UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN ASSOCIATION FOR HOMECARE 1707 L Street, N.W., Suite 350 Washington, D.C. 20036, and HOME MEDISERVICE, INC. 540 S. Union Avenue Havre de Grace, Maryland 21078, Plaintiffs, v. KATHLEEN SEBELIUS, Secretary, U.S. Department of Health and Human Services, 200 Independence Avenue, S.W. Washington, D.C. 20201, Defendant.	Civil Action No. _____

COMPLAINT

Plaintiffs, American Association for Homecare and Home MediService, Inc., by and through their undersigned attorneys, bring this action against defendant Kathleen Sebelius, in her official capacity as the Secretary ("the Secretary") of the United States Department of Health and Human Services ("HHS"), and state as follows:

Preliminary Statement

1. Unless enjoined by this Court, or timely rectified voluntarily by the Secretary, beginning on July 1, 2013, the Secretary will implement Round 2 of the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (for brevity, "DME") Competitive Bidding Program ("CBP") through an undisputed *ultra vires* violation of her own regulations by having used bids submitted by DME suppliers without required State and local licenses to determine (a) which DME suppliers will be allowed to provide DME to Medicare beneficiaries on or after July 1, 2013 ("the successful bidders") and (b) the amount that Medicare will pay successful bidders. Plaintiffs are aware that the Secretary has sent letters to unlicensed

successful bidders in the State of Tennessee in the past week giving notice of the Secretary's decision to modify executed Round 2 CBP contracts to remove all awards issued to unlicensed bidders, which the Secretary now concedes were "erroneous" because bids from unlicensed bidders were "void *ab initio*." *See* Exhibit A (June 13, 2013 letter from the Centers for Medicare & Medicaid Services ("CMS") (redacted) giving notice to unlicensed successful bidder in Tennessee that the Secretary "is modifying the executed contract to remove the erroneous award(s)."). This action, however, will not put all properly licensed bidders in Tennessee in the position they would have been if the Secretary had, as she was required to have done, rejected the bids submitted by unlicensed bidders. Plaintiffs are not aware of similar letters being sent in other States, even though plaintiffs have reason to believe that unlicensed bidders received Round 2 CBP contracts in many other States. By this action, Plaintiffs seek to require the Secretary to redetermine successful bidders, and recalculate the payment amount, in every State where the Secretary accepted bids from unlicensed bidders, after eliminating all contracts and bids from unlicensed bidders.

2. The requirement that Round 2 CBP bidders have all necessary State and local licenses could not be more clear:

> In order to submit a bid to participate in the CBP, "[e]ach supplier must have all State and local licenses required to perform the services identified in the request for bids."

42 C.F.R. §414.414(b)(3). To enforce this requirement, the Secretary stated unequivocally:

> We will reject a bid that does not demonstrate that the supplier has met our bidding requirements. As a result, only bids from eligible, qualified, and financially sound suppliers will be used to determine the single payment amounts and select contract suppliers.

72 Fed. Reg. 18036 (April 10, 2007). The Secretary's bidding instructions stated: "Bids will be disqualified if a bidder does not meet all state licensure requirements for the applicable product categories. . . ." Round 2 and National Mail-Order Competitions, Request for Bids (RFB) Instructions at 3, *at* http://www.dmecompetitivebid.com/Palmetto/Cbic.nsf/files/R2_RFB.pdf/$File/R2_RFB.pdf.

3. Notwithstanding this simple, direct nondiscretionary duty, "approximately 30 out of the 98 contract suppliers in the Tennessee Competitive Bidding Areas ["CBAs"]" are unlicensed. *See* Exhibit B (June 14, 2013 letter from CMS Administrator to Congressman David Roe). In fact, of the 799 contracted bidders nationwide (CMS Press Release, Contract Suppliers Selected Under Medicare Competitive Bidding Program (Apr. 9, 2013), *at* *http://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-Releases/2013-Press-Releases-Items/2013-04-092.html*), there were more than 110 unlicensed bidders in Maryland alone, which accounted for approximately one-third of all successful bidders in that State and which the Secretary is "aware of," but "is reviewing the situation to determine the appropriate action to take." *See* Exhibit C ("Medicare Program Eliminates 30 Out-of-State Suppliers," The Tennessean, June 18, 2013, at 2 (citing CMS spokeswoman)). Plaintiffs are currently aware of similar licensing issues in Texas, Connecticut, Virginia, Ohio, North Carolina, and Washington State, and are in the process of gathering information to show that this issue exists in other states as well. The acceptance of bids from unlicensed bidders to provide DME in Tennessee, Maryland, and other States harmed both successful and unsuccessful licensed bidders in those States by causing:

a. The Medicare payment amount resulting from the CBP to be improperly low because it is indisputable that the elimination of unlicensed bidders will cause Medicare payment amounts under the CBP to increase;

b. The rejection of the bids from licensed bidders that should have been accepted; and

c. Licensed bidders that were offered contracts to reject the contracts because the Medicare payment amount was improperly low.

For example, in the Baltimore, Maryland CBA, 36 of the 102 successful bidders were not licensed as of May 29, 2013. That figure was likely higher on May 1, 2012, which was the Round 2 licensure deadline.

4. Plaintiffs seek mandamus relief to require the Secretary to follow her own rules by (a) rescinding, as void *ab initio*, contracts for all successful bidders that were not properly

licensed in the State of the successful bid as of May 1, 2012 and (b) putting the licensed bidders in any State with unlicensed successful bidders in the position the licensed bidders would have been if the Secretary had rejected the bids from the unlicensed bidders, including (but not limited to) (i) determining the proper Medicare payment amount that is required after eliminating the effect of the unlicensed bidders, (ii) giving contracts to licensed bidders that were improperly rejected, and (iii) giving licensed bidders, that did not accept contracts because the payment amount was too low, the opportunity to accept contracts at the correct bid amounts.

5. Plaintiffs are aware that Congress has limited the scope of judicial review of the Secretary's discretion regarding implementation of the CBP. 42 U.S.C. §1395w-3(b)(11). But Plaintiffs are not here challenging the Secretary's policy choices regarding implementation of the CBP. Rather, Plaintiffs here challenge the Secretary's unlawful refusal to follow her own legally-binding, nondiscretionary rules. Indeed, as explained in more detail below, the issue of unlicensed suppliers improperly being permitted to participate in the CBP was the subject of Congressional hearings at least as far back as 2008 and the Secretary has repeatedly told Congress that she would not allow unlicensed bidders to participate in the CBP. Congress did not, and could not under the separation of powers clause of the United States Constitution and other authorities, strip this Court of its authority to (a) review *ultra vires* agency action and (b) order the executive to follow her own legally-binding rules – rules that Congress had every reason to expect the Secretary to adopt and enforce. Plaintiffs have no other adequate remedy, either judicial or administrative, to redress the Secretary's unlawful actions, thereby requiring action by this Court.

Jurisdiction and Venue

6. This action arises under Title XVIII of the Social Security Act, 42 U.S.C. §§1395 *et seq*. (the "Medicare Act").

7. This Court has jurisdiction under 28 U.S.C. §§1331 (federal question) and 1361 (mandamus).

8. Venue lies in this judicial district under 28 U.S.C. §1391.

Parties

9. Plaintiff American Association of Homecare ("AAHomecare") is a membership association comprised of, and representing, DME suppliers, DME manufacturers, and other organizations in the homecare community. AAHomecare members serve the medical needs of millions of Medicare beneficiaries who require medical devices and supplies for use in the home, including: (a) oxygen equipment and therapy, (b) mobility assistance technologies, (c) medical supplies, (d) inhalation drug therapy, (e) home infusion, and (f) other DME, therapies, services, and supplies. AAHomecare's membership, which includes plaintiffs Home MediService, Inc., reflects a broad cross-section of the homecare community, including providers of all sizes operating approximately 3,000 locations in all 50 states and the District of Columbia. AAHomecare's activities in support of the homecare community include advocacy before all three branches of the Federal government on the CBP and other matters, as well as counseling its members regarding government relations and legal compliance. AAHomecare includes many other members who also will be harmed if Round 2 of the CBP were to go into effect on July 1, 2013, as scheduled, without the elimination nationwide of the effect of the Secretary's unlawful acceptance of bids from unlicensed bidders, and who could bring this action in their own right, but who are not required to do so.

