Vial Electronic Mail

December 20, 2016

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Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Room 5309
Washington D.C. 20201

RE: **2017 Durable Medical Equipment Fee Schedules**

Dear Ms. Hoffman:

We have become aware of a significant discrepancy in the way the Centers for Medicare and Medicaid Services (CMS) calculated the 2017 fee schedules for stationary oxygen. We are compelled to bring this issue to your attention. The Agency incorrectly applied a budget neutrality "offset" to the 2017 rural fee schedules for stationary oxygen equipment. The result is that the 2017 rates for oxygen concentrators coded under E1390 in rural areas are now well below the regional competitive bidding rates from which they were derived. This outcome is inconsistent with the laws and regulations that govern Medicare reimbursement for oxygen and oxygen equipment.

CMS adopted this offset in 2006 as part of a decision to pay more for so called oxygen generating portable equipment (OGPE) than it would for traditional portable equipment.[1] In turn, CMS decreased the payment for stationary oxygen equipment. CMS reasoned the offset was necessary to keep changes in overall oxygen payments budget neutral consistent with the statute authorizing Medicare to pay for different categories of oxygen equipment.[2] It was designed to account for higher expenditures for OGPEs as more beneficiaries used that technology.

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[1] 42 CFR § 414.226

[2] 42 USC § 1395m (a) (9) (D) (ii)

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By its terms, the regulation establishing the offset for E1390 concentrators applies to the unadjusted fee schedules under the fee schedule methodology mandated by Congress under § 1834 (a) of the Social Security Act (SSA).[3] In contrast, the 2017 fee schedules for concentrators in rural areas are based on information from competitive bidding programs under the methodology in 42 CFR § 414.210 (g). These two regulations, § 414.226 and § 414.210 (g), describe different reimbursement methodologies that do not overlap. Section 414.226 applies to fee schedules based on suppliers' *reasonable charges* from 1986 to 1987. Section 414.210 (g) applies to fee schedules based *on regional average special payments amounts* (SPAs) from competitive bidding areas (CBAs).

We discuss our concerns in more detail below.

I. The budget neutrality offset for E1390 concentrators applies only to oxygen payment amounts computed from suppliers' reasonable charges as described § 1834(a) (5) and (9) of the SSA.

By way of background, Medicare makes one monthly bundled fee schedule payment for oxygen and oxygen equipment. This means that payment for oxygen contents is bundled with the payment for oxygen equipment and supplies. Congress adopted the oxygen fee schedule methodology under § 1834(a) of the SSA in 1989. Fee schedules were based on suppliers' *reasonable charges* for oxygen and oxygen equipment during the base year 1986-1987. For years after 1992, §§ 1834a (5) and (9) stipulate that the monthly payment amount for oxygen and oxygen equipment is the "*national limited payment rate*" determined by § 1834a (9) (B).[4] Congress has the power to adjust fee schedules up or down annually. If Congress does not act, updates to the fee schedules, known as the covered item update, equal the increase or decrease in the consumer price index (CPI) for the preceding year.

The fee schedule payment under §§ 1834a (9) is also "modality neutral," meaning that the bundled fee schedule rate is the same without regard to the "modality" of the oxygen a beneficiary receives. Suppliers receive the same payment for the stationary system whether the system is a concentrator or a liquid or gas system that requires oxygen "refills." They also receive an "add-on" payment for portable equipment.[5] Portable equipment requires content refills which can also be either liquid or gaseous oxygen. Of the three stationary systems, concentrators have been somewhat more cost effective for suppliers because they do not require costly deliveries of content refills.

In 1997, under the Balanced Budget Act, Congress authorized CMS to pay different amounts for different categories of oxygen equipment as long as the payment changes were budget neutral.[6] CMS implemented this authority in 2006, establishing new payment rules that would pay more for some oxygen equipment than others. The rules, codified under § 414.226, provide for higher payment rates for OGPE and offsets the higher rates by a payment reduction for stationary systems to maintain budget neutrality for oxygen payments overall.

Section 414.226 establishes a rate for all stationary systems with add-on payments depending on the type of equipment. Under the new rules, stationary systems that were OGPE received a higher add-on than traditional stationary equipment because OGPEs are capable of producing refills for portable equipment. CMS intended for the higher payment to compensate suppliers for the acquisition costs of OGPEs which

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[3] 42 USC § 1395m; 42 CFR § 41.226 (c)
[4] §1395m (a) (9) (C) (iv)
[5] § 1395m (a) (5) (B)
[6] § 1393m (a) (9) (D)

are more expensive for suppliers to buy than traditional concentrators. One assumption underlying §414.226 was that OGPEs would prove more cost effective over the long term for suppliers by eliminating costly home deliveries, so over time more beneficiaries would migrate to these devices.

Beginning in 2007, § 414.226 required CMS to determine *national monthly limited payment rates* for separate classes of oxygen equipment."[7] And the rules state that fee schedules for stationary systems are subject to annual payment reductions to ensure budget neutrality for oxygen payments.[8]

The regulation itself supports the conclusion that the budget neutrality applies only to charge based reimbursement under § 1834 (a). First, § 414.226 (c) (2) states:

> The rate for items described in paragraph (c)(1)(i) [stationary equipment] of this section is equal to the weighted average fee schedule amount established under paragraph (b)(5) of this section reduced by $1.44.[9]

Next, cross references to § 414.226 (b) (5) refers to the national limited payment amount computations stipulated by Congress under § 1834 (a). Section 414.226 (b) (5) cross references § 414.226 (b) (4) which in turn cross references 42 CFR § 414.220 (d), (e) and (f). Section 414.220 describes the national limited payment amount computations required under § 1834 (a). Paragraph 414.220 (d) describes the covered item update for years following 1990. Section 414.220 (e) explicitly states that fee schedule amounts after 1990 are equal to the national limited payment amount:

> (e) Calculating the fee schedule amounts for years after 1990. For years *after 1990*, the *fee schedule amounts* are *equal* to *the national limited payment amount*.

Section 414.220 (f) also describes the computations for determining national limited payment amounts:

> (4) For 1994 and subsequent years, the national limited payment amount is equal to one of the following:(i) If the local payment amount is not in excess of the median, nor less than 85 percent of the median, of all local payment amounts—100 percent of the local payment amount.(ii) If the local payment amount exceeds the median—100 percent of the median of all local payment amounts.(iii) If the local payment amount is less than 85 percent of the median—85 percent of the median of all local payment amounts.[10]

Importantly, the computation formula under § 414.220 (f) matches up with the formula for computing national limited payment amounts under § 1834 (a) (9) (B):

> (B) Computation of national limited monthly payment rate. With respect to the furnishing of an item in a year, the Secretary shall compute a national limited monthly payment rate equal to—
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> > (iii) for 1994, the local monthly payment rate computed under subparagraph (A)(ii) for the item for the year, except that such national

[7] § 414.226 (c) (1) (i) through (v)
[8] § 414.226 (c) (2)
[9] *Ibid*.
[10] § 414.2220 (e) and (d).

> limited monthly payment rate may not exceed 100 percent of the median of all local monthly payment rates computed for the item under such subparagraph for the year and may not be less than 85 percent of the median of all local monthly payment rates computed for the item . . . for the year[11]

Finally, to ensure budget neutrality from year to year, § 414.226 (c) (6) requires CMS to adjust the national limited monthly fee schedules for stationary equipment annually:

> (6) Beginning in 2008, CMS makes an annual *adjustment to the national limited monthly payment rate* for items described in paragraph (c)(1)(i) of this section to ensure that such payment rates do not result in expenditures for any year that are more or less than the expenditures that would have been made if such classes had not been established.[12]

Read together, the provisions of §§ 414.226 (b) and (c) and §§ 414.220 (d), (e), and (f) follow the rules for computing the Medicare oxygen fee schedule amounts Congress established under § 1834 (a). The annual budget neutrality reduction for stationary equipment under § 414.226 (c) (2) applies only to the national limited payment amount for oxygen and oxygen equipment which are based on suppliers' reasonable charges from 1986 through 1987.

II. **The 2017 fee schedules for areas outside CBAs are not based on suppliers' reasonable charges.**

The 2017 fee schedules for areas outside CBAs are computed from regional competitive bidding SPAs derived from suppliers' bids for the classes of oxygen equipment described under § 414.226.

The budget neutrality reduction under § 414.226 for stationary equipment does not apply to payment amounts based on a competitive bidding payment methodology.

Congress added a competitive bidding payment methodology for determining DME reimbursement under the Medicare Modernization Act of 2003.[13] Contrary to the fee schedules Congress established under §1834 (a), competitive bidding SPAs are not based on supplier's reasonable charges. The SPAs are based instead on suppliers' *bids* to furnish DME items to Medicare beneficiaries, including the classes of oxygen equipment described under § 414.226.[14] Congress adopted competitive bidding on the assumption that a methodology presumably based on "market" forces would generate savings for Medicare compared to fee schedules based on suppliers' charges which were widely viewed as "inherently inflationary."

Under competitive bidding, CMS solicits suppliers' bids for Medicare covered items identified by their applicable HCPCS code. CMS converts the bids for individual items to a "composite bid" for items in a

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[11] § 1395m (a) (9) (B) (iii).

[12] § 414.226 (c) (6).

[13] 42 USC 1395w-3

[14] 42 CFR § 414. 408 (1) states:

> Monthly payment amounts for oxygen and oxygen equipment.
> (1) Basic payment amount. Subject to the provisions of paragraph (i)(2) of this section, *the single payment amounts for oxygen and oxygen equipment are calculated based on the bids submitted and accepted* for the furnishing on a monthly basis of each of the five classes of oxygen and oxygen equipment described in § 414.226(c)(1).

product category then arrays them from lowest to highest.[15] Then CMS determines how many suppliers must win to maintain access for beneficiaries in a CBA. The bid point where access and price intersect is the pivotal bid. CMS awards contracts to suppliers that bid at or below the pivotal and otherwise meet supplier standards. CMS calculates the SPA as the median between the pivotal and lowest bids.[16]

Congress recognized that a methodology using SPAs to determine DME payment amounts was fundamentally different from a methodology that based payment on suppliers' charges. So Congress amended § 1834 (a) (1) by adding paragraphs (F) and (G) authorizing CMS to deviate from a reasonable charges methodology and use instead one that computes payment rates using "information" from competitive bidding programs beginning in 2016.[17] CMS also recognized the fundamental distinction between charged based and "market" based reimbursement in rules promulgated to implement § 1834 (a) (1) (F) and (G). CMS distinguished fee schedules based on SPAs from charge based fee schedules under § 1834 (a), defining the former as the "adjusted" fee schedules.

The new rules abandon fee schedules based on charge data and replace them with adjusted fee schedules derived from SPAs for items in in regional CBAs. CMS determines a regional price for each state in the contiguous United States equal to the un-weighted average SPA for the item, subject to national floors and ceilings.[18] The rules modify this methodology for areas outside CBAs that are not part of the contiguous United States, for products and services for which there is limited competitive bidding data, and other items specifically described in the rule.[19] Finally, unlike the "unadjusted" fee schedules for stationary equipment under § 414.226 which must be updated annually, CMS will update adjusted fee schedules only when new SPA data for a region become available.[20]

III. Applying a payment reduction designed for fee schedules based on suppliers' reasonable charges to adjusted fee schedules derived from SPAs results in payment amounts for E1390 concentrators that are well below the SPAs on which they are based.

As we discussed above unadjusted fee schedules derived from reasonable charge data are fundamentally different from and incompatible with the adjusted fee schedules derived from "market" based SPAs. These two payment methodologies are as different as apples and oranges and cannot be combined. But in computing the 2017 adjusted fee schedules for areas outside CBAs, CMS did just that. That is, CMS applied the budget neutrality adjustment for stationary equipment reimbursable under the unadjusted charge based fee schedules to the adjusted fee schedules based on SPAs from regional CBAs, resulting in extraordinary payment reductions in the 2017 adjusted fee schedule payment for E1390. Imposing this additional reduction on top of already significantly reduced adjusted fee schedule rates is akin to "double dipping" payment reductions. The chart below shows the impact of these reductions on 2017 adjusted payment rates for E1390**.**

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[15] *Ibid.*
[16] 42 § 414.416
[17] 42 CFR § 1395m (F) and (G).
[18] 42 CFR § 414.210 (g) (1).
[19] *S*ee 42 CFR § 414.210 (g)
[20] 42 CFR § 414.210 (g) (8), *Updating adjusted fee schedules*.

CBA ROUND	CBA REGION	HCPCS CODE	CBA RATE	1.1.2017 RURAL RATE	% DIFFERENCE
Round 1 2017	Miami-Fort Lauderdale-West Palm Beach, FL	E1390	$90.01	$77.16	-14.28%
Round 2 Recompete	Birmingham-Hoover, AL	E1390	$89.86	$77.16	-14.13%
Round 2 Recompete	Knoxville, TN	E1390	$87.00	$77.16	-11.31%
Round 2 Recompete	Raleigh, NC	E1390	$86.84	$77.16	-11.15%
Round 2 Recompete	Asheville, NC	E1390	$86.84	$77.16	-11.15%
Round 2 Recompete	Memphis, TN	E1390	$86.84	$77.16	-11.15%
Round 2 Recompete	Nashville-Davidson--Murfreesboro--Franklin, TN	E1390	$86.84	$77.16	-11.15%
Round 2 Recompete	Chattanooga, TN	E1390	$86.17	$77.16	-10.46%
Round 2 Recompete	Albuquerque, NM	E1390	$86.09	$77.16	-10.37%

Congress recognized the fundamental differences between these two methodologies by creating *new* authority under § 1395w-3 for competitive bidding programs. And it took advantage of competitive bidding rates in areas outside CBAs by authorizing CMS to establish new adjusted fee schedules based solely on data from competitive bidding SPAs. CMS has likewise understood at least implicitly that the methodologies for the adjusted and unadjusted fee schedules are so different the Agency cannot superimpose the elements of one on the other. From the inception of the competitive bidding program, which the Agency itself designed, CMS has not ever applied the charge based budget neutrality reduction for stationary equipment under § 414.226 to competitive bidding SPAs for stationary oxygen equipment. The Agency's rational for applying those budget neutrality adjustments to the 2017 adjusted fee schedule for stationary equipment is unclear.

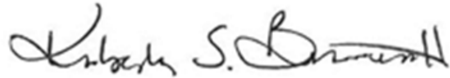
The regulatory history of the rules CMS promulgated to implement these two different payment authorities also strongly support our conclusion that a budget neutrality adjustment for stationary oxygen equipment cannot be applied to the adjusted fee schedules for stationary equipment. CMS promulgated § 414.210 (g) in 2014, well after the 2006 implementation date of § 414.226. But § 414.210 (g) does not cross reference § 414.226 except to identify the five classes of oxygen equipment that rule establishes. And it is evident from each rule's language that they apply to payment rates determined under their respective methodologies. Aside from extensive references to the national limited payment amount under § 414.226 and to competitive bidding SPAS under § 414.210 (g), the rules specify different time frames for updating fee schedules. The former specifies annual updates to ensure budget neutrality of payment changes for oxygen equipment whereas the latter requires payment updates when new SPA data from regional CBAs are available.

IV. Medicare improperly reduced payments for E1390 concentrators under the 2017 adjusted fee schedules by applying a budget neutrality offset intended to apply only to the charge based unadjusted fee schedules. The 2017 adjusted fee schedule payments for stationary oxygen equipment must follow the requirements of § 414.210 (g).

In conclusion, we reiterate that 2017 payment rates for stationary oxygen under the adjusted fee schedules include payment reductions intended for payment updates under charged based fee schedules. *only*. CMS cannot apply elements of a charged based methodology to payments rates determined by "market" forces. We request that CMS recalculate these rates consistent with the requirements of § 414. 210 (g). Given the approaching January 1, 2017 effective date for the new fee schedules, this issue urgently concerns AAHomecare members.

Thank you for considering this very important issue. I will call you next week to follow-up on a resolution.

Sincerely,



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