TESTIMONY OF
THE DEPARTMENT OF THE ATTORNEY GENERAL
TWENTY-SEVENTH LEGISLATURE, 2014

ON THE FOLLOWING MEASURE:
S.B. NO. 2031, S.D. 2, H.D. 1, RELATING TO HEALTH.
S.B. NO. 2031, S.D. 2, H.D. 2 PROPOSED, RELATING TO HEALTH.

BEFORE THE:
HOUSE COMMITTEE ON CONSUMER PROTECTION & COMMERCE

DATE: Wednesday, March 19, 2014 **TIME:** 2:10 p.m.

LOCATION: State Capitol, Room 325

TESTIFIER(S): David M. Louie, Attorney General, or
Lori K. Aquino, Deputy Attorney General

Chair McKelvey and Members of the Committee:

The House Committee on Health requested that "the Department of the Attorney General provide follow up information to the Committee on Consumer Protection & Commerce on the licensing and in-state requirements for suppliers under the State of Tennessee's Competitive Bidding Program." (Stand. Com. Rep. No. 976-14)

Our research indicates that Tennessee is the only state to have passed a law requiring physical presence for Medicare DMEPOS vendors. We note that the Healthcare Association of Hawaii (HAH) in its advocacy of this bill has not cited to a single other state as having such a law, confirming our findings.

Tennessee's physical presence requirement is part of a licensing program for home medical equipment. It is a program not narrowly tailored to only apply to Medicare but applies to all vendors of "home medical equipment," as that term is defined by Tennessee administrative regulation. In specific, under Tenn. Code Ann. section 68-11-226(a), all providers of "home medical equipment" with a "principal place of business outside the state" must "maintain an office or place of business within this state."

The Medicare National Bidding Program was created by federal statute in 2003,[1] but was instituted in stages ("rounds"), with the program applying to Tennessee and Hawaii in July of 2013. In anticipation of phase implementation, the Centers for Medicare and Medicaid Studies (CMS), the federal agency within the U.S. Department of Health and Human Services (DHHS)

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[1] Medicare DMEPOS Competitive Bidding Program, Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, section 302, 117 Stat. 2066.

charged with administering the program, received bids from prospective vendors and entered into three-year contracts for the various regions. As indicated by the CMS website, for Round 2, CMS has entered into contracts with vendors both in Hawaii and across the country to supply Medicare DMEPOS products to Medicare beneficiaries. The three-year contracts for Hawaii went into effect on July 1, 2013.

Tennessee, also part of Round 2, apparently enacted its physical presence licensing program prior to the time CMS began accepting bids for Tennessee. This is evidenced in the CMS administrator's letter (Exhibit A hereto), dated June 14, 2013, in which she states that:

> We have determined that certain out-of-state suppliers that were licensed in their home state, but that did not meet all aspects of **existing** Tennessee licensing requirements **at the time of bid submission**, were awarded contracts.
> (emphasis added)

DHHS' federal regulation pertaining to Medicare DMEPOS suppliers, 42 C.F.R. section 424.57, provides that "[i]f a State requires licensure to furnish certain items or services, a DMEPOS supplier (A) Must be licensed to provide the item or services; and (B) May contract with a licensed individual or other entity to provide the licensed services unless expressly prohibited by state law."

It appears that in the spring of 2013 CMS was not aware of or overlooked the Tennessee physical presence licensing requirement and approved Medicare DMEPOS providers who did not comply with that requirement. U.S. Congressional delegates for Tennessee brought the matter to CMS' attention (Exhibit B hereto) and the response was Exhibit A in which CMS voided certain vendor contracts.[2] However, the American Association of Homecare and Home Mediservice, Inc., (AAH/HMI) wanted CMS to void *all of the Medicare DMEPOS contracts for Tennessee* and start the bidding process over. AAH/HMI wanted the entire bid process voided in order to "put all properly licensed bidders in Tennessee in the position they would have been" if DHHS had at the outset "rejected the bids submitted by the unlicensed bidders." Complaint, Preliminary Statement (Exhibit C, without exhibits). AAH/HMI sued Kathleen Sebelius, Secretary of the DHHS, in a complaint filed in federal court in the District of Columbia on June

[2] The date of CMS' letter is unclear as it is stamped June 14, 2013, but appears to respond to Representative Roe's letter dated June 24, 2013.

19, 2013. AAH/HMI asked the federal court to enjoin CMS from continuing to carry out the competitive bidding program for Tennessee on the ground that CMS was not following its own regulation (requiring vendors to comply with state licensing).

