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New Developments in Part D Vaccine Administration and Access

BY WENDY KRASNER AND SUSAN INGARGIOLA

The Centers for Medicare & Medicaid Services (“CMS”) was hard at work as 2006 drew to a close implementing changes made by Congress that would allow for payment of Part D vaccine administration under Medicare Part B in 2007. This move addressed a problem that has been plaguing the Medicare drug benefit since its inception one year ago: how to ensure beneficiary access to Part D vaccines in the absence of a clear mechanism to reimburse providers for the time and effort involved in administering such vaccines.

Just before wrapping up its 109th session, Congress passed the Tax Relief and Healthcare Act (TRHCA),¹ which included a provision to ensure that providers are reimbursed for administering Part D vaccines under Part B in 2007 and under Part D in 2008 and thereafter. Congress’ move represents what some perceive as the first significant change to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”).²

¹ Pub. L. No. 109-432

² Pub. L. No. 108-173, codified at 1860D of the Social Security Act, 42 U.S.C. § 1302, 1395w-101 through 1395w-152.

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The Problem

The problem Congress tackled derived from the fact that Medicare Part D is an outpatient drug benefit, meaning that most medicines covered under Part D are available to patients at pharmacies. Vaccines, in contrast, are typically purchased by a physician and administered in the physician’s office. Prior to passage of the MMA, Medicare only covered vaccines that were statutorily-mandated (pneumococcal, influenza, and hepatitis B) and others that were required for the treatment of illness and injury. The program did so under Part B, providing reimbursement to the physician for the vaccine itself and for its administration.

In an effort to expand access to preventive therapies, Congress expressly listed vaccines as covered Part D drugs when it created the new Part D drug benefit. In implementing Part D, however, CMS was unable either to establish a broad enough definition of dispensing fee to accommodate vaccine administration or to reconcile conflicting payment rules that it interpreted as preventing reimbursement for vaccine administration under either Medicare Parts B or D.

Background

Recognizing that the lack of an administration fee for vaccines could lead to diminished access to these important therapies for patients, CMS initially set out in the Part D final rule a policy that allowed for administration fees to be payable under Part B, noting that, “costs of vaccine administration may be included in physician fees under Part B since Part B pays for the

medically necessary administration of non-covered drugs and biologicals.”³

However, after determining that Medicare Part B rules that base payment on whether a medication is reasonable and necessary for the diagnosis or treatment of an illness or injury preclude payment for administration of Part D *preventive* therapies like vaccines, CMS retreated from its initial policy in May 2006. CMS had previously dispelled ideas that provider administration fees could be bundled into the Part D dispensing fee, citing the narrow definition of dispensing fee put forth in the final rule.⁴

Thus, physicians and pharmacies that administer vaccines found themselves with few options for obtaining reimbursement for this important service and Medicare Part D enrollees were left to suffer the results of this of this impediment to access.

Congress Steps In

Frustrated at the lack of reimbursement for vaccine administration under either Medicare Parts B or D, Congress included the following provision in the TRHCA:

SEC. 202. PAYMENT FOR ADMINISTRATION OF PART D VACCINES. (a) Transition for 2007—Notwithstanding any other provision of law, in the case of a vaccine that is a covered Part D drug under section 1860D-2(e) of the Social Security Act (42 U.S.C. 1395w-102(e)) and that is administered during 2007, the administration of such vaccine shall be paid under part B of title XVIII of such Act as if it were the administration of a vaccine described in section 1861(s)(10)(B) of such Act (42 U.S.C. 1395w(s)(10)(B)).

(b) Administration Included in Coverage of Covered Part D Drugs Beginning in 2008- Section 1860D-2(e)(1) of the Social Security Act (42 U.S.C. 1395w-102(e)(1)) is amended, in the matter following subparagraph (B), by inserting “(and, for vaccines administered on or after January 1, 2008, its administration)” after “Public Health Service Act”.

CMS Administration Fee Implementation Efforts for Benefit Year 2007⁵

CMS has already taken a number of steps to implement the new administration fee payment requirements, which took effect on January 1, 2007, including creating a new G Code (G0377: Administration of vaccine for Part D drug) to facilitate the billing and reimbursement of physician vaccine administration. CMS has also directed Medicare contractors to permit payment to Medicare-enrolled pharmacies under Part B for administration of a Part D-covered vaccine. The Part B allowable charge for G0377, effective for 2007, is \$19.33. Thus the Medicare payment is 80 percent of that

amount or \$15.46, assuming the beneficiary’s Part D deductible is met. The beneficiary pays \$3.87 as a coinsurance payment, plus any Part D deductible payment that may be due. To communicate these changes to physicians and other providers who bill Medicare contractors for services, CMS has issued a number of Medicare Learning Network (MLN) Matters articles as of January 4, 2007.

Other Part D Vaccine Access Issues

In addition to the lack of an administration fee prior to January 1, 2007, access to Part D vaccines administered in a physician’s office has also been impeded by the fact that stand-alone Part D plans do not contract directly with physicians. This means that there is no real-time billing mechanism in place to allow patients to pay only their required cost-share upon receipt/administration of a Part D vaccine. Instead, they are typically required to pay the full cost of the vaccine upfront. They then have to submit a paper claim to their Part D plan to receive reimbursement for the cost of the vaccine.

Acknowledging that its use of this out-of-network procedure was burdensome to patients, CMS outlined a number of in-network and “facilitated out-of-network” approaches in May 2006 that plans could implement, including one in which physicians would electronically bill, in real-time, Part D plans using a commercially-developed web-based system.⁶ CMS continues to work with Part D plans and physicians to implement strategies that allow patients to pay only their applicable cost-share when accessing Part D vaccines in the physician office.

CMS Administration Fee Implementation Efforts for Benefit Year 2008

Clearly, CMS has acted swiftly to ensure that, for 2007, beneficiary access to Part D vaccines is no longer impeded by the lack of a provider administration fee. However, the challenge of implementing Subsection (b) of Section 202 of the TRHCA, which includes vaccines under the definition of “covered Part D drug” as of January 1, 2008, looms large.

Among other open issues, CMS will have to consider the following: 1) Exactly how to structure guidelines on the payment of these fees from Part D plans to providers and on the reporting requirements applicable to such payments; 2) Whether Part D plans will have complete discretion in setting fee rates or whether Medicare will have to play a role since Part D plans do not negotiate with physicians; and 3) Whether providers can wave a beneficiary’s cost-share.

There is also the question of timing, as CMS will have to give Part D plans guidance, perhaps through an expedited rulemaking, in time for them to include projected costs for vaccine administration in their Part D

³ 70 Fed. Reg. 4194, 4231.

⁴ See May 8, 2006 CMS memorandum to Part D plans from Abby L. Block, Director of CMS’ Center for Beneficiary Choices regarding “Increasing Part D Vaccine Access.” Accessible at http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/MemoVaccineAccess_05.08.06.pdf.

⁵ See CMS Change Request 5443, 5459, and 5486 Accessible at <http://www.cms.hhs.gov/Transmittals/downloads/R2580TN.pdf>. See also Medicare Learning Network Articles 5443 and 5459 Accessible at <http://www.cms.hhs.gov/MLNMattersArticles/2006MMAN/List.asp#TopOfPage>

⁶ See May 8, 2006 CMS memorandum to Part D plans from Abby L. Block, Director of CMS’ Center for Beneficiary Choices regarding “Increasing Part D Vaccine Access.” Accessible at http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/MemoVaccineAccess_05.08.06.pdf CMS also proposed a number of other options to improve patient access to vaccines, including what it called the “in-network specialty pharmacy distribution” option, the “in-network retail pharmacy access” option, and the “model vaccine notice for physicians” option.

bids due later this spring. At the same time, Part D plans will likely be expanding their coverage of vaccines on their Part D formularies, a result of the U.S. Pharmacopeia proposal to classify each type of Part D vaccine as a separate Formulary Key Drug Type (“FKDT”) in the draft Medicare Model Guidelines Version 3.0, applicable to benefit year 2008. All Part D plans must include at least one drug per FKDT in their formularies.

Longer-Term Implications

Perhaps the most important implication of Congress’ move to pay for vaccine administration fees under Part D beginning in 2008 will be the precedent it may set for covering, under Part D, drugs currently covered under Part B and typically administered in a physician office.

The issue of a transition of Part B drugs to Part D was first raised upon passage of the MMA, which included a provision at Section 1860D-42 requiring the Secretary to study the option of transitioning outpatient drug coverage in Part B to Part D and to report to Congress on

the feasibility of that transition. Secretary Leavitt delivered the report prior to the January 2005 deadline, finding that such a change would not be desirable for most categories of Part B drugs, but may be worth considering for a limited number of categories.⁷

Indeed, the B and D drug overlap issues have been some of the most complex and confusing raised during the first year of implementation. Recently, some Part D plans have even reportedly requested that CMS transition all Part B drugs to Part D in an effort to streamline the overlap difficulties.

Given this interest, the system CMS puts in place to pay for vaccine administration fees under Part D could serve as a model for implementing a Part B to Part D switch. Surely, stakeholders will be watching this one closely.

⁷ “Report to Congress: Transitioning Medicare Part B Covered Drugs to Part D,” Michael Leavitt, Secretary of Health and Human Services, 2005. Accessible at <http://www.npaf.org/pdf/cmsspartBreport.pdf>.