary; they can be for individual services or a general fee for a group of services provided over a specific period, as in a "concierge fee." While these allowable fees were intended to pay physicians for services that are not covered by Medicare, there are a number of examples of physicians charging extra for services that are part of routine caregiving and are therefore already built into Medicare payments. For example, some providers have charged patients extra fees to assist in coverage determinations and appeals for Medicare coverage of health services and prescriptions. Providers may also charge fees for copies of medical records and other documentation. Appeals for coverage require copies of medical records and letters from physicians that demonstrate the medical necessity of specific treatments and tests. For instance, prior authorizations require patients to demonstrate that other treatments have been tried but are ineffective or unsafe; a consumer can only be successful in an initial coverage determination or appeal if the physician participates in the process. These services are part of providing treatment for patients, and therefore physicians should not be permitted to charge extra fees for this type of assistance.

In some instances the fees are not only inappropriate but also disproportionate to the value of the service provided. For example, a consumer reported to Medicare Rights that a physician's office planned to charge $750 for a case report, which is a summary and history of the development of the patient's condition. Currently, there is no guidance on what amount would be considered an appropriate fee for a particular service. While we believe that a case report is not a service for which a physician is allowed to charge an extra fee, even if such a charge were allowed, the fee is excessive for the service provided.

According to the alert from OIG, "[W]hen participating providers request any other payment for covered services from Medicare patients they are liable for substantial penalties and exclusion from Medicare and other Federal health care programs."[9] CMS must be clear that misuse of these extra fees constitutes fraud, for which there are consequences. For these reasons, it is imperative that CMS issue more comprehensive rules and guidance on allowable extra fees, and clarify rules to providers, and OIG must continue to strengthen its enforcement efforts.

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[8] Office of Inspector General, *OIG Alerts Doctors About Added Charges for Covered Services: Extra Contractual Charges Beyond Medicare's Deductible, Coinsurance: A Potential Assignment Violation.* March 31, 2004.
[9] *Id.*