The federal court refused to enjoin CMS. Excerpts from the hearing on the motion to enjoin DHHS are attached as Exhibit D. The federal judge denied injunctive relief to AAH/HMI concluding that there was no subject matter jurisdiction and that federal law "explicitly barred" judicial review of CMS' Medicare contracts, under 42 U.S.C. section 1395w-3(b)(11). DHHS subsequently moved to dismiss the AAH/HMI complaint but before the motion could be heard *AAH/HMI voluntarily dismissed its action* on September 5, 2013. (Exhibit E)

Accordingly, neither Tennessee's licensing law nor what CMS has done with Tennessee's Medicare DMEPOS vendors in any way supports bill draft, S.B. No. 2031, S.D. 2, H.D. 1, which proposes a non-licensing law and imposes a physical presence on only Medicare DMEPOS vendors. The current bill version remains, as set forth in our recurring testimony in opposition to this bill, preempted by federal law.

It should be noted that CMS has expressly warned states about imposing new licensing requirements in order to avoid preemption. "States may not purport to exempt a law from preemption on the grounds that it is a licensure law by imposing requirements not generally associated with obtaining a license as a condition of retaining a license." Medicare Managed Care Manual, Chapter 10, Rev. 103, 11-04-11. A physical presence requirement is not an established license requirement for suppliers of medical equipment in Hawaii.

Despite all the above, we offer the following recommendations to S.B. No. 2031, S.D. 2, H.D. 1, which may increase the bill's chances of surviving federal preemption:

1. Revise the bill to make it part of a licensing program.[3] This would allow the law a chance to fall within the state licensing exception to the preemption doctrine, as reflected in 42 C.F.R. section 424.57.

[3] The original bill versions in both the House and Senate proposed a physical presence requirement as an amendment to the Department of Human Services' chapter 346, HRS. The S.B. No. 2031, S.D. 1 version was a licensing program with complaints filed with the Office of Consumer Protection. The subsequent S.D. 2, which crossed over to the House, reverted substantially to the prior version of the bill draft, without a licensing program.

2. Amend the definition of "supplier" to mean all suppliers of DMEPOS, not just those who are participating in Medicare's competitive bidding program. The definition of DMEPOS will need to be made more specific, either in the statute or through authorized administrative rules, so that it is very clear which businesses must be licensed and which need not be.

3. To avoid direct conflict with the federal regulation, provide an alternative method of licensing where a vendor chooses not to maintain a physical presence in the state. This could include submission of relevant documentation, annual reports to the licensing agency, and licensure fees.

4. Licensing requirements for suppliers of DMEPOS should be express and the requirements imposed similar to those already employed by licensing agencies in the State. "Deeming" licensure (as was provided for in S.D. 1) is nebulous and would seem to lead to confusion, particularly for consumers who may or may not know if a vendor is in fact licensed.

5. Provide that the law would be effective only after the public has been given notice of receipt of a letter of approval from CMS that the law is a proper state licensure provision and not preempted by federal law. It is our understanding that CMS reviews Medicare preemption issues with states on a case-by-case basis.

The proposed S.B. No. 2031, S.D. 2, H.D. 2, addresses our first recommendation by creating a licensing program administered by the Executive Office on Aging. While this is an improvement over the current bill version, we continue to have concerns over the narrow scope of the bill in that it targets only Medicare vendors. We also find the "deeming" wording of the proposed version potentially confusing to consumers. It is also unclear how consumers will know how to verify that suppliers are licensed or what recourse consumers will have when dealing with unlicensed vendors.

Finally, we reiterate that CMS has already entered into three-year contracts for the Hawaii region. Even if this bill were to become law, it is unclear whether CMS will void the existing contracts, as it did in Tennessee, because the physical presence requirement was not a licensing requirement *at the time of the bidding*. See Exhibit B. Based on the federal lawsuit discussed above, it appears likely that any Hawaii licensing law requiring physical presence would only apply for the next contractual bid period.

We respectfully recommend that the Committee hold this bill to the extent it remains in its current version and that, if a version of proposed H.D. 2 is adopted, it address our recommendations.

Congress of the United States
Washington, DC 20515

June 24, 2013

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Tavenner:

We write with great concern regarding Centers for Medicare and Medicaid Services (CMS) policy of providing non-licensed Durable Medical Equipment (DME) providers with Medicare contracts to supply DME products in Tennessee; disregarding Tennessee state licensure law. Given your confirmation that 30 of 98 contract suppliers in the Tennessee Competitive Bidding Areas did not meet Tennessee State licensing requirements, we respectfully request that you delay implementation of Round 2 until the following outstanding questions have been resolved.

Your letter dated June 14, 2013 verified that nearly one-third of suppliers awarded contracts in Tennessee were in fact not in compliance with Tennessee state law, which raises serious concerns over the accuracy of the surveillance and monitoring program you referenced in your response. Tennessee law requires "physical presence" in our state as a prerequisite to obtaining a license to provide medical equipment. Was this pre-requisite taken into consideration as CMS's process of preventing fraud and abuse in the DME program? Of the 30 contracts, did any falsely represent themselves as having met state licensure when they did not meet the requirements? How will CMS hold the suppliers accountable for submitting falsified documentation to a government agency?