10. Plaintiff Home MediService, Inc. is a DME supplier that has been participating in the Medicare program since 1971. Plaintiff Home MediService, Inc. is licensed in the State of Maryland as a "residential service agency" ("RSA") and has been so licensed since 1999, which is when the license was first required. Plaintiff Home MediService, Inc., which currently supplies a broad range of DME to Medicare beneficiaries in Maryland, Pennsylvania and other States, submitted bids on seven product categories in both the Philadelphia-Camden-Wilmington CBA and the Baltimore-Towson CBA and was a successful bidder for four product categories in the Baltimore-Towson CBA (Hospital Beds and Related Accessories, Support Surfaces (Group 2 Mattresses and Overlays), Walkers and Related Accessories, and CPAP [*i.e.*, continuous positive airway pressure] Devices, Respiratory Assist Devices, and Related Supplies and Accessories)

and two product categories in the Philadelphia-Camden-Wilmington CBA (Beds and Support Surfaces). Plaintiff Home MediService, Inc. entered into contracts to provide Beds and Support Surfaces in the Philadelphia-Camden-Wilmington and Baltimore-Towson CBAs, but declined to enter into contracts for Walkers and CPAP Devices in the Baltimore-Towson CBA because the Medicare payment amounts for these two product categories were too low, even though Plaintiff Home MediService, Inc. would have done so if the payment amounts for those product categories would have been higher. If Round 2 of the CBP goes into effect on July 1, 2013, Plaintiff Home MediService, Inc. will be harmed because (a) the Medicare payment amount for the four product categories for which Plaintiff Home MediService, Inc. has CBP contracts is lower than it should be as a result of the Secretary using bids from unlicensed suppliers to determine that payment amount, (b) it was offered contracts to provide Walkers and CPAP Devices in the Baltimore-Towson CBA, which it rejected because the payment amount was too low, and (c) it could have potentially received contracts in the product categories where it was unsuccessful if the unlicensed bidders had been disqualified..

11. Defendant Kathleen Sebelius is the Secretary of the United States Department of Health and Human Services, the federal department which contains CMS. The Secretary, the federal official responsible for administering the Medicare program, has delegated that responsibility to CMS. Before June 14, 2001, CMS was known as the Health Care Financing Administration ("HCFA"). In this complaint, for simplicity, we generally refer to the agency as "CMS," even for events before June 14, 2001.

Medicare Program Payment for DME

A. General Background of the Medicare Program

12. The Medicare Act establishes a program of health insurance for the aged, disabled, and individuals with end-stage renal disease. 42 U.S.C. §§1395-1395ccc; 42 C.F.R. Parts 400–1004. Medicare includes Parts A through E. This action arises solely under Part B (covering non-hospital medical needs, including DME).

13. Under 42 U.S.C. §1395hh(a)(1), the Secretary is required to "prescribe such regulations as may be necessary to carry out the administration" of the Medicare program. That statute also states:

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

42 U.S.C. §1395hh(a)(2).

14. CMS has contracted out many Medicare administrative functions to private organizations. *See, e.g.*, 42 U.S.C. §§1395h and 1395kk. Crucially for purposes of this complaint, the Secretary has delegated many of the functions relating to the implementation of the CBP to the Competitive Bidding Implementation Contractor ("CBIC"), which at all times relevant to this complaint has been Palmetto GBA. 42 U.S.C. §1395w-3(b)(9); 42 C.F.R. §414.406(a).

B. Medicare Coverage and Payment of DME

15. DME is critical to the successful treatment of illnesses and diseases. Due to their conditions, Medicare beneficiaries require a disproportionately high level and quantity of health care services, including DME. DME is supplied by hospitals, physician offices, and, as relevant here, independent DME suppliers. Many Medicare beneficiaries, particularly those who use oxygen equipment, have long-standing relationships with their DME suppliers to meet their sometimes emergent medical needs.

16. Medicare Part B provides for coverage and payment for "medical and other health services" provided to Medicare beneficiaries, which includes DME. 42 U.S.C. §§1395k(a) and 1395x(n) and (s). Medicare Part B covers, among other things, the rental or purchase of DME, "[s]upplies necessary for the effective use of DME other than inhalation drugs," "[e]nteral

nutrients, equipment, and supplies," and "[o]ff-the-shelf orthotics," 42 C.F.R. §414.402, collectively known as DMEPOS (which we refer to herein simply as DME, for brevity), for use in the patient's home. 42 U.S.C. §§1395k, 1395x(n); *see id.* §1395w-3. To be covered by Medicare, medical devices that fit within the Medicare definition of "DME" must also be found to be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. §1395y(a).

17. DME suppliers that want to participate in Medicare must meet a myriad of requirements, including "[i]f a State requires licensure to furnish certain items or services a [DME] supplier – (A) [m]ust be licensed to provide the item or service. . . ." 42 C.F.R. §424.57(c)(1)(ii)(A). This is because, as a matter of Federalism, Medicare has, throughout its history, required facilities, physicians, and suppliers to meet State licensing requirements. 42 C.F.R. §424.510(d)(iii)(A) ("Providers and suppliers must meet the following enrollment requirements [...] (iii) Submission of all documentation, including--(A) All applicable Federal and State licenses. . . ."); 42 C.F.R. §424.516(a)(2) ("CMS enrolls and maintains an active enrollment status for a provider or supplier when that provider or supplier certifies that it meets, and continues to meet, and CMS verifies that it meets, and continues to meet, all of the following requirements [...] (2) Compliance with Federal and State licensure. . . ."); 42 C.F.R. §482.11(b) ("The hospital must be--(1) Licensed; or (2) Approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing hospitals."); 42 C.F.R. §424.521(a) ("Physicians, nonphysician practitioners and physician and nonphysician practitioner organizations may retrospectively bill for services when a physician or nonphysician practitioner or a physician or a nonphysician organization have met all program requirements, including State licensure requirements. . . .").

18. Before the advent of the CBP, any DME supplier that met Medicare eligibility requirements could provide DME to Medicare beneficiaries. As a result of the CBP, Medicare-participating suppliers are prohibited from providing DME encompassed within the CBP unless they have a CBP contract, even if they are willing to accept the Medicare payment amount established under the CBP.

19. Medicare historically paid for DME "using a different fee schedule for each class of covered items." H.R. Rep. No. 108-391, at 572 (2003). CMS developed the fee schedule for each item of DME by using "a weighted average of either local or regional prices, subject to national limits (both floors and ceilings)" that were updated annually. *Id*.

20. Claims for Medicare payment for DME items supplied to Medicare beneficiaries are presented to DME Medicare Administrative Contractors ("DMACs"). DMACs adjudicate these claims as contracted agents of the Secretary. The country is divided into four geographic jurisdictions, each of which has its own DMAC. A DME supplier must submit each of its claims to the DMAC having jurisdiction for reimbursement of that claim. 42 C.F.R. §424.32.

The Medicare DME Competitive Bidding Program

A. Statutory Background of the CBP

21. In the late 1990s – in light of "[n]umerous studies conducted by the HHS Office of the Inspector General as well as GAO hav[ing] found the government-determined fee schedule for [DME] too high for certain items," H.R. Rep. No. 108-178(II), at 192 (2003) – Congress authorized the Secretary to undertake several demonstration projects to determine the feasibility of using a competitive bidding process for establishing Medicare payment rates for DME. *See* Balanced Budget Act of 1997, Public Law 105-33, §4319 (Aug. 5, 1997) ("The Secretary shall implement not more than 5 demonstration projects under which competitive acquisition areas are established for contract award purposes for the furnishing under this part of

the items and services"). Under these demonstration projects, rather than setting DME payments directly, CMS invited suppliers in a geographical area (referred to as "competitive bidding area" or "CBA") to submit bid prices at which they would be willing to furnish particular DME products to Medicare beneficiaries. *Id*. After receiving bids, and removing bids from ineligible entities, CMS added up the proposed market shares – starting with the lowest bidder – until the number of bidders accepted had sufficient market share to assure that DME would be accessible to all Medicare beneficiaries in the entire market, and awarded exclusive contracts to those selected bidders at the median proposed price among successful bidders. *See* 72 Fed. Reg. 17992, 18042 (Aug. 10, 2007); King, K. Medicare: CMS Working to Address Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program, GAO-10-27 (Washington, DC Nov. 6, 2009) at 15.

22. Satisfied with the results of these CMS demonstration projects, Congress enacted the CBP on December 8, 2003, as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173 (“MMA"). *See* 42 U.S.C. §1395w-3. In doing so, Congress required the Secretary to conduct "a competition among entities supplying items and services," 42 U.S.C. §1395w-3(b)(1), where suppliers would submit bids that specify a set price for the provision of all of the DME items and services within a particular “product category” for a period of up to three years. 42 U.S.C. §1395w-3(b)(6)(B). Congress also mandated that the Secretary ensure that "[t]he total amounts to be paid to contractors in a competitive bidding area are expected to be less than the total amounts that would otherwise be paid." 42 U.S.C. §1395w-3(b)(2)(A)(ii).

23. In enacting the CBP, Congress limited administrative or judicial review of certain aspects of the Secretary's discretionary implementation of the CBP by 42 U.S.C. §1395w-3(b)(11), which states, *in toto*, as follows:

> There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of—
>
> (A) the establishment of payment amounts under paragraph (5);
> (B) the awarding of contracts under this section;
> (C) the designation of competitive acquisition areas under subsection (a)(1)(A) and the identification of areas under subsection (a)(1)(D)(iii);
> (D) the phased-in implementation under subsection (a)(1)(B) and implementation of subsection (a)(1)(D);
> (E) the selection of items and services for competitive acquisition under subsection (a)(2) of this section;
> (F) the bidding structure and number of contractors selected under this section; or
> (G) the implementation of the special rule described in paragraph (10).

Congress, however, did not, and could not under the separation of powers clause of the United States Constitution and other authorities, strip this Court of its authority to review *ultra vires* agency action and to order the executive to follow her own legally-binding rules. *See Marbury v. Madison*, 1 Cranch 137 (1803); *Bartlett v. Bowen*, 816 F.2d 695, 704-07 (D.C. Cir. 1987); *Aid Ass'n for Lutherans v. USPS*, 321 F.3d 1166, 1173 (D.C. Cir. 2003) ("[T]he case law in this circuit is clear that judicial review is available when an agency acts *ultra vires*.").

24. Under the MMA, the CBP was to be implemented in three rounds: (1) initially in 10 CBAs in 2007; (2) extended to an additional 91 CBAs in 2011; and (3) extended nationwide after that. 42 U.S.C. §1395w-3(a)(1)(B)(i). However, following Round 1, after the House Ways and Means Committee held a hearing on the bidding process on July 15, 2008, Congress enacted the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA"), Pub. L. No. 110-275, §154, which *inter alia* delayed implementation of the CBP for two years. MIPPA effectively negated Round 1 bids submitted, reinstated temporarily the DME fee-schedule system

in place before the MMA, and mandated the Secretary to conduct a new round of bidding during 2009 (the "Round 1 Rebid") similar to that previously conducted under the MMA, with certain modifications, including a reduction from 10 to 9 CBAs, not relevant here. 42 U.S.C. §1395w-3(a)(1)(D).

25. On April 10, 2007, the Secretary issued a final rule implementing the CBP ("the Final Rule"). 72 Fed. Reg. 17992 (Apr. 10, 2007). In 2011, CMS initiated Round 2 of the CBP and winning bidders were announced on April 9, 2013. Round 2 contracts and prices are scheduled to become effective on July 1, 2013. The CBP applies to the following nine product categories (each product category includes many items of DME and bids for a product category were required to include bids for every type of DME in the category): (1) Oxygen Supplies and Equipment, (2) Standard (Power and Manual) Wheelchairs, Scooters, and Related Accessories, (3) Enteral Nutrients, Equipment and Supplies, (4) CPAP Devices, Respiratory Assist Devices, and Related Supplies and Accessories, (5) Hospital Beds and Related Accessories, (6) Walkers and Related Accessories, (7) Support Surfaces (Group 2 Mattresses and Overlays), (8) Negative Pressure Wound Therapy (NPWT) Pumps and Related Supplies and Accessories, and (9) Mail Order Diabetes Test Strips. CBIC, Fact Sheet Round 2 Items & Services (June 2012), *at* *http://www.dmecompetitivebid.com/Palmetto/Cbic.Nsf/files/Rd2_Bidding_ItemsServices0811.pdf*. Because diabetic test strips are to be provided solely by mail order, 42 U.S.C. at §1395w-3(b)(10), it is only the other eight product categories that are at issue in this action.

26. If the Secretary determines that she has not contracted with a sufficient number of suppliers necessary to provide DME to all of the Medicare beneficiaries in a CBA, the Secretary can "contact the remaining contract suppliers for that product category to determine if they could absorb the unmet demand." 72 Fed. Reg. at 18044. Moreover, "[i]f the remaining contract

suppliers could not absorb the unmet demand in a timely manner, [the Secretary] proposed to refer to the list of suppliers that submitted bids for that product category in that round of competitive biding in that CBA, use the list of composite bids that [she] arrayed from lowest to highest, and proceed to the next supplier on the list." *Id*.

B. Congressional Concern that CBP Bidders Meet State Licensing Requirements

27. Although Medicare program savings are an important reason that Congress enacted the CBP, Congress has also long been concerned that Medicare respect State licensing laws. Thus, following Round 1 of the CBP, during a hearing held by the House Ways and Means Committee on May 6, 2008, CMS was questioned about the Secretary's handling of bidders that did not meet State licensing requirements. 2008 Hearing Tr. at 87 (statement of Accredited Medical Equipment Providers of America, Inc. identifying a provider that had won a bid for a CBA in Florida without proper licensure) ("The first line in the Rules For Bid (RFB) states that 'All suppliers must—meet any local or state licensure requirements, if any for the item being bid.' Clearly this bid winner did not meet the requirements for the bid he won in Miami and Orlando. I also believe that it was not the intent of Congress to allow something like this to happen.").

28. In 2009, CMS conceded in a Government Accountability Office ("GAO") Report that CMS had not taken the necessary safeguards to ensure that proper State licenses were in place for qualifying suppliers during Round 1 of the CBP.

> Whether suppliers had the required DME state licenses was to be determined as part of the accreditation process. However, CMS acknowledged that it checked supplier licenses after contract offers were made and Palmetto GBA officials acknowledged that some suppliers were awarded CBP contracts even though they did not have the necessary state licenses at the time contracts were awarded.

King, K. Medicare: CMS Working to Address Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program, GAO-10-27 (Washington, DC Nov. 6, 2009) at 23. The GAO Report further noted that the agency assured that these errors would be corrected going forward.

> Suppliers participating in the round 1 rebid must have all local and state licenses for a product category in a CBA at the time of bid submission in order to be considered for a CBP contract. According to CMS, this is not a change from CBP round 1. However, there were issues during the first round that complicated licensure verification. CMS and Palmetto GBA acknowledged and some trade association representatives told us that some suppliers were offered CBP contracts during CBP round 1 for product categories for which they were not properly licensed. Therefore, for the round 1 rebid, CMS has further clarified the licensure requirement, stating that suppliers must be licensed for the product category in the CBA in which they are bidding and if a CBA covers more than one state, the supplier needs to obtain applicable licensure in all states. To ensure that the licensure requirement is met, CMS is improving quality assurance checks to confirm that suppliers are properly licensed prior to accepting suppliers' bids in the CBP round 1 rebid.

