



Via email to secretary@hhs.gov

February 28, 2017

The Honorable Tom Price, MD
Secretary
The U.S. Department of Health and Human Services
200 Independence Avenue, S. W.
Washington, D. C. 20201

RE: REGULATORY MODIFICATIONS TO DMEPOS ADJUSTED FEE SCHEDULES

Dear Secretary Price:

On behalf of American Association for Homecare (AAHomecare), I respectfully request that you review the current policies related to the Medicare benefit for Durable Medical Equipment (DME) and take action to make changes to ensure beneficiaries have access to this cost-effective mode of care.

Suppliers and Medicare beneficiaries have seen business disruptions, interruptions in continuity of care, and barriers to access DME items resulting from the inherently flawed competitive bidding (CB) program. Adjusted fee schedules in non-competitive bid areas, which are based on single payment amounts (SPAs) from competitive bidding areas (CBAs), are as much as 74% below unadjusted fee schedule rates for the same items. The unprecedented magnitude of these cuts and the short lead time the Centers for Medicare and Medicaid Service (CMS) gave suppliers to adapt to them has begun to erode access to DME for beneficiaries living in non-CBAs.

This is the first of two letters the Association will submit to the Department of Health and Human Services (HHS) regarding CMS' CB program for DME and the Agency's application of those rates to DME items in areas outside CBAs. In this letter, I request for you to take immediate action to provide relief to DME providers and patients in non-CBAs, which have experienced dramatic reimbursement cuts over a short 6-month period.

AAHomecare will submit to HHS a second letter that analyzes critical design flaws in the CB program, highlights its disruptive effects on suppliers and beneficiaries, and proposes ways the Agency can adjust the program to resolve these fundamental weaknesses.

I would like to emphasize that AAHomecare supports a well-designed, market-driven Medicare CB program; one that results in true competition and that does not restrict beneficiaries' access to the equipment, supplies, and services they need. The Association appreciates the opportunity to submit this information and we look forward to working with you to address problems with the current DME Medicare benefit.

EXECUTIVE SUMMARY

The statute authorizing CMS to establish adjusted fee schedules explicitly required CMS to consider the costs of furnishing durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) in non-CBAs. CMS did not follow this mandate, stating it lacked evidence to support that any differences exist in the costs of furnishing DMEPOS in CBAs and non-CBAs.¹ As a result, adjusted fee schedule rates for DMEPOS are as much as 74% below unadjusted rates for the same item. Furthermore, CMS gave suppliers only six months to phase-in the new rates, disrupting suppliers' ability to serve beneficiaries in non-CBAs, and leaving beneficiaries who need equipment and supply items to face a looming crisis in access to DMEPOS.

Congress intervened to slow the transition to the new rates under the 21st Century Cures Act (Cures Act),² but the intervention does not fully address the long-term effects of unsustainably low reimbursement on suppliers and beneficiaries in non-CBAs. The Secretary, however, has an opportunity to correct the procedural and substantive deficiencies in the methodology CMS used to adopt the new rates. The President recently signed two executive orders directing agencies to carefully review pending and new regulations before giving them effect.³ These directives align with the Administration's policy of ensuring that regulations are not so burdensome they hinder businesses' ability to create and sustain jobs, and by extension, in this context, diminish access for beneficiaries in need of care.

The orders also direct agencies to eliminate "existing costs associated with prior regulations" following the requirements of the Administrative Procedure Act (APA)⁴ which we interpret to include the full array of tools available to agencies under the APA. AAHomecare believes the Secretary can use an interim final rule (IFR) to suspend or repeal application of adjusted fee schedules in non-CBAs and implement a fee schedule methodology informed by the reports on the impact of CB and adjusted rates that

¹ Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, 79 FR 66229 (November 6, 2014).

² Extension of the Transition to New Payment Rates For Durable Medical Equipment under the Medicare Program, § 16007, Cures Act, PL 114-255, December 13, 2016.

³ Executive Order 13771, *Reducing Regulation and Controlling Regulatory Costs*, 82 FR 9339 (February 3, 2017); Memorandum for the Heads of Executive Departments and Agencies Regulatory Freeze Pending Review, January 20, 2017, available at: <https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies>

⁴ 5 U.S.C. § 553.

Congress directed CMS to produce under the CB provisions of the Social Security Act (SSA) and its amendments.

RECOMMENDED CMS ACTION

AAHomecare recommends CMS use an IFR to revise 42 C.F.R. § 414.210(g) to repeal the full phase-in of the adjusted fee schedules in non-CBAs originally scheduled to take effect July 1, 2016, freeze the 50/50 blended rate which took effect on January 1, 2016, and amend the methodology for determining adjusted fee schedules. This action would be consistent with the Administration’s statement of regulatory policy and is necessary to stem the erosion of the DMEPOS benefit in non-CBAs.

I. Adjusted Fee Schedules

A. Legislative and Regulatory History for Adjusted Fee Schedules

1. The “Unadjusted” Fee Schedules

Congress adopted the DMEPOS fee schedule methodology under § 1834(a) of the SSA in 1987 (the “unadjusted fee schedules”).⁵ Unadjusted fee schedules were based on suppliers’ reasonable charges for furnishing DMEPOS during the base year 1986-1987 to ensure they captured suppliers’ costs of doing business with Medicare. Monthly unadjusted payment rates equal the “national limited payment rate” for the type of DMEPOS item. Congress has the power to adjust the rates 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 adjusted by a productivity factor.

2. Competitive Bidding Programs

The Medicare Modernization Act of 2003 (MMA) gave CMS new authority under § 1847 of the SSA to use a CB methodology for paying for DMEPOS.⁶ The MMA directed CMS to phase-in the program starting with the ten largest metropolitan and statistical areas (MSAs) in 2007, followed by 91 of the largest MSAs in 2011.⁷ Unlike unadjusted fee schedules under § 1834(a), CB SPAs are based on suppliers’ bids to furnish DME items to Medicare beneficiaries in a CBA. SPAs, arguably, should reflect suppliers’ cost of doing business in a CBA. However, CMS’ program design systematically skews bid pricing downwards, making SPAs poor proxies for the costs of furnishing DMEPOS to beneficiaries.

CMS calculates SPAs by first soliciting suppliers’ bids for Medicare-covered items identified by their applicable HCPCS code. Then the Agency converts the bids for individual items to a “composite bid” for

⁵ Omnibus Budget Reconciliation Act of 1987 (OBRA), PL 100-203 (1987).

⁶ PL 108-173 (2003); 42 U.S.C. § 1395w-3

⁷ 42 U.S.C. § 1395w-3, amended by § 154 of the Medicare Improvements and Patient Protection Act of 2008 (MIPPA), (Pub. L. 110-275) and § 6410(a) of the Affordable Care Act, PL 111-148 (2010)

items in a product category and arrays bids from the lowest to the highest bid.⁸ Next, CMS determines how many suppliers must win a contract to maintain access for beneficiaries in a CBA. The bid point where access and price intersect is the pivotal bid, or clearing price. Although CMS awards contracts to suppliers that bid at or below the pivotal bid, SPAs (the actual payment amount contracted suppliers receive) are below clearing prices because CMS established the SPA at the median of the pivotal and lowest bid.

This one design feature completely undermines the value of SPAs as proxies for suppliers' costs of furnishing DMEPOS in a CBA. Roughly half of the winning bidders receive less than their bid amounts; the other half receives more. Bidders whose bids established the clearing price must accept about 50% less than the price they estimated would cover their costs plus a profit margin. Bidders who bid below the median bid get a windfall – a contract that guarantees them reimbursement in excess of their low ball winning bid. AAHomecare membership informed us that the central *quid pro quo* of CB – lower Medicare reimbursement in exchange for higher patient volumes – has proved illusory at best.

3. The “Adjusted” Fee Schedules

Not all areas met the requirements for what constituted a CBA under the CB law, and some areas were statutorily excluded from the program altogether.⁹ To take advantage of the program's savings in areas outside CBAs still using unadjusted fee schedules, Congress amended § 1834(a), giving CMS authority to adjust DMEPOS payment rates in non-CBAs using “information” from CB programs.¹⁰ The statute directed CMS to promulgate regulations to specify how it would determine new rates and required CMS to consider the costs of furnishing DMEPOS in non-CBAs.¹¹

CMS promulgated rules to implement adjusted DMEPOS fee schedules in 2014.¹² The new rules abandoned unadjusted fee schedules and replaced them with adjusted payment rates using regional SPAs (RSPAs). Generally, adjusted fee schedule rates equal the weighted average RSPA for an item subject to national floors and ceilings. When fully implemented as of January 1, 2017, adjusted fee schedules represent payment cuts of as much as 74% below unadjusted fee schedules rates for a DMEPOS item.

The chart that follows on the next page shows the magnitude of these cuts on a number of CB items:

⁸ See 42 CFR §§ 414.400 -414.426.

⁹ 42 U.S.C. § 1395w-3 (a) (1) (D) (iii)

¹⁰ 42 U.S.C. § 1395m (a) (1) (F) (G).

¹¹ § 1395m (a) (1) (G) states in part:

In promulgating such regulation, the Secretary **shall** consider the costs of items and services in areas in which such provisions would be applied compared to the payment rates for such items and services in competitive acquisition areas.

¹² 42 CFR § 414.210 (g); Medicare Program; *End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies*, 79 FR 66120 (November 6, 2014).

REGION	HCPCS CODE	HCPCS DESCRIPTION	2015 FEE SCHEDULE	1/1/2017 AVERAGE NON-CBA RATE	2017 NON-CBA v 2015 FEE SCHEDULE
FAR WEST	E0277	LOW AIR LOSS MATTRESS	\$665.31	\$168.06	-74.70%
MIDEAST	K0003	MANUAL WHEELCHAIR LIGHT WEIGHT	\$93.40	\$30.05	-67.80%
NEW ENGLAND	K0001	MANUAL WHEELCHAIR STANDARD	\$56.58	\$20.05	-64.60%
ROCKY MTN	E2402	NPWT PUMP	\$1,642.09	\$587.93	-64.20%
PLAINS	E0601	CPAP	\$104.58	\$39.59	-62.10%
GREAT LAKES	E0470	RAD, BILEVEL	\$237.73	\$106.73	-55.10%
SOUTHEAST	A7034	PAP, MASK NASAL INTERFACE	\$112.53	\$54.47	-51.60%
SOUTHWEST	B4035	ENTERAL SUPPLY KIT, PUMP	\$11.95	\$5.18	-56.70%

B. Deficiencies In CMS' Rulemaking Procedures

Many of the decisions CMS made in establishing the adjusted fee schedules seemed designed to drive the new payment amounts downward. First, CMS interpreted statutory language authorizing the Agency to use "information" from CB to adjust rates as requiring it to use SPA data only. Many commenters objected to this decision, arguing that SPAs, as fashioned by CMS, skew bid prices downwards, encouraging low ball bidding. Because SPAs are lower than clearing prices, suppliers who submit very low bids are guaranteed to win, but these low-ball bidders can be reasonably sure the SPA will be higher than their bids.

CMS also did not consider the costs of servicing beneficiaries in non-CBAs, which are more rural and sparsely populated than CBAs. We believe this omission is a key flaw in the Agency's rulemaking. Although the proposed rule acknowledged that Congress required the Agency to consider the "costs of items and services" in non-CBAs, CMS did not follow the mandate. The Agency did not try to understand the demographic and economic conditions that distinguish one CBA from another, let alone non-CBAs from CBAs.

Asserting without any substantive discussion that there is no conclusive evidence to support that any cost differences exist, CMS used a 1996 Agency study to decide:

[T]here is no conclusive evidence that urban and rural costs differed significantly or that the cost of furnishing DME items and services were higher in urban versus rural areas or vice versa.¹³

Without *any* evidence beyond the 18-year old study, CMS concluded it did “not *believe*” the cost of furnishing DMEPOS outside CBAs would deviate significantly from a national average price based on SPAs, ignoring comments asking CMS to quantify price differences.¹⁴

The Agency’s Regulatory Flexibility Act (RFA) analysis also fell short of standards. CMS limited its RFA analysis to broad statements about the impact adjusted rates would have on a substantial number of small suppliers, but failed to substantiate any of its claims. Among other deficiencies, the Agency made no effort to quantify how many suppliers would be affected by the new rates or how the rates would affect suppliers. CMS also did not say whether it had considered less burdensome alternatives to provisions of the rule as the RFA requires. For example, CMS did not explain why the Agency chose to use RSPAs for the new fee schedules instead of clearing prices which would have resulted in higher reimbursement for suppliers.

C. Impact of The Unadjusted Fee Schedules

1. Supplier Closures

As noted in the chart above, adjusted rates for DMEPOS are as much as 74% below unadjusted fee schedule rates for the same item. These radical payment cuts have had almost immediate consequences for suppliers and beneficiaries in non-CBAs. Suppliers of all sizes have felt the effects of these unsustainably low rates. Our larger regional and national members report they have closed locations in more remote areas because they can no longer offset the costs of running remote facilities with revenue from their other branches. AAHomecare members also tell us that suppliers in non-CBAs have stopped furnishing some types of DMEPOS altogether.

It is still too soon to have accurate figures on suppliers’ sales and closures in response to the adjusted rates, but we know from CMS data that there are 38% fewer suppliers enrolled in Medicare today than there were in 2013.¹⁵ Given the unprecedented magnitude of the payment cuts under the adjusted rates, it is reasonable to expect a high rate of supplier attrition in non-CBAs if adjusted rates remain at current levels.

¹³ Medicare Program; *End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies*, 79 FR 40208 at 40279.

¹⁴ Medicare Program; *End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies*, 79 FR 66229 (November 6, 2014).

¹⁵ See CMS DMEPOS supplier directory, available at: <https://data.medicare.gov/data/supplier-directory>

2. Beneficiary Access

CMS maintains it lacks evidence of barriers to access for beneficiaries in non-CBAs, noting that assignment rates have remained stable since the program's inception.¹⁶ We believe CMS' analysis of the data is flawed. The Agency's assignment rate data from January 2016, and even data from later that year are incomplete because the data are mostly from the period before adjusted fee schedules became fully effective. Furthermore, assignment rates are a poor measure of access because the data are from submitted claims and, therefore, they do not show how many beneficiaries did not get a DMEPOS item they needed or who paid for DMEPOS without filing an unassigned claim. Although a key measure of access is whether beneficiaries receive DMEPOS they need on a timely basis, assignment rates do not capture how long beneficiaries waited to receive DMEPOS or the quality of the equipment, supplies, and services they received.

3. Dual Eligible Beneficiaries

Certain beneficiary populations already face hurdles in obtaining DMEPOS. Last year, in a request for information on coordinating DMEPOS care for dual eligible beneficiaries, CMS highlighted its concerns that dual eligible beneficiaries often are unable to access the DMEPOS items they need.¹⁷ In a 2015 report, the Agency raised its concerns that qualified Medicare beneficiaries (QMBs) face even bigger hurdles in accessing DMEPOS because states limit Medicaid reimbursement for their copays and deductibles when Medicare is the primary payer.¹⁸ The law also prohibits suppliers from balance billing QMBs, leading CMS to conclude that QMBs are likely to forego treatment with DMEPOS altogether.

This conclusion presents important public health and fiscal policy concerns. The DMEPOS benefit is the primary chronic care benefit for Medicare and Medicaid beneficiaries. A number of studies show that chronically ill and disabled individuals fare better and have improved outcomes when they receive treatment with DMEPOS.¹⁹ Adequate access to DMEPOS is imperative if public health care benefit

¹⁶ CMS published claims data to show the adequacy of the new payment amounts for DMEPOS in non-CBAs, stating that the data, "shows that suppliers in all areas where the adjusted DMEPOS fee schedule rates have been implemented have continued to accept these adjusted rates as payment in full, suggesting that the adjusted fee schedule rates continue to be more than adequate in covering the costs of furnishing the DMEPOS items in all areas." *See Monitoring Data Shows Adequacy of New Payment Amounts for DMEPOS in Non-Competitively Bid Areas*, Centers for Medicare and Medicaid Services (2016, May 17), available at: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-05-17.html>

¹⁷ *See Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model*, 81 FR 42801 (June 30, 2016).

¹⁸ *Access to Care Issues Among Qualified Medicare Beneficiaries (QMBs)*, available at:

[https://www.cms.gov/.../Access to Care Issues Among Qualified Medicare Beneficiaries.pdf](https://www.cms.gov/.../Access%20to%20Care%20Issues%20Among%20Qualified%20Medicare%20Beneficiaries.pdf)

¹⁹ *See for example*, Landers, S. *Why Health Care Is Going Home*, *New England Journal of Medicine*, October 20, 2010; Oba, Y. *Cost-Effectiveness of Long-Term Oxygen Therapy for Chronic Obstructive Pulmonary Disease*,

programs want to avoid or postpone confining beneficiaries to more expensive institutional care. Adequate access includes more than merely ensuring beneficiaries eventually get physical possession of a piece of equipment or supply item; to be effective, treatment with DMEPOS must be timely. And to ensure beneficiaries safely use DMEPOS items, they must also have access to the services and support functions suppliers routinely provide. Access hurdles for dual eligible beneficiaries who need DMEPOS in and out of CBAs will continue to grow. Dual eligible beneficiaries in non-CBAs will remain especially vulnerable as long as reimbursement for DMEPOS stays at the current adjusted fee schedule levels.

4. Suppliers' Operational Viability

A report by Dobson Davanzo & Associates examining suppliers' costs and the adequacy of CB reimbursement bears out the concerns over access to DMEPOS.²⁰ The authors concluded that prevailing SPAs do not fully cover suppliers' cost of furnishing DMEPOS to beneficiaries. On average, SPAs account for only 88% of suppliers' costs, including their acquisition costs for equipment and supplies, and overhead costs for services they perform to safely furnish DMEPOS to beneficiaries in their homes.²¹

The report underscores what AAHomecare has told CMS from the start of the CB programs: SPA amounts are not accurate proxies for the cost of furnishing DMEPOS in a CBA. This is true in large part because of the program's many design flaws and from the "all or nothing" nature of the program, making it imperative for smaller local suppliers to win their bids. It is not unreasonable to conclude from the reports' findings that suppliers in non-CBAs will experience similar, if not larger reimbursement shortfalls at current adjusted fee schedule rates.

D. Congressional Oversight of the Adjusted Fee Schedules

Congress recognized the need to intervene to protect access to DMEPOS in non-CBAs, and took action under § 16007(a) of the Cures Act. Section 16007(a) retroactively delayed the full phase-in of adjusted fee schedules that became effective July 1, 2016. The statute states:

The Secretary of Health and Human Services shall extend the transition period described in clause (i) of section 414.210(g)(9) of title 42, Code of Federal Regulations, from June 30, 2016, to December 31, 2016 [.]²²

Section 16007(a) provided a necessary remedy in the short term. But a mere delay of these extraordinary cuts does not redress their effects on beneficiaries and suppliers over time. Congress understood as much and directed CMS to report on their impact during the 2016 phase-in.²³ Section

American Journal of Managed Care, February 2009; Lau, J., *et al.*, *Long-Term Oxygen Therapy for Severe COPD*, June 11, 2004, Tufts-New England Medical Center Evidence Based Practice Center.

²⁰ *Analysis of the Cost of Providing Durable Medical Equipment to the Medicare Population Measuring the Impact of Competitive Bidding*, Dobson DaVanzo & Associates, LLC for AAHomecare (2016)

²¹ *Id.* at 6.

²² § 16007 (a), PL 114-255 (December 13, 2016).

²³ Section 16007 (b) directs CMS to report to Congress by January 12, 2017 on the unadjusted fee schedules' effect on suppliers and beneficiary access during 2016. Section 16007 (b), states in part:

16007(b) of the Cures Act explicitly directs CMS to produce this report by January 12, 2017. To our knowledge, the Agency has not done this. Section 16007(b)(1)(B) states:

The Secretary of Health and Human Services shall, not later than January 12, 2017, submit to the Committees on Ways and Means and on Energy and Commerce of the House of Representatives, and to the Committee on Finance of the Senate, a report on the findings of the study conducted under paragraph.

The President signed the Cures Act into law on December 13, 2016, giving CMS one month to deliver the information Congress requested and leaving the adjusted fee schedules in effect as of January 1, 2017.

E. Administrative Oversight

The Secretary has broad discretion to administer the Medicare and Medicaid programs by issuing regulations and departing from formal rulemaking procedures when necessary for “good cause” to implement new rules.²⁴ When an agency determines it has good cause to forego formal rulemaking, it may issue an IFR with a comment period. An IFR is usually effective within 60 days of appearing in the Federal Register, but remains subject to change pending an agency’s review of the public comments.

We believe the Secretary has an opportunity to address the procedural and substantive shortcomings of § 414.210(g). The President recently signed two executive orders directing Agencies to undertake a careful review of pending and new regulations before giving them effect.²⁵ The directives align with the Administration’s policy of ensuring regulations are not so burdensome they hinder businesses’ ability to create and sustain jobs, or by extension, in this context, diminish beneficiaries’ access to care. The January 30 order also directs Agencies to eliminate “existing costs associated with prior regulations”

(b) STUDY AND REPORT.—

(1) STUDY.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study that examines the impact of applicable payment adjustments upon—

(i) the number of suppliers of durable medical equipment that, on a date that is not before January 1, 2016, and not later than December 31, 2016, ceased to conduct business as such suppliers; and

(ii) the availability of durable medical equipment, during the period beginning on January 1, 2016, and ending on December 31, 2016, to individuals entitled to benefits under part A of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) or enrolled under part B of such title.

²⁴ 42 U.S.C § 1395hh and APA, 5 U.S.C. § 553 (b) (B) which states in part:

[W]hen the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

²⁵ Executive Order 13771, *Reducing Regulation and Controlling Regulatory Costs*, 82 FR 9339 (February 3, 2017); Memorandum for the Heads of Executive Departments and Agencies Regulatory Freeze Pending Review, January 20, 2017, available at: <https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies>;

following the requirements of the APA, which we interpret to include the full array of tools available to agencies under the APA.²⁶

Using an IFR to suspend or repeal the adjusted fee schedules and amend the fee schedule methodology under § 414.210(g) fits within the Administration’s regulatory policy and the President’s executive orders. This approach would prevent the attrition of suppliers in non-CBAs, preserving access to DMEPOS for beneficiaries. The approach also gives the Secretary the opportunity to amend § 414.210(g) informed by the reports Congress requested under § 16007(b), in order to fully effectuate the statutory mandates.

An important rule of statutory construction is that statutes should not be construed in ways that reduce some of their provisions to “surplusage.”²⁷ Every word in a statute has meaning and should be given effect. In this case, the presumption must be made that Congress requested a report under § 16007(b) so it could monitor the new payment rates’ effect on access to DMEPOS and determine whether to intervene on the rates again. Congress had a reason for requiring CMS to produce the report, otherwise § 16007(b) is a surplusage with no meaning.

The legislative history of § 16007 supports these conclusions. In 2016, the House and Senate introduced bills to delay the unadjusted fee schedules and require CMS to produce quarterly reports on the impact of new payment rates on suppliers and beneficiaries.²⁸ The bills ultimately were amended and attached to the Cures Act, retaining a revised reporting requirement under § 16007(b), but the statutory purpose in this case was thwarted because Congress passed the Cures Act as it closed the session.

Congress also directed CMS to report annually on the overall impact of the CB programs, but CMS has not published a report since 2011.^{29,30} Again, every part of a statute has a purpose that must be given its full effect. As with its adoption of § 16007(b), we must presume Congress wanted these reports to inform its oversight of the program. Given the magnitude of the cuts under the adjusted fee schedules, we are concerned that access to DMEPOS in non-CBAs will deteriorate quickly if the Secretary waits for CMS to finalize the overdue reports and publish a notice of proposed rulemaking (NPRM) to amend § 414.210(g).

Using an IFR to suspend or repeal rules implementing the adjusted fee schedules would also allow the Secretary to align the transition to DMEPOS adjusted fee schedules with similar transitions to payment adjustments in other Medicare benefits. For example, § 3131 of the Affordable Care Act (ACA), called for adjustments in Medicare payments to home health agencies (HHAs). The statute provided a four-year phase-in of the adjustments and required CMS to monitor the effect of adjusted payments on access to

²⁶ *Ibid.*

²⁷ *Corley v. U.S.*, 556 U.S. 303 (2009)

²⁸ H.R. 5210 and S. 2736, respectively, available at: <https://www.congress.gov>

²⁹ 42 USC § 1395w-3 (f) requires the Agency to appoint a competitive bidding ombudsman to “respond to complaints and inquiries made by suppliers and individuals relating to the application of the competitive acquisition program under this section.” The statute directs the ombudsman to file annual reports to Congress.

³⁰ *Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program 2011 Report to Congress*, Centers for Medicare & Medicaid Services, available at:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Competitive_Acquisition_Ombudsman.html

home health services.³¹ Likewise, the transition to the skilled nursing facility (SNF) prospective payment system (PPS) called for a three-year phase-in during which SNFs received blended rates.³² And CMS transitioned adjustments to drug payments under the end stage renal disease (ESRD) benefit over four years.³³ Unlike CMS' abrupt transition to fully effective adjusted DMEPOS rates, the goal in each example above was to minimize disruption to providers in order to protect beneficiaries' access as providers adjusted to the new rates.

The "totality" of the circumstances determines whether an Agency has good cause for issuing an IFR. Adopting an IFR strategy in this case would allow the Agency to meet statutory mandates that CMS has mostly ignored by amending § 414.210(g) using information Congress intended to facilitate its CB program oversight, preserve suppliers' ability to serve beneficiaries in non-CBAs, and avert a looming access crisis for beneficiaries.

II. Recommendation

AAHomecare recommends that CMS issue an IFR to revise 42C.F.R. § 414.210(g) to repeal the full phase-in of the adjusted fee schedules in non-CBAs originally scheduled to take effect July 1, 2016, freeze the 50/50 blended rate which took effect on January 1, 2016, and amend the methodology for determining adjusted fee schedules. This action would be consistent with the Administration's statement of regulatory policy and is necessary to stem the erosion of the DMEPOS benefit in non-CBAs.

Sincerely,



Tom Ryan
President and CEO
American Association for Homecare

³¹ PL Law 111-148 (March 23, 210).

³² See Medicare Program; *Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities* 64 Fed. Reg. 41684 (July 30, 1999)

³³ Medicare Program; *End-Stage Renal Disease Prospective Payment System*, 75 Fed. Reg. 49030 (August 12, 2010)