We are concerned that out-of-state bidders skewed the bidding process, and ultimately impacted the median pricing for affected product categories. Tennessee has a unique tax system with no state income tax, yielding higher consumption taxes which were most likely not taken into account by CMS with the lower bids by out-of-state suppliers. Can CMS verify that in addition to Tennessee state licensure law, bids also took into account state and local taxes to accurately claim the cost of delivering goods and services in a given area?

While there is some relief that CMS is taking steps to void potentially fraudulent contracts, with thirty fewer suppliers than originally expected there is likely to be a significant impact in patient access to life saving DME goods and services. We strongly urge you to allow qualified bidders who were not awarded a contract in Round 2 of the program to re-bid in order to assure that patients have timely access to a quality services and providers ready to meet their medical needs.

EXHIBIT "A"

The disappointing news that CMS awarded contracts to unlicensed providers requires your agency to delay implementation of Round 2 in order to provide the agency adequate time to re-examine those suppliers that may have otherwise been awarded a contract and been able to service patients in need of life sustaining supplies. We are concerned that if this program were to go into effect on July 1, 2013, Tennesseans would not have access to enough licensed companies contracted by Medicare to supply DME products.

Thank you for your attention to our urgent concerns.

Sincerely,

Diane Black
Member of Congress

Phil Roe, MD
Member of Congress

Marsha Blackburn
Member of Congress

Chuck Fleischmann
Member of Congress

John Duncan
Member of Congress

Scott DesJarlais, MD
Member of Congress

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.

EXHIBIT "B"

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

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

EXHIBIT "C"

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), *see 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

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN ASSOCIATION FOR HOMECARE, et al.,	:	
	:	Docket No.: CA 13-922
Plaintiffs,	:	
	:	Washington, DC
vs.	:	4:30 p.m., Thursday
	:	June 27, 2013
KATHLEEN SEBELIUS,	:	
	:	
Defendant.	:	
	X	

REPORTER'S OFFICIAL TRANSCRIPT OF MOTION FOR TRO
BEFORE THE HONORABLE BERYL A. HOWELL
UNITED STATES DISTRICT JUDGE

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Also Present: JOCELYN BEER, HHS

The Court Reporter: CHANTAL M. GENEUS, RPR, CRR
Certified Realtime Reporter
Registered Professional Reporter
United States District Court
333 Constitution Avenue, NW
Washington, DC 20001

Proceedings reported by machine shorthand. Transcript produced by computer-aided transcription.

EXHIBIT "D"

that we have provided to the defendant by e-mail an hour or so ago with an updated list of states that have license issues. If I may present that.

THE COURT: Yes. Please give it to my courtroom deputy.

MR. ROTH: We've been in the process of trying to identify states that have this unlicensed issue. To the extent a state doesn't have a licensing issue, then they would not be within the scope of their relief that we are seeking from this Court, Your Honor.

THE COURT: What about based on the declaration provided by the director of the bidding program? I think his name is Michael Keane. It said that HHS has investigated certain allegations that contracts were awarded to unlicensed suppliers and found those allegations to be groundless.

So do those states continue to appear on your list?

MR. ROTH: Well, Your Honor, we have -- we can specifically address one of the states that Mr. Keane addressed.

THE COURT: I think there were four that he said that the allegations turned out to be baseless: California, Michigan, Georgia, New York.

So, really, the answer I was expecting from you was, well, we meant the Eleventh Amendment, but we forgot to cite it or something like that.

What is the clause under the Constitution under which your claim -- that you claim was violated?

MR. ROTH: It would simply be the authority of the courts under Article III to enforce a judicial power of the country, Your Honor.

THE COURT: I see. Okay. All right.

Now, you were getting into some of the more significant -- and to my mind, and I'll be honest with you -- issues about my subject matter jurisdiction here to even review your claims.

Now, I know you claim that I do -- I am not barred by 1395w-3(b)(11) -- and let's just call it (b)(11) for short -- from reviewing these claims. And, as I understand it, you are asserting that because the Secretary violated her own regulations in her conduct of the bidding program, her actions were *ultra vires* and, therefore, not only do I not have to be barred by sovereign immunity the federal government has, but I also don't have to be barred by (b)(11) in reviewing these claims.

Do I have that right?

MR. ROTH: That is correct, Your Honor.

THE COURT: I read your reply brief. And even looking at the cases that you've cited, I really -- as I understand it in the cases that I've reviewed, the *ultra vires* doctrine has usually only been applied when the -- an agency has acted outside of its statutorily delegated authority, not when an agency has violated its own regulation. Errors by agencies don't trigger the *ultra vires* doctrine.