Id. at 36 (emphasis added).

29. Licensing concerns have continued to haunt the CBP. In a statement before the House Ways and Means Committee on May 9, 2012, Laurence Wilson, Director of the Chronic Care Policy Group, CMS, explained the "number of different tools that Medicare uses to screen a provider, both within the competitive bidding program and outside of the competitive bidding program," including licensing standards. 2012 Hearing Tr. at 37, *at* http://waysandmeans.house.gov/news/documentsingle.aspx?DocumentID=326363. ("But we absolutely want to assure the qualifications of a provider. So there are many Medicare requirements, supplier standards that have to be met. We also look at the state licensing, the accreditation program, which relies on quality standards. There is a specific set of qualities.").

C. How DME Payments are Determined Under the CBP

30. Winning CBP bids were used to establish Medicare's single payment amounts for each DME item included in each product category in each CBA. For each item in a product category, the CBIC arrayed the winning bids in each CBA from lowest to highest and then added up the proposed market shares – starting with the lowest bidder – until the number of bidders accepted had sufficient market share to assure that DME would be accessible to all Medicare beneficiaries in the entire CBA, and awarded exclusive contracts to those selected bidders at the median proposed price among successful bidders. *See* 72 Fed. Reg. 17992, 18042 (Aug. 10, 2007). The use of the median in setting the single payment amount meant that Medicare's payment amount could be less than, or more than, a particular winning supplier's actual bid for an item. As a result, if any winning bid below the median was from an unlicensed bidder, the bid would have caused the payment amount to be lower than it should have been. Moreover, to the extent that bidders are added, whether in the State of Tennessee or elsewhere, the bidders to be added will have higher bids than the earlier successful bidders, thereby causing a higher median price and, indisputably resulting in a higher Medicare payment amount.

D. The Secretary Required Proper State Licensure as a Condition of Bidding and Stated She Would Reject Any Application that Does not Meet State Licensure Requirements for Even a Single State.

31. In a regulation addressing the "conditions for awarding contracts," the Secretary adopted basic supplier eligibility requirements, one of which is that "[e]ach supplier must have all State and local licenses required to perform the services identified in the request for bids." 42 C.F.R. § 414.414(b)(3), s*ee also* 72 Fed. Reg. at 18035-37. In the preamble to the Final Rule, the Secretary stated unequivocally that she would reject bidders that do not meet State licensure requirements. *Id*. at 18036 ("We will not award a contract to any supplier that does not meet our

bidding requirements. . . .We will reject a bid that does not demonstrate that the supplier has met our bidding requirements. As a result, only bids from eligible, qualified, and financially sound suppliers will be used to determine the single payment amounts and select contract suppliers.").

32. The requirement for State licensure at the time of bid submission was also set forth in the application for bidders to participate in the CBP, which stated:

> Bids will be disqualified if a bidder does not meet all state licensure requirements for the applicable product categories and for every state in a CBA. Every supplier location is responsible for having all applicable license(s) for each state in which it provides services.

See Form A, OMB No. 0938-1016, CMS-10169A (07/09), *at* *http://www.dmecompetitivebid.com/Palmetto/Cbic.Nsf/files/R2_RFB_Form_A.pdf/$File/R2_RFB_Form_A.pdf*. It was also included in the Secretary's bidding instructions, which stated: "Bids will be disqualified if a bidder does not meet all state licensure requirements for the applicable product categories…" CBIC, Round 2 and National Mail-Order Competitions, Request for Bids (RFB) Instructions at 3, *at* *http://www.dmecompetitivebid.com/Palmetto/Cbic.nsf/files/R2_RFB.pdf/$FIle/R2_RFB.pdf*.

33. Lest there be any question about the need for bidders to meet State license requirements as a condition for bid submission, the CBIC sent a blast email on May 1, 2012, the Round 2 licensure deadline, stating in its entirety:

> **Reminder:** If you are a supplier participating in Round 2 and/or the national mail-order competition of the Medicare Durable Medical Equipment, Prosthetics, and Supplies (DMEPOS) Competitive Bidding Program, you must have all applicable state licenses on file with the National Supplier Clearinghouse (NSC). Bidding suppliers must ensure that copies of applicable state licenses are RECEIVED by the NSC on or before Tuesday, May 1, 2012. **Don't wait – submit the required licenses to the NSC TODAY!**
>
> With the approaching deadline. bidding suppliers should fax copies of their licenses to the NSC at **803-382-2407.** The fax machine will accept licenses 24 hours a day until **11:59:59 p.m. Eastern Time, Tuesday, May 1, 2012.**

> Bids will be disqualified if the bidder does not meet all state licensure requirements to furnish the applicable product categories in every state in a competitive bidding area.
>
> A licensure directory for each state, the District of Columbia, and the territories may be found on the NSC website at www.palmettogba.com/NSC. State licensure requirements change periodically and may have exceptions, so the NSC's licensure directory serves only as a guide. It remains your responsibility to ensure compliance with the most current state and federal laws and regulations.
>
> Please do not respond to this message. For more information on licensure requirements, you may refer to the Licensure for Bidding Suppliers Fact Sheet and the Request for Bids (RFB) Instructions. Do NOT send copies of licenses to the Competitive Bidding Implementation Contractor (CBIC). If you have any questions, please contact the CBIC customer service center at 877-577-5331 between 9 a.m. and 5:30 p.m. Eastern Time.

See Exhibit D.

Statement of Facts

34. Many states have adopted license requirements that must be met before a supplier can provide DME in the eight product categories included in the CBP. It is undisputed that the Secretary has awarded contracts to bidders that did not meet State license requirements. In many instances, compliance with State licensure laws has been determined within the past month or two. There is little doubt that the number of bidders that were unlicensed as of the Round 2 licensure deadline of May 1, 2012, was significantly higher.

35. In the State of Tennessee, the Secretary has acknowledged that "approximately 30 out of the 98 contract suppliers in the Tennessee Competitive Bidding Areas ["CBAs"]" were unlicensed. *See* Exhibit B (June 14, 2013 letter from CMS Administrator to Congressman David Roe). The Secretary now concedes that these contracts were "erroneous" because bids from unlicensed bidders were "void *ab initio.*" *Id.* However, as recently as April 16, 2013, the Secretary proposed to allow contracts for unlicensed successful bidders go into effect on July 1, 2013 if the proper license was obtained by that date. *See* Exhibit E (April 16, 2013 letter from

CBIC to unlicensed contract awardee). This obviously violated the Secretary's rules and regulations. Thus, it is not surprising that the Secretary recently changed course, albeit without going far enough.

36. The State of Maryland requires DME suppliers to have a Maryland RSA license before they can provide any DME item in any of the eight CBP product categories in a patient's home in Maryland. Maryland Health-General Article §19-4a-02. The counties of the State of Maryland are located within three CBAs. In Maryland, the State licensing agency determined that, as of May 29, 2013, 112 of the 333 successful CBP bidders in the three Maryland CBAs did not have the license required by the State of Maryland to provide the DME item that the bidder was authorized to provide under its CBP contracts. This represents approximately one-third of all bidders.

37. Under the Secretary's rules, the bids for all unlicensed bidders in the CBP were required to have been rejected. As a result, the bids from unlicensed bidders should not have been used to determine the amount that Medicare would pay for DME items included within the CBP. Moreover, the Secretary should not have used unlicensed bidders to determine whether there were a sufficient number of successful bidders to assure that all Medicare beneficiaries in all CBAs have access to the DME items included in the CBP. While adding licensed suppliers, to replace suppliers that would be eliminated if this Court requires the Secretary to follow her rules by rejecting bids from unlicensed bidders, might address the demand shortage issue, it would not rectify the bid distortion caused by the Secretary having accepted bids from unlicensed applicants. Rather, it would magnify that distortion because the bidders to be added will have higher bids than the earlier successful bidders, thereby causing a higher median price and, indisputably resulting in a higher Medicare payment amount.

38. Plaintiffs seek mandamus relief to require the Secretary to follow her own rules and regulations by (a) rescinding the contracts for all bidders that were not properly licensed at the Round 2 licensure deadline of May 1, 2012 (and not only those in Tennessee) and (b) taking the remedial steps necessary as a result of the invalidation of these unlawful contracts to put all properly-licensed bidders in the position they would have been if the Secretary had followed her own rules and regulations, including (but not limited to):

i. Recalulating the correct Medicare payment amount for each product category in each CBA with unlicensed successful bidders;

ii. Redetermining which bids from licensed bidders should have been accepted; and

iii. Giving licensed bidders that were offered contracts but rejected them because the Medicare payment amount was improperly low another chance to accept the bids after being given the corrected Medicare payment amount.

39. Plaintiffs are aware that Congress has limited the scope of judicial review of the Secretary's discretion regarding implementation of the CBP. 42 U.S.C. §1395w-3(b)(11). But Plaintiffs are not here challenging the Secretary's policy choices. Rather, Plaintiffs here challenge the Secretary's unjustifiable refusal to follow her own nondiscretionary rules. This Court has jurisdiction under 28 U.S.C. §1361 (mandamus) because Congress did not, and could not under the separation of powers clause of the United States Constitution and other authorities, strip this Court of its authority to review *ultra vires* agency action and to order the executive to follow her own legally-binding rules – rules that Congress had every reason to expect the Secretary to adopt and enforce. Plaintiffs have no other adequate remedy, either judicial or administrative, to redress the Secretary's unlawful actions, thereby requiring action by this Court.

40. This Court also has jurisdiction to hear this case under 28 U.S.C. §1331 because a finding by this Court that it lacks mandamus jurisdiction could foreclose Plaintiffs' ability to

obtain judicial review of the Secretary's unlawful failure to follow her own rules and regulations. Where a plaintiff is challenging administrative action (or inaction) by the Secretary for which jurisdiction is not provided under the Social Security Act, the Supreme Court has held that jurisdiction for such review is available under 28 U.S.C. §1331 because of "the strong presumption that Congress intends judicial review of administrative action." *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986); *see also Shalala v. Illinois Council on Long Term Care*, 529 U.S. 1 (2000).

COUNT I
Decision is Contrary to the Law

41. Plaintiffs hereby incorporate by reference paragraphs 1 through 40 herein.

42. The Secretary's failure to reject CBP bids from bidders to provide DME in a State where the bidders did not, as of May 1, 2012, have all required State and local licenses, was unlawful under the Secretary's rules and other authority. Despite the requirement of her rules, and the promises made to Congress, the Secretary has failed not only to reject the CBP bids from unlicensed bidders, but she actually entered into contracts with them. These contracts must be invalidated because the bids of these bidders should have been rejected.

43. Plaintiffs are entitled to an order requiring the Secretary to (a) rescind the contracts for all bidders that were not properly licensed at the Round 2 licensure deadline of May 1, 2012 (not only those in Tennessee) and (b) take the remedial steps necessary as a result of the invalidation of these unlawful contracts to put all properly-licensed bidders in the position they would have been if the Secretary had followed her own rules and regulations, including (but not limited to) (i) recalculating the correct Medicare payment amount, (ii) redetermining which bids from licensed bidders should have been accepted, and (iii) giving licensed bidders that were

offered contracts but rejected them because the Medicare payment amount was improperly low another chance to accept the bids after being given the corrected Medicare payment amount.

COUNT II
Mandamus

44. Plaintiffs hereby incorporate paragraphs 1 through 43, herein.

45. The Secretary's failure to reject CBP bids from bidders to provide DME in all States where the bidders did not, as of May 1, 2012, have all required State and local licenses, was unlawful under the Secretary's rules and other authority. Despite the requirement of her rules, and the promises made to Congress, the Secretary has failed not only to reject the CBP bids from unlicensed bidders, but she actually entered into contracts with them. These contracts must be invalidated because the bids of these bidders should have been rejected.

46. The Secretary has the non-discretionary duty to reject CBP bids from suppliers who were not licensed in the States for which they are seeking to provide DME. Thus, Plaintiffs are entitled to the issuance of a writ of mandamus requiring the Secretary to (a) rescind the contracts for all bidders that were not properly licensed at the Round 2 licensure deadline of May 1, 2012 (and not only those in Tennessee) and (b) take the remedial steps necessary as a result of the invalidation of these unlawful contracts to put all properly-licensed bidders in the position they would have been if the Secretary had followed her own rules and regulations, including (but not limited to) (i) recalculating the correct Medicare payment amount, (ii) redetermining which bids from licensed bidders should have been accepted, and (iii) giving licensed bidders that were offered contracts but rejected them because the Medicare payment amount was improperly low another chance to accept the bids after being given the corrected Medicare payment amount.

COUNT III
All Writs Act

47. Plaintiffs hereby incorporate paragraphs 1 through 46, herein.

48. The Secretary's failure to reject CBP bids from bidders to provide DME in all States where the bidders did not, as of May 1, 2012, have all required State and local licenses, was unlawful under the Secretary's rules and other authority. Despite the requirement of her rules, and the promises made to Congress, the Secretary has failed not only to reject the CBP bids from unlicensed bidders, but she actually entered into contracts with them. These contracts must be invalidated because the bids of these bidders should have been rejected.

49. The Secretary has the non-discretionary duty to reject CBP applications from suppliers who are not licensed in the States for which they are seeking to provide DME. Thus, under the All Writs Act, 28 U.S.C. §1651, and other authority, Plaintiffs are entitled to issuance of an order requiring the Secretary to (a) rescind the contracts for all bidders that were not properly licensed at the Round 2 licensure deadline of May 1, 2012 (and not only those in Tennessee) and (b) take the remedial steps necessary as a result of the invalidation of these unlawful contracts to put all properly-licensed bidders in the position they would have been if the Secretary had followed her own rules and regulations, including (but not limited to) (i) recalculating the correct Medicare payment amount, (ii) redetermining which bids from licensed bidders should have been accepted, and (iii) giving licensed bidders that were offered contracts but rejected them because the Medicare payment amount was improperly low another chance to accept the bids after being given the corrected Medicare payment amount.

COUNT IV
United States Constitution – Separation of Powers Clause

50. Plaintiffs hereby incorporate paragraphs 1 through 49, herein.

51. The Secretary's failure to reject CBP bids from bidders to provide DME in all States where the bidders did not, as of May 1, 2012, have all required State and local licenses, was unlawful under the Secretary's rules and other authority. Despite the requirement of her rules, and the promises made to Congress, the Secretary has failed not only to reject the CBP bids from these bidders, but she actually entered into contracts with them. These contracts must be invalidated because the bids of these bidders were required to have been rejected.

52. The Secretary has the non-discretionary duty to reject CBP bids from suppliers who are not licensed in the States for which they are seeking to provide DME. Thus, this Court has jurisdiction over this action under the separation of powers clause of the United States Constitution, and other authorities to order the Secretary to (a) rescind the contracts for all bidders that were not properly licensed at the Round 2 licensure deadline of May 1, 2012 (and not only those in Tennessee) and (b) take the remedial steps necessary as a result of the invalidation of these unlawful contracts to put all properly-licensed bidders in the position they would have been if the Secretary had followed her own rules and regulations, including (but not limited to) (i) recalculating the correct Medicare payment amount, (ii) redetermining which bids from licensed bidders should have been accepted, and (iii) giving licensed bidders that were offered contracts but rejected them because the Medicare payment amount was improperly low another chance to accept the bids after being given the corrected Medicare payment amount.

IRREPARABLE HARM

53. The Secretary's failure to reject CBP bids from bidders to provide DME in States where the bidders did not, as of May 1, 2012, have all required State and local licenses, was unlawful under the Secretary's rules and other authority. Despite the requirement of her rules, and the promises made to Congress, the Secretary has failed not only to reject the CBP bids from unlicensed bidders, but she actually entered into contracts with them. These contracts must be

invalidated because the bids of these awardees should have been rejected. The Secretary's failure to follow her own rules threatens to cause severe and irreparable injury to Plaintiffs and all other properly-licensed Medicare-participating DME suppliers that sought to participate in the CBP.

54. Successful properly-licensed bidders will be severely and irreparably harmed because they will be subject to Medicare payments amounts that were based, in part, on bids that should have been rejected.

55. Successful properly-licensed bidders will also be severely and irreparably harmed to the extent that they rejected contracts offered by the Secretary because the Medicare payments amounts for the product categories included in the contracts were lower than they would have been if the bids from unlicensed bidders had been rejected. The Medicare beneficiary patients of these suppliers also will be harmed by their inability to continue to obtain services from their longstanding DME suppliers, which will also significantly impact patient care.

56. Unsuccessful properly-licensed bidders will be severely and irreparably harmed because they will be entirely excluded from providing certain DME to patients that they have been serving for many years, even decades, having been displaced by unlicensed bidders whose bids the Secretary unlawfully failed to reject. The Medicare beneficiary patients of these suppliers also will be harmed by their inability to continue to obtain services from their longstanding DME suppliers, which will also significantly impact patient care.

57. Other than this action, Plaintiffs have no adequate remedy, either judicial or administrative, to redress the Secretary's unlawful actions.

INJUNCTIVE RELIEF IS NECESSARY

58. To prevent Plaintiffs and other DME suppliers from being irreparably harmed, the Secretary and her agents must be enjoined from unlawfully implementing Round 2 of the CBP until the Secretary has (a) rescinded the contracts for all bidders that were not properly licensed at the Round 2 licensure deadline of May 1, 2012 (and not only those in Tennessee) and (b) taken the remedial steps necessary as a result of the invalidation of these unlawful contracts to

put all properly-licensed bidders in the position they would have been if the Secretary had followed her own rules and regulations, including (but not limited to) (i) recalculating the correct Medicare payment amount, (ii) redetermining which bids from licensed bidders should have been accepted, and (iii) giving licensed bidders that were offered contracts but rejected them because the Medicare payment amount was improperly low another chance to accept the bids after being given the corrected Medicare payment amount.

Requested Relief

WHEREFORE, Plaintiffs request:

1. An order enjoining the Secretary and her agents from implementing Round 2 of the CBP, which is scheduled to go into effect on July 1, 2013; until she has (a) rescinded the contracts for all bidders that were not properly licensed at the Round 2 licensure deadline of May 1, 2012 (and not only those in Tennessee) and (b) taken the remedial steps necessary as a result of the invalidation of these unlawful contracts to put all properly-licensed bidders in the position they would have been if the Secretary had followed her own rules and regulations, including (but not limited to) (i) recalculating the correct Medicare payment amount, (ii) redetermining which bids from licensed bidders should have been accepted, and (iii) giving licensed bidders that were offered contracts but rejected them because the Medicare payment amount was improperly low another chance to accept the bids after being given the corrected Medicare payment amount.

2. Issuance of a writ of mandamus requiring the Secretary to (a) rescind the contracts for all bidders that were not properly licensed at the Round 2 licensure deadline of May 1, 2012 (and not only those in Tennessee) and (b) take the remedial steps necessary as a result of the invalidation of these unlawful contracts to put all properly-licensed bidders in the position they would have been if the Secretary had followed her own rules and regulations, including (but not limited to) (i) recalculating the correct Medicare payment amount, (ii) redetermining which bids from licensed bidders should have been accepted, and (iii) giving licensed bidders that were

offered contracts but rejected them because the Medicare payment amount was improperly low another chance to accept the bids after being given the corrected Medicare payment amount.

4. Legal fees and costs of suit incurred by Plaintiffs; and

5. Such other relief as this Court may consider appropriate.

DATED: June 19, 2013

Respectfully submitted,

HOOPER, LUNDY & BOOKMAN, P.C.

By: /s/ Robert L. Roth

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Attorneys of Record for Plaintiffs

EXHIBIT A

PALMETTO GBA
A CELERIAN GROUP COMPANY

June 13, 2013

[redacted]

Contract Number: [redacted]

Dear [redacted]:

On April 9, 2013, the Competitive Bidding Implementation Contractor (CBIC) mailed you a fully executed contract for Round 2 of the Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program. The contract included a product category(s) in a Tennessee competitive bidding area (CBA)(s). After further review, we have confirmed that your bid for the Tennessee competition(s) does not comply with the eligibility requirements specified in the regulations and the request for bids (RFB) instructions. Specifically, suppliers must meet state licensure requirements for each product category and each state in a CBA in order for the submitted bid to be eligible for award (42 C.F.R. §414.414 and RFB pgs. 3, 5). Your company did not have a Medicare enrolled location licensed in Tennessee by the Round 2 licensure deadline of May 1, 2012.

The RFB also stated that all bids would be considered final, and could not be amended by the bidder, after the close of the bid window (RFB pgs. 9-10, 15). The only permitted changes to a submitted bid after the close of the bid window are the submission of additional financial documents permitted under the covered document review process (RFB pg. 26). Given these facts and after further review, the Agency has determined that these requirements do not permit the granting of a grace period after the close of the bid window for the purpose of curing a non-financial defect in the submitted bids.

As a result of this defect in your company's bid, the award of the contract with [redacted] for the product category(s) for the Tennessee CBA(s) listed below is void *ab initio*. That is, under the Eligibility Rules a supplier must meet the licensing requirements for each CBA for which a bid is submitted or that bid will be disqualified (RFB pg. 3). Because your company did not possess a properly licensed location within the Tennessee CBA(s) by the licensure deadline, that portion of your bid was automatically disqualified and was ineligible for award.

continued on page 2

Memphis, TN-MS-AR — Enteral Nutrients, Equipment and Supplies

As a result, the Agency is modifying the executed contract to remove this erroneous award(s). Please note that this action does not affect any other product categories or CBAs for which you received a fully executed contract. Attached are the revised Attachment A and B for your contract, which lists the CBAs and product categories included under your contract and the locations eligible to furnish and bill for items and services under the contract respectively.

If you have any questions or concerns, please contact the CBIC customer service at 877-577-5331 between 9 a.m. and 5:30 p.m. Eastern Time.

Sincerely,

Laurence Wilson
Director, Chronic Care Policy Group
Center for Medicare
Centers for Medicare & Medicaid Services

Enclosures:

1. Attachment A
2. Attachment B

EXHIBIT B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

JUN 14 2013

The Honorable David Roe
U.S. House of Representatives
Washington, DC 20515

Dear Representative Roe:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates you bringing these concerns to our attention. The DMEPOS competitive bidding program is an essential tool to help Medicare set appropriate payment rates for DMEPOS items by replacing the existing outdated, excessive fee schedule amounts with market-based prices. We are pleased that this program has already resulted in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and taxpayers, and reducing over-utilization and fraud. Additionally, the program has ensured continued beneficiary access to high quality items and services without compromising beneficiary health or safety.

CMS successfully implemented Round 1 of the program on January 1, 2011 in nine metropolitan areas after making a number of improvements, including new requirements from Congress, and after working closely with stakeholders. The CMS Office of the Actuary projects that the program will save $25.8 billion for Medicare over 10 years, and save another $17.2 billion for beneficiaries through lower coinsurance and premiums. We implemented an active surveillance and monitoring program to identify any issues and have found no disruption in access or negative health consequences for beneficiaries. In addition, CMS has received only a handful of complaints from beneficiaries about the program.

CMS contracts with qualified DMEPOS suppliers. Prior to awarding contracts, each supplier is carefully screened to ensure that it is accredited under applicable Medicare quality standards, as well as meets rigid financial standards, specific Medicare supplier enrollment requirements, and state licensing standards. In some cases, states change their licensing requirements or reinterpret *existing ones during the supplier bidding process. In such cases, suppliers would need to come* into compliance by the program implementation date.

In response to your letter, we have carefully examined Tennessee licensing requirements and we have spoken with state officials in order to obtain clarity on their requirements. We have determined that certain out-of-state suppliers that were licensed in their home state, but that did not meet aspects of existing Tennessee licensing requirements at the time of bid submission, were awarded contracts. As a result, CMS will take steps to void contracts for these suppliers in the Tennessee competitive bidding areas, consistent with the policies and guidelines established for the competitive bidding program. This applies to approximately 30 out of the 98 contract suppliers in the Tennessee Competitive Bidding Areas.

Given the large number of in-state suppliers, including grandfathered suppliers, we are confident that beneficiaries will continue to have access to a wide variety of quality items and services in the state. In addition, we may consider making new awards to qualified and licensed suppliers in the future. We will continue to examine this issue and closely monitor the situation in the state.

Thank you for contacting CMS about this important program. We expect that Medicare beneficiaries in Tennessee and across the country will benefit from this important program as it expands in 2013. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner

Marilyn Tavenner

EXHIBIT C

THE TENNESSEAN

June 18, 2013

Medicare program eliminates 30 out-of-state suppliers

Medicare says companies didn't meet Tennessee requirements

By Getahn Ward
| The Tennessean

The federal Medicare program has dropped nearly a third of the companies chosen to continue supplying home medical equipment to beneficiaries statewide, leaving even fewer suppliers as part of its controversial competitive bidding program set to kick off in Tennessee in less than two weeks.

The contracts were voided because those 30 out-of-state suppliers that had won didn't meet Tennessee licensing requirements when they submitted bids, said Marilyn Tavenner, administrator of the Centers for Medicare and Medicaid Services.

Her disclosure in a letter to the state's congressional delegation is a small win for many Tennessee-based vendors that lost bidding contracts and won't be reimbursed for any supplies sold to Medicare beneficiaries starting July 1.

But Tavenner stopped short of agreeing with ATHOMES, the statewide industry trade group, that the entire results of the competitive bidding process should be scrapped and restarted. The group had argued that CMS violated its own rules by not ensuring that applicants were properly licensed in the states where they were trying to do business.

"This is government at its worst," said Ben Shapiro, chief operating officer of Ed Medical, a Hendersonville-based supplier bracing to lose a quarter of its revenue because it didn't win a local contract. "It will create a real access problem. It's just going to disrupt the whole competitiveness that now exists in the marketplace."

But in her response to the lawmakers, Tavenner said given the large number of in-state suppliers remaining, she was confident beneficiaries will continue to have access to a variety of quality items and services and that her agency might consider making new awards in the future.

"We will continue to examine this issue and closely monitor the situation in the state," Tavenner said.

Through the competitive bidding program, which is being expanded to 91 metro areas including Nashville, federal officials expect billions of dollars in savings from dealing with fewer vendors. According to results from other cities in the program, Medicare was able to cut prices for many offerings — including wheelchairs, crutches and blood pressure monitors — in half.

Lawmakers express their concerns

Last week, more than 200 members of Congress wrote CMS urging a delay in implementing the latest round of the program amid concerns about its structure and licensure issues, such as the one raised in Tennessee.

"The Tennessee delegation wants to make absolutely certain that patients have reliable access to the durable medical equipment supplies that they need, that the law is followed, and that Tennessee businesses are given a level playing field," said U.S. Rep. Phil Roe, R-TN. He was among the

lawmakers urging the delay and is a co-sponsor of legislation that seeks to replace the competitive bidding program with a market pricing program.

Roe and other lawmakers said they were encouraged by some actions CMS has taken, but added that there's more to be done.

"I fear that the winning bid rates have been inaccurately calculated given the inclusion of now voided bids, and I worry that Medicare beneficiaries in Tennessee will not have sufficient options to receive necessary durable medical equipment given the large number of voided bids," said U.S. Rep. Marsha Blackburn, R-Brentwood. "Patients in Tennessee could suffer the access-to-care issues that may arise given the volume of voided bids. Finally, I continue to have reservations about this program going live in less than two weeks with potentially similar problems in other states."

CMS also was made aware of legitimate licensing issues in Maryland and is reviewing the situation to determine the appropriate action to take, said Tami Holzman, a spokeswoman.

"Competitive bidding is working and is saving taxpayers and beneficiaries billions of dollars," she said. "We remain confident that seniors will have access to their equipment, (and) savings will continue."

Additional Facts

What it means for consumers

With the debut of competitive bidding in Tennessee on July 1, Medicare beneficiaries could see changes in the companies that can supply them with durable medical equipment and diabetes testing supplies. In many cases, patients may find their current suppliers still can supply them with equipment but those vendors would be paid at the new lower Medicare rates. Critics say the changes could result in longer wait times and equipment shortages for some patients.

EXHIBIT E

PALMETTO GBA
A CELERIAN GROUP COMPANY

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

April 16, 2013

[redacted]

Dear [redacted]

The Centers for Medicare & Medicaid Services issued you a fully executed DMEPOS Competitive Bidding contract on April 9, 2013, to provide specified competitively bid items in the state of Tennessee. As a reminder, Article II of the contract requires that you comply with all State and local laws, including applicable licensure requirements. In addition, Article IX of the contract requires that locations providing bid items meet Medicare quality and supplier standards, which includes compliance with applicable state licensure requirements.

Bids were evaluated and contracts offered based on the licensure requirements on the National Supplier Clearinghouse (NSC) DMEPOS State Licensure Directory as of January 30, 2012, which was the day Round 2 bidding opened. Since that date, the Tennessee licensure requirements have been updated on the NSC directory with a notation that states:

F- In addition, by both law and regulation, in order to be licensed to ship medical equipment into this State, a provider must maintain an office in Tennessee. That provision is located in 1200-08-29-.06(5) and states: (5) Physical Location - Each parent and/or branch shall: (a) Be located in Tennessee; (b) Be staffed during normal business hours and have a working telephone; (c) Be used for the dispensing, servicing, and storage of home medical equipment or related health care services; (d) Meet all local zoning requirements; and (e) Have all required current licenses and/or permits conspicuously posted in the agency.

Therefore, in order to be in compliance with the terms of the contract you must have a Medicare-enrolled location that is licensed in the state of Tennessee on or before July 1, 2013, to furnish the competitively bid items specified in your contract. To add enrolled locations to your contract, please use the contract supplier location update form on the Competitive Bidding Implementation Contractor (CBIC) website, www.dmecompetitivebid.com. To enroll a new location in Tennessee, you must submit your properly completed 855-S Supplier Enrollment form to the NSC no later than May 15, 2013. Prior to submission of your application, you must be able to demonstrate compliance with all DMEPOS supplier standards. This includes, but is not limited to: the enrolling location must be open and operational, have appropriate licensure and accreditation, have sufficient inventory on hand or through inventory contract(s), and have proper surety bond and liability insurance in place. To expedite the enrollment process, please ensure that all sections of the 855-S are complete and all required documentation, including the application fee, is included. A site visit will be performed prior to enrollment and issuance of billing privileges. Your application to enroll a new location in Tennessee should be mailed to:

National Supplier Clearinghouse
P.O. Box 100236
Columbia, SC 29202-3236

For complete enrollment instructions, please go to the NSC website at palmettogba.com/NSC or call 866-238-9652.

If you plan to subcontract certain allowable services, it is important to remember that both the contract (primary) supplier and the subcontractor must be in compliance with the supplier standards, including meeting applicable state licensure requirements. Failure to comply with state licensure requirements or any other requirement delineated in the DMEPOS competitive bidding contract will result in a breach of your entire competitive bidding contract for all competitions.

Please contact the CBIC customer service center at 877-577-5331 between 9 a.m. and 5:30 p.m., Monday through Friday Eastern time, if you have any questions about the information outlined in this letter.

Sincerely,

Jean Catalano

Jean Catalano
Program Manager
Competitive Bidding Implementation Contractor

CIVIL COVER SHEET

JS-44 (Rev. 3/13 DC)

I. (a) PLAINTIFFS
AMERICAN ASSOCIATION FOR HOMECARE, et al.,
1707 L Street, N.W., Suite 350
Washington, D.C. 20036

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF 11001
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS
KATHLEEN SEBELIUS, Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT 11001
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)
Robert L. Roth, Esq.
Hooper, Lundy & Bookman, P.C.
975 F Street, N.W., Suite 1050
Washington, D.C. 20004 (202) 580-7701

ATTORNEYS (IF KNOWN)

II. BASIS OF JURISDICTION
(PLACE AN x IN ONE BOX ONLY)

- ○ 1 U.S. Government Plaintiff
- ○ 3 Federal Question (U.S. Government Not a Party)
- ◉ 2 U.S. Government Defendant
- ○ 4 Diversity (Indicate Citizenship of Parties in item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) FOR DIVERSITY CASES ONLY!

	PTF	DFT		PTF	DFT
Citizen of this State	○ 1	○ 1	Incorporated or Principal Place of Business in This State	○ 4	○ 4
Citizen of Another State	○ 2	○ 2	Incorporated and Principal Place of Business in Another State	○ 5	○ 5
Citizen or Subject of a Foreign Country	○ 3	○ 3	Foreign Nation	○ 6	○ 6

IV. CASE ASSIGNMENT AND NATURE OF SUIT
(Place an X in one category, A-N, that best represents your Cause of Action and one in a corresponding Nature of Suit)

○ **A. *Antitrust***
- ☐ 410 Antitrust

○ **B. *Personal Injury/ Malpractice***
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Medical Malpractice
- ☐ 365 Product Liability
- ☐ 367 Health Care/Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Product Liability

◉ **C. *Administrative Agency Review***
- ☒ 151 Medicare Act

Social Security
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

Other Statutes
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 890 Other Statutory Actions (If Administrative Agency is Involved)

○ **D. *Temporary Restraining Order/Preliminary Injunction***

Any nature of suit from any category may be selected for this category of case assignment.

(If Antitrust, then A governs)

○ **E. *General Civil (Other)*** OR ○ **F. *Pro Se General Civil***

Real Property
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent, Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

Personal Property
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

Bankruptcy
- ☐ 422 Appeal 27 USC 158
- ☐ 423 Withdrawal 28 USC 157

Prisoner Petitions
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Conditions
- ☐ 560 Civil Detainee – Conditions of Confinement

Property Rights
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

Federal Tax Suits
- ☐ 870 Taxes (US plaintiff or defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

Forfeiture/Penalty
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

Other Statutes
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 430 Banks & Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions
- ☐ 470 Racketeer Influenced & Corrupt Organization

- ☐ 480 Consumer Credit
- ☐ 490 Cable/Satellite TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions (if not administrative agency review or Privacy Act)

○ G. *Habeas Corpus/ 2255* ☐ 530 Habeas Corpus – General ☐ 510 Motion/Vacate Sentence ☐ 463 Habeas Corpus – Alien Detainee	○ H. *Employment Discrimination* ☐ 442 Civil Rights – Employment (criteria: race, gender/sex, national origin, discrimination, disability, age, religion, retaliation) *(If pro se, select this deck)*	○ I. *FOIA/Privacy Act* ☐ 895 Freedom of Information Act ☐ 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	○ J. *Student Loan* ☐ 152 Recovery of Defaulted Student Loan (excluding veterans)
○ K. *Labor/ERISA (non-employment)* ☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 740 Labor Railway Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	○ L. *Other Civil Rights (non-employment)* ☐ 441 Voting (if not Voting Rights Act) ☐ 443 Housing/Accommodations ☐ 440 Other Civil Rights ☐ 445 Americans w/Disabilities – Employment ☐ 446 Americans w/Disabilities – Other ☐ 448 Education	○ M. *Contract* ☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholder's Suits ☐ 190 Other Contracts ☐ 195 Contract Product Liability ☐ 196 Franchise	○ N. *Three-Judge Court* ☐ 441 Civil Rights – Voting (if Voting Rights Act)

V. ORIGIN

◉ 1 Original Proceeding ○ 2 Remand from State Court ○ 3 Remanded from Appellate Court ○ 4 Reinstated or Reopened ○ 5 Transferred from another district (specify) ○ 6 Multi-district Litigation ○ 7 Appeal to District Judge from Mag. Judge

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)
This action seeks mandamus and other relief relating to the Medicare Program, 42 U.S.C. 1395w-3.

VII. REQUESTED IN COMPLAINT CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 **DEMAND $** **JURY DEMAND:** Check YES only if demanded in complaint YES ☐ NO ☒

VIII. RELATED CASE(S) IF ANY (See instruction) YES ☐ NO ☒ If yes, please complete related case form

DATE: 6/19/13 **SIGNATURE OF ATTORNEY OF RECORD** _____

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and services of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the cover sheet.

I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff if resident of Washington, DC, 88888 if plaintiff is resident of United States but not Washington, DC, and 99999 if plaintiff is outside the United States.

III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.

IV. CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of the case.

VI. CAUSE OF ACTION: Cite the U.S. Civil Statute under which you are filing and write a brief statement of the primary cause.

VIII. RELATED CASE(S), IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.

AO 440 (Rev. 12/09; DC 03/10) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

AMERICAN ASSOCIATION FOR HOMECARE. et al.

Plaintiff

v.

KATHLEEN SEBELIUS, Secretary, United States Department of Health and Human Services

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Kathleen Sebelius, Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Robert L. Roth, Esq.
Hooper, Lundy & Bookman, P.C.
975 F Street, N.W., Suite 1050
Washington, D.C. 20004

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* .....
was received by me on *(date)* .....

☐ I personally served the summons on the individual at *(place)* .....
on *(date)* ; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* .....
, a person of suitable age and discretion who resides there,
on *(date)* , and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* , who is
designated by law to accept service of process on behalf of *(name of organization)* .....
on *(date)* ; or

☐ I returned the summons unexecuted because ; or

☐ Other *(specify)*:

My fees are $ for travel and $ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date:

Server's signature

.....
Printed name and title

.....
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 12/09; DC 03/10) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

AMERICAN ASSOCIATION FOR HOMECARE, et al.

Plaintiff

v.

KATHLEEN SEBELIUS, Secretary, United States Department of Health and Human Services

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Eric H. Holder, Jr., Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530-0001

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Robert L. Roth, Esq.
Hooper, Lundy & Bookman, P.C.
975 F Street, N.W., Suite 1050
Washington, D.C. 20004

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: .....

Signature of Clerk or Deputy Clerk

Civil Action No.

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☐ I personally served the summons on the individual at *(place)* .....

on *(date)* ..... ; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* .....

, a person of suitable age and discretion who resides there,

on *(date)* , and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* , who is

designated by law to accept service of process on behalf of *(name of organization)* .....

on *(date)* ; or

☐ I returned the summons unexecuted because ; or

☐ Other *(specify)*:

My fees are $ for travel and $ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date:

Server's signature

.....

Printed name and title

.....

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 12/09; DC 03/10) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

AMERICAN ASSOCIATION FOR HOMECARE, et al.

Plaintiff

v.

KATHLEEN SEBELIUS, Secretary, United States Department of Health and Human Services

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Ronald C. Machen, Jr., U.S. Attorney
U.S. Attorney's Office for the District of Columbia
555 4th Street, N.W.
Washington, D.C. 20530

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Robert L. Roth, Esq.
Hooper, Lundy & Bookman, P.C.
975 F Street, N.W., Suite 1050
Washington, D.C. 20004

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk

Civil Action No.

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☐ I personally served the summons on the individual at *(place)* .....

on *(date)* ; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* .....

, a person of suitable age and discretion who resides there,

on *(date)* , and mailed a copy to the individual's last known address; or

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on *(date)* ; or

☐ I returned the summons unexecuted because ; or

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Date:

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc: