Illegal or Just Ill-conceived?

Site Neutrality and the Legal Battle to Stop Its Implementation

BY LAURA FRYAN & NICK KOPCHO

In November 2018, the Centers for Medicare and Medicaid finalized several changes to the Medicare Hospital Outpatient Prospective Payment System (OPPS) that will greatly affect providers throughout 2019 and beyond. One of the most important changes is referred to as "site neutrality." This article will discuss site neutrality, the implications of this radical change in CMS policy, and the ongoing lawsuit that ensued after the final rule was published.

Provider-based status is a Medicare payment designation that allows physician offices that are integrated with a hospital to bill Medicare as a hospital outpatient department and thereby receive higher payments. CMS previously championed provider-based facilities as offering important potential benefits, such as increased beneficiary access and integration of care, which may improve quality of care. By contrast, a freestanding facility, like a physician office, furnishes services to Medicare beneficiaries, but not in connection with a hospital. Medicare pays for physician services provided in freestanding facilities using the Medicare Physician Fee Schedule (MPFS). Under the MPFS, CMS reimburses the provider for the cost of the physician service (i.e., the professional component) and the operational expense for the facility, such as the cost of equipment and overhead (i.e., the facility component). In contrast, a provider-based facility, which operates under the ownership, administrative, and financial control of a hospital, bills as an outpatient department of the hospital under the OPPS. Provider-based facilities may be on campus (within 250 yards of the main buildings of the main provider) or off campus (more than 250 yards but less than or equal to 35 miles from the main buildings of the main provider).

Traditionally, under CMS's provider-based rules, qualifying off-campus physician offices have been able to bill for clinic visits and other services at the higher OPPS rate, whereas a freestanding facility bills for the same clinic visit at the lower MPFS rate. The final 2019 OPPS rule will effectively lower the payment for clinic visits at such off-campus physician offices to the equivalent payment under the MPFS. The affected clinic visit code, HCPCS code G0463 (hospital outpatient clinic visit for assessment and management of a patient), is the most common service billed under OPPS. In 2019, CMS will reimburse clinic visits at 70% of the OPPS rate. In 2020 and beyond, CMS will reimburse clinic visits at 40% of the OPPS rate. Currently, the OPPS rate for a clinic visit is approximately $116 with $23 being the average beneficiary copayment. The adjustment down to the MPFS equivalent rate in 2020 will reduce the payment to $46 and a beneficiary copayment of $9. This is what is referred to as site neutrality, signifying that the provider-based physician offices that previously could bill a higher payment rate for clinic visits will no longer enjoy this privilege.

This represents a continuing, systematic reversal of policy at CMS. The 2015 Bipartisan Budget Act effectively quashed the expansion of off-campus provider-based departments by providing that only those off-campus provider-based facilities that billed for provider-based services before November 2, 2015, would continue to receive the higher provider-based payment after January 1, 2017. These grandfathered provider-based departments are referred to as "excepted" off-campus provider-based departments. CMS then proposed site neutrality for the 2017 OPPS rule, but did not finalize this proposal. This time, in the 2019 OPPS rule, providers are facing the inevitable implementation of site neutrality. CMS is unabashed about its move to promote site neutrality between hospitals and other outpatient facilities to encourage services to shift from a hospital setting to a lower cost setting like an ASC.

On December 4, 2018, in order to stop the implementation of site neutrality, the American Hospital Association, a national advocate for nearly 5,000 hospitals, health care systems, networks and other providers of care; the Association of American Medical Colleges which is comprised of all 152 accredited U.S. and 17 accredited Canadian medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic societies; and hospitals in Michigan, Maine, and Washington filed a lawsuit against Alex M. Azar II, in his official capacity as Secretary of Health and Human Services.

The lawsuit asserts that Congress laid out a clear distinction between excepted off-campus provider-based departments, which meet the specified grandfathering requirements mentioned above, and non-excepted off-campus provider-based departments, and that 42 U.S.C. §1395l(t)(21)(C) makes clear that services provided at excepted and non-excepted off-campus provider-based departments should be paid pursuant to different payment systems. But, despite these statutes, the 2019 OPPS Final Rule effectively abolishes any distinction between excepted and non-excepted entities by subjecting them both to the same payment system and rate.

The lawsuit supports its argument against the site-neutrality rule by noting that Congress previously established a structure for CMS to make annual Medicare payment changes for hospital outpatient covered services. The Medicare statute authorizes CMS, on an annual basis, to review and revise the "groups, the relative payment weights, and the wage and other adjustments ... to take into account changes in medical practice, changes in technology, the

addition of new services, new cost data, and other relevant information and factors." See 42 U.S.C. §1395l(t)(9)(A). But the statute also includes the critical requirement that any such adjustments be budget neutral. See 42 U.S.C. §1395l(t)(9)(B). Specifically, CMS may not reduce Medicare Part B spending by selectively slashing the payment rates for specific types of services.

If CMS wishes to make non-budget-neutral cuts to payments under the OPPS, the statute also provides a separate mechanism for the agency to do so. First, CMS must "develop a method for controlling unnecessary increases in the volume of covered [hospital outpatient department] services." See 42 U.S.C. §1395l(t)(2)(F). Once the method is identified, CMS can make non-budget-neutral adjustments to address those unnecessary increases in volume — but only through across-the-board adjustments to all items or services paid under the OPPS. Specifically, if CMS determines that the "volume of services ... [has] increased beyond amounts established through those methodologies," CMS "may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year." See 42 U.S.C. §1395l(t)(9)(C).

CMS, however, failed to follow the requirements in these statutes as the 2019 Final Rule purports to do precisely what Congress expressly prohibited: CMS seeks to reduce total payments for covered hospital outpatient services for 2019 by hundreds of millions of dollars by targeting a select group of services for non-budget neutral payment adjustments. If CMS wants to make cuts to payment rates in order to control unnecessary increases in the volume of hospital services, it must do so across the board, to all services and items under the OPPS, by using the conversion factor. If CMS instead wants to make adjustments to payment rates for specific services, it must do so in a budget-neutral manner.

In sum, the lawsuit alleges that CMS has acted in clear violation of its statutory authority for two separate reasons: (i) the site neutral policy violates the Medicare statute's mandate of budget neutrality; and (ii) the site neutral policy violates the statutory mandate that excepted and non-excepted provider-based departments must be treated differently. The plaintiffs are seeking an order for preliminary and permanent injunctive relief vacating and barring CMS from enforcing the changes made to the OPPS for 2019, requiring CMS to conform its payment policies and conduct to the requirements of the Medicare Act, and ordering that CMS provide immediate payment of any amounts improperly withheld as a result of the unauthorized conduct described above.

Site neutrality represents a drastic change in policy for CMS and significantly slashes payments to hospitals with grandfathered off-campus provider-based departments. The implication of site neutrality is that hospitals will no longer receive much of an added benefit from a reimbursement perspective for services at an off-campus provider-based department. As CMS now attempts to drive business away from hospital-owned locations to freestanding facilities, the lawsuit against CMS demonstrates that providers will fight back to stop the implementation of ill-conceived policies like site neutrality. The lawsuit also has broader implications regarding CMS' authority to make payment adjustments, and it remains to be seen how the court addresses this far-reaching issue.

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