So, I mean, I -- I really want you to explain to me or confirm for me that you are not saying here that the agency has acted outside of its statutory authority.

That's not what you're claiming, right?

MR. ROTH: That's correct, Your Honor.

THE COURT: All right.

Okay. So now let's turn to the concern that I have, which is that if I would accept your perspective on the breadth of the *ultra vires* doctrine, that it applies when an agency violates any one of its own regulations and any time an agency violates its own regulations, sovereign immunity is out the window; any statutory judicial bar to review is out the window. I really want you to answer what is left of sovereign immunity or the statutory bar in (b)(11).

Medicare supplier. And the amended complaint, at ECF Number 7 on the docket, is now the operative complaint in this action.

Pending before the Court is the plaintiffs' TRO application pursuant to Federal Rule of Civil Procedure 65 and Local Rule 65.1. In the TRO application, the plaintiffs seek to enjoin the HHS Secretary from going forward with the planned July 1, 2013, implementation of Round 2, the Medicare DME competitive bidding program, or CBP program, until the Secretary has "eliminated the effect of her having unlawfully entered into CBP contracts with bidders that were not properly licensed under state law. That's ECF Number 8 at Page 1.

Specifically, the plaintiffs allege the Secretary's use of bids submitted by DME suppliers without required state and local licenses to determine which DME suppliers will be allowed to provide DME to Medicare beneficiaries on or after July 1, 2013, and the amount that Medicare will pay successful bidders is an *ultra vires* violation of the Secretary's own regulations. It's also at ECF Number 8 at Page 8.

The plaintiffs argue that they have satisfied all four of the relevant factors the Court must consider in deciding whether to grant the

(2008) and Shirley v. Sebelius, 388, which is a DC Circuit case from 2011.

The DC Circuit has nevertheless, despite its strongly suggestive dicta, explicitly abstained from deciding this question. See *Sherley*, 644 F.3d 393 observing that, "We need not wade into this circuit's split today. Thus, absent binding authority or clear guidance, the Court finds that the most prudent course is to bypass this unresolved issue and proceed to explain why a TRO is not appropriate under the sliding scale framework.

If the plaintiffs cannot meet the less demanding sliding scale standard than *a fortiori*, they cannot satisfy the more stringent standard alluded to by the Supreme Court and the Court of Appeals.

That being said, meeting the requisite burden for -- in meeting the requisite burden for injunctive relief, it's particularly important for the movant to demonstrate a likelihood of success on the merits. See *Konarski v. Donovan*, 763 F. Supp.2d., District Court case from DC (2011). See also *Greater New Orleans Fair Housing Action Center versus U.S. Department Of Housing and Urban Development*, 639 F.3d 1078, which is a DC Circuit case from 2011.

The Court finds the plaintiffs have not

satisfied any of the four injunctive relief factors. I'm going to address each of those factors in turn starting with the likelihood of success on the merits.

Integrally intertwined with the consideration of the plaintiffs' likelihood of success on the merits is the threshold question of whether this Court has jurisdiction to hear the plaintiffs' claims.

The Court determines that it is highly likely that it does not have jurisdiction for two reasons: One, it is unclear from the face of the plaintiffs' amended complaint on what basis this Court has subject matter jurisdiction of the plaintiffs' claims; and, two, the plaintiffs' claims are explicitly barred by 42 U.S.C. 1395w-3(b)(11).

Even if this Court had jurisdiction to consider the plaintiffs' claims, it appears based on the record that the Secretary has complied with or is in the process of complying with the regulation she has set forth in administering the CBP process. I'm going to address these issues in turn.

Turning, first, to whether it has jurisdiction to consider the plaintiffs' claims, federal courts are courts of limited jurisdiction. They may exercise only those powers authorized by the

Section 1361 does not, by itself, operate as a waiver of sovereign immunity. See, for example, *Washington Legal Foundation versus U.S. Sentencing Commission*, a DC Circuit case from 1996 which collects a number of cases in that regard.

Thus, Section 1361 only provides an additional remedy where jurisdiction already exists. And, as I discussed, I have significant concern whether such jurisdiction exists here after reviewing the plaintiffs' amended complaint.

Similarly, the All Writs Act of 28 U.S.C. 1651(a) also does not provide a basis for subject matter jurisdiction in the face of the government sovereign immunity.

While the amended complaint leaves significant questions to the Court about whether the plaintiffs have indeed demonstrated subject matter jurisdiction, it is more clear that Congress has chosen to expressly preclude review of plaintiffs' claims under 42 U.S.C. 1395w-3(b)(11)(A).

The fact that federal courts are vested with jurisdiction over all civil actions in 1331 does not mean that all federal courts may exercise jurisdiction over all civil actions. Congress can withhold from any court of its creation jurisdiction of any of the

Court case from 2005 which held that the erroneous exercise of statutory authority does not convert it to an *ultra vires* act. That case cited *Larson*, a domestic and foreign commerce court, Supreme Court case from 1949, where the Supreme Court said, a claim of error in the exercise of that power is not sufficient for the action of -- a state action to be considered *ultra vires*.

In short, the Court disagrees with the plaintiffs' theory that an agency violation of its own regulations constitutes a trigger that allows plaintiffs to bring a lawsuit regarding issues otherwise expressly precluded by statute from judicial review.

The plaintiffs have cited no case that would support the sweeping theory, and the Court has not found any reason to depart from the DC Circuit's conclusion in *Texas Alliance* that "The presumption of reviewability here is overcome by the specific and emphatic statutory language prohibiting judicial review of the competitive bidding procedure.

Therefore, since the plaintiffs' claims are expressly precluded by statute, the plaintiffs are unlikely to succeed on the merits of their claims. But even if the plaintiffs' claims were not barred and

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN ASSOCIATION FOR HOMECARE, *et al.*, Plaintiffs, v. KATHLEEN SEBELIUS, Secretary, Department of Health and Human Services, Defendant.	Civil Action No. 13-00922-BAH

NOTICE OF DISMISSAL WITHOUT PREJUDICE

Pursuant to Federal Rule of Civil Procedure 41(a)(1)(i), Plaintiffs American Association of Homecare, *et al.*, by and through their undersigned attorney, hereby dismiss, without prejudice, the above-captioned case against defendant Kathleen Sebelius, in her official capacity as Secretary of the United States Department of Health and Human Services. Defendant Secretary has not served either an answer or a summary judgment motion in this case.

Respectfully submitted,

Dated: September 5, 2013

/s/Robert L. Roth

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EXHIBIT "E"

NEIL ABERCROMBIE
GOVERNOR

PATRICIA McMANAMAN
Director

BARBARA A. YAMASHITA
DEPUTY DIRECTOR

STATE OF HAWAII
DEPARTMENT OF HUMAN SERVICES
P. O. Box 339
Honolulu, Hawaii 96809-0339

March 19, 2014

TO: The Honorable Angus L.K. McKelvey, Chair
House Committee on Consumer Protection and Commerce

FROM: Patricia McManaman, Director

SUBJECT: **S.B. 2031, S.D. 2, H.D.1 - RELATING TO HEALTH**

Hearing: Wednesday, March 19, 2014; 2:10 p.m.
Conference Room 325, State Capitol

PURPOSE: The purpose of this bill is to require vendors who have been awarded contracts through the Centers for Medicare and Medicaid Services durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) bidding program to have a physical presence in Hawaii.

DEPARTMENT'S POSITION: The Department of Human Services (DHS) opposes this bill.

The DHS administers the state's Medicaid program. This bill would insert into DHS' chapter 346, a requirement for the DHS to regulate Medicare DMEPOS providers. The durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) program is a Medicare program; it is not a Medicaid program.

The DHS does not have the authority nor enforcement powers or the resources to regulate vendors and suppliers conducting business in the State.

It is also our understanding that states do not have authority over Medicare contracts and programs. The one exception may be through state licensing requirements. Requiring that a Medicare vendor have a physical presence in Hawaii may only be possible through state licensing requirements. The DHS does not license providers, including Medicare providers.

The DHS defers to the Department of Attorney General on the legal issues of this bill.

Thank you for the opportunity to testify on this measure.

Healthcare Association of Hawaii

Wednesday – March 19, 2014 – 2:10pm
Conference Room 325

The House Committee on Consumer Protection and Commerce

To: Representative Angus L.K. McKelvey, Chair
Representative Derek S.K. Kawakami, Vice Chair

From: George Greene
President & CEO
Healthcare Association of Hawaii

Re: Testimony in Support
SB 2031, SD 2, HD 1 — Relating to Health
PROPOSED SB 2031, SD2, HD2 – Relating to Health

The Healthcare Association of Hawaii (HAH) is a 116-member organization that includes all of the acute care hospitals in Hawaii, the majority of long term care facilities, all the Medicare-certified home health agencies, all hospice programs, as well as other healthcare organizations including durable medical equipment, air and ground ambulance, blood bank and respiratory therapy. In addition to providing quality care to all of Hawaii's residents, our members contribute significantly to Hawaii's economy by employing nearly 20,000 people statewide.

Thank you for the opportunity to testify in strong support of SB 2031, SD2, HD1 which would require vendors who supply durable medical equipment (DME) to the residents of Hawaii through the Centers for Medicare and Medicaid Services' (CMS) nationwide Competitive Bidding Program to have a physical presence in the state. HAH also strongly supports the Proposed SB 2031, SD2, HD2, which would create a basic licensing program for DME suppliers participating in the nationwide competitive bidding program and would require such suppliers to maintain an adequate in-state presence.

Medicare beneficiaries in Hawaii are experiencing a reduction in access to quality care as a result of the change in the way Medicare purchases DME. Round 2 of Medicare's DME Competitive Bidding Program began July 1, 2013 in Honolulu County. The unintended consequences of the implementation of this national program in Hawaii have been disastrous. Only 13 of the 97 vendors selected to supply the state with DME are located within the state of Hawaii. The minimum shipping time from the mainland to Hawaii is two to four days, and the typical wait time for physician-ordered wheelchairs and hospital beds is four to eight weeks. These vendors do not have special phone or service hours to account for the time difference, which means when Medicare beneficiaries in Hawaii call after 11 a.m., the offices are closed.

Without access to timely, local services, Medicare beneficiaries in Hawaii have been forced to forego necessary DME devices. This restricted access to care has led to reductions in health, increases in

preventable admissions and readmissions, increases in costs to beneficiaries and the Medicare system and impact on quality of life for Medicare patients.

SB 2031, SD2, HD1 and the Proposed SB 2031, SD2, HD2, would require Medicare DME vendors to have a physical presence in the State, which would ensure that vulnerable Medicare patients receive DME critical to their care by requiring vendors to have an in-state presence. DME suppliers are required under federal law to comply with all applicable state regulations as a prerequisite to qualifying for the nationwide Competitive Bidding Program. (42 CFR 424.57(c)(1)(ii).) As a result, if SB 2031, SD2, or the Proposed SB 2031, SD2, HD2, is enacted, out of state DME suppliers that did not maintain an in-state presence would be ineligible for supplying Medicare DME to Hawaii's patients. This would allow patients to procure DME from alternate, in-state vendors who would be able to timely supply critical DME to Hawaii's Medicare patients.

The failure of the nationwide Competitive Bidding Program has led to at least one other state enacting an in-state presence law for DME suppliers. The Tennessee Department of Health, Board for Licensing Health Care Facilities, adopted Rule 1200-08-29-.06(5), which imposes a similar in-state presence requirement on out of state DME suppliers. (Available at http://www.state.tn.us /sos/rules /1200/1200-08/1200-08-29.20120402.pdf.) In June 2013, Marilyn Tavenner, the CMS Administrator, validated Tennessee's in-state presence law by voiding the contracts of thirty DME suppliers who failed to meet Tennessee's in-state presence requirements. (Letters attached; available at https://s3.amazonaws.com/aafh/downloads/308/HHS_Lawsuit_061913.pdf?1371669910 at pp. 27-38.) As such, it is clear that states have the authority to require an in-state presence of DME suppliers participating in the nationwide competitive bidding program.

In sum, HAH respectfully asks the committee to pass SB 2031, SD2, HD1, or the Proposed SB 2031, SD2, HD2, which would ensure that Hawaii's Medicare DME patients have access to critical, life-sustaining medical supplies.

Thank you for the opportunity to testify in strong support of SB 2031, SD2, and the Proposed SB 2031, SD2, HD2.

Healthcare Association of Hawaii

Tuesday February 11, 2014

To: Lori K. Aquino
Deputy Attorney General
State of Hawaii
Health & Human Services Division

From: George Greene
President & CEO
Healthcare Association of Hawaii

RE: Preemption Analysis of Proposed HB 2528, HD2 [Proposed SB 2031, SD2, HD2]

The Attorney General has asked for an analysis of federal preemption as it relates to HB 2528. At the hearing before the House Committee on Health, the Attorney General raised preemption concerns with HB 2528 because, in the Attorney General's view, HB 2528 "conflicts with federal law,"—namely the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)—"because it imposes on federally approved DMEPOS suppliers the additional requirement of a physical presence in Hawaii." (HB 2528, Late Testimony of the Attorney General, January 31, 2014, p. 1 [AG Testimony].) The Attorney General did, however, note that "exceptions to this broad preemption pertain to *state laws and regulations regarding licensing* and plan solvency." (AG Testimony, pp. 1-2 [italics added].) As such, we have submitted a draft proposed HB 2528, HD2 to the House Committee on Consumer Protection & Commerce—which is drafted as a state licensing law and which we shared with the Attorney General's office—and offer the following analysis of that proposal.

Analysis

The Supremacy Clause of the United States Constitution provides Congress with the authority to preempt state law. (*See* U.S. Const., art. VI.) And the United States Supreme Court has recognized that federal preemption of state law can occur in three different areas: (1) where Congress explicitly preempts state law; (2) where preemption is implied because Congress has occupied the entire field; and (3) where preemption is implied because state law actually conflicts with federal law. (*Schneidewind v. ANR Pipeline Co*., 485 U.S. 293, 299-300 (1988); *Bank of America v. City & County of San Francisco*, 309 F.3d 551, 558 (9th Cir. 2002).) Nevertheless, "[c]onsideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law. (*Maryland v. Louisiana*, 451 U.S. 725, 746 (1981), citing *Rice* v. *Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947).)

In examining HB 2525, HD2—the Healthcare Association of Hawaii's (HAH) draft proposed durable medical equipment (DME) licensing bill—we must assume that Congress did not intend

to preempt state law unless there is an actual conflict between the language in the draft proposed HB 2525, HD2 and the MMA and related federal regulations. As such, we believe that the Legislature has the authority to regulate DME suppliers unless the provisions of the draft proposed HB 2528, HD2 actually conflict with federal law. HAH's draft proposed HB 2528, HD2 does not conflict with federal statute or regulation.

As the Attorney General points out, "[f]ederal regulation 42 C.F.R. § 424.57 sets forth the standards for DMEPOS suppliers." (AG Testimony, p. 1.) Under 42 Code of Federal Regulations §424.57(c), a "supplier must meet and must certify in its application in its application for billing privileges that it meets and will continue to meet . . . State licensure and regulatory requirements." (42 CFR 424.57(c)(1).) Further, "[i]f a State requires licensure to furnish certain items or services, a [DME] supplier . . . must be licensed to provide the item or service." (*Id.*) Thus, the federal regulation expressly provides that states may impose licensing requirements on DME suppliers, and further requires DME suppliers to meet such state licensing laws as a prerequisite to participation in the federal program. As a result, the licensure requirements contained in HAH's draft proposed HB 2528, HD2 do not conflict with 42 CFR §424.57(c), which clearly allows states to impose licensing requirements on DME suppliers.

The Attorney General also expressed the view that "section l856(b)(3) of the MMA broadened the scope of federal preemption of state law governing plans serving Medicare beneficiaries." (AG Testimony, p. 1.) Section 232 of the MMA, however, expressly exempts "State licensing laws" from preemption:

> **SEC. 232. AVOIDING DUPLICATIVE STATE REGULATION.**
> (a) IN GENERAL.—Section 1856(b)(3) (42 U.S.C. 1395w–26(b)(3)) is amended to read as follows:
> ''(3) RELATION TO STATE LAWS.—The standards established under this part shall supersede any State law or regulation
> (**other than State licensing laws** or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part.

(MMA, §232(a), emphasis added.) As such, state licensing laws—such as that proposed by HAH's draft proposed HB 2528, HD2—are not preempted by federal law, and are expressly exempted from preemption under the MMA.

The Legislature has the inherent authority—derived from its traditional police power—to adopt laws for the wellbeing and security of its citizenry. "The police power of the State is broad and extends to the public safety, health, and welfare." (*State v. Ewing*, 81 Haw. 156, 164 (Haw. St. App. 1996), citing *State v. Lee*, 55 Haw. 505, 513, 523 P.2d 315, 319 (1974) [holding statutes "reasonably related to the preservation of public health, safety, morals or general welfare of the public" are within the State's legitimate exercise of the police power]; see also *State v. Lee*, 51 Haw. 516 (1970); *State v. Diamond Motors, Inc*., 50 Haw. 33 (1967).) Here, the Legislature—were it to enact HAH's draft proposed HB 2528, HD2—would be acting under its traditional police power to protect its vulnerable Medicare patients by ensuring they receive timely delivery of critical DME supplies.

In sum, the state licensure program contemplated by HAH's draft proposed HB 2528, HD2 is not preempted by federal law. The applicable federal statute and related regulations all expressly

recognize the state's authority to regulate DME suppliers through state licensure. And the state has authority under its traditional police power to adopt laws for the safety, public health, and general welfare of the public such as the DME licensing and patient safety program offered under HAH's draft proposed HB 2528, HD2.

The Healthcare Association of Hawaii (HAH) surveyed providers for examples of DME supply –related stories highlighting serious patient difficulties in obtaining timely, critical DME supplies. The following are responses HAH received from providers.

Patient and provider names are redacted to preserve patient confidentiality.

Oahu home health agency

Today, we had another example of problems ordering and receiving a standard 30 inch sliding transfer board for a pt we have had on service for over 2 months. After receiving all the paperwork and making numerous phone calls with both [local DME award vendor] and [local vendor that did not win an award], we are told this item is not stocked on the islands. I finally had a friend copy and make a sliding board for this patient, paid him $25 out of my own pocket, and provided the sliding transfer board myself. Oahu home health agency

Oahu hospital

1. There are limited choices resulting in delays in discharging the patient.
2. Patient care is impeded by the competitive bidding process. We are limited to ordering from certain vendors who it appears cannot handle the demands or others require a minimum of 2 items before filing in our order. We end up faxing, sometimes for hours, just to get the order to the vendor.
3. There is no "choice" when it comes to wheelchairs as [local DME award vendor] is the only vendor that has that DME contract. There have been situations when vendors are not able to service the patient, for one reason or another, and they simply send the order to another vendor, but without discussing it with the patient or the Case Manager --thus, impeding communication, coordination, and limiting patient choice.
4. There are reports from Home Health Care agencies that [local DME award vendor] does not have an RN or RD to do the teaching for their enteral patients, rather have used their driver to teach how to do TubeFeeding at home. As a result, Home Care Agencies have had several patients readmitted to the hospital for aspiration and have reported this to the appropriate CMS department.

Oahu skilled nursing facility

A medically fragile patient who has Respiratory disease and is fed via Gastric Tube, will be going home to Wailuku, Maui in about 10 days.

The company on the mainland that [Medicaid managed care plan] contracted with is [mainland award vendor]. Apparently, since our doctor and Social Worker had several conversations with both [Medicaid managed care plan] and [mainland award vendor] staff, regarding the arrival and accessibility of equipment he needs, they have realized that they could not effectively get this boy's equipment to him as needed. They share they "are making other plans" as I write this to you.

Oahu home health agency

Female Home health pt referred for management of pressure ulcer on lower back. At SOC, RN requested hospital bed and Hoyer lift via [local DME award vendor], Medicare vendor for competitive bid contract. Forms sent to MD's office, forms not completed properly per [local DME award vendor]. No instructions provided for MD and no customer svc at Vendor to assist MD office in completing forms properly to meet Medicare criteria. This process has been going on for 3 wks. Family having difficulty repositioning

pt and daughter in law has injured her back. Both the hospital bed and the Hoyer lift have not been delivered as yet. The home health RN has been frustrated as she feels helpless in assisting with the paper work between the vendor and the MD to be completed in order to process the order. This vendor has expressed that they are unable to manage the orders coming in.

Oahu home health agency
[Local DME award vendor], vendor for Medicare competitive bid contract, President of company informing staff with equipment orders - expressed desire to set up a contract with home health agency. Also expressed his (vendor) frustration in not being able to keep up with orders. Staff contacting vendor with 4 phone calls on this particular pt case, left msgs and no follow up for 2 wks until staff left a threatening msg.

[Local DME award vendor], vendor for Medicare competitive bid contract, was faxed a request for a hospital bed for pt. Pressure ulcer became worsened and had to be re-hospitalized as the bed was not delivered until 4 wks later. Concern is that these worsened outcomes impacts home health agency outcomes such as in "Home Health Compare".

Oahu home health agency
Pt. discharged on 092513 from Rehab and Nursing facility, youth front wheeled walker with 5" wheels/ from [local DME award vendor]- ordered 102913. So far, 3 phone calls were made to [local DME award vendor], and pt still has not received walker. Latest phone call to [local DME award vendor] on 110813, we were told "sometime next week" family would be contacted. As of today, family has not been contacted, walker has not been delivered.

Oahu home health agency: Patient readmission to the hospital
[Local DME award vendor] wins the DME Competitive Bidding and signs an exclusive contract with a healthcare provider. The healthcare provider agreed on the exclusive contract with one DME Company because this DME Vendor agreed to coordinate the DME needs for all their patients (i.e., the Case Manager or Discharge Planner will only have to contact one DME Company). However, [local DME award vendor] lacked the expertise to provide a specialty service that the patient needed. The patient needed enteral feeding supplies, which they delivered, but there were no instructions or nutritional counseling provided. The lack of expertise resulted in the patient's readmission to the hospital.

Oahu home health agency: DME Competitive Bidding does not offer patient choice
A patient was discharged from the hospital, and safety equipment was needed for the home. After three fax messages and numerous phone calls (at least four) to contact [local DME award vendor], the suction equipment and bed were delivered three days later. This posed a safety issue to the patient who needed the suction machine and hospital bed. Before DMEPOS Competitive Bidding Program implementation, patients could reach out to a DME supplier that could provide prompt service from a local office and warehouse.

Neighbor Island skilled nursing facility
One of our problems is that our local vendors do not participate in the competitive bidding program. Because of this, we do not have a vendor that is responsible for providing DME to our

residents upon d/c. The vendors that we work with now, have different policies (which continues to change) with regard to required documentation for DME.

We are in the process of scheduling in-services with the different vendors to assist us with preparing for DME documentation and/or other steps necessary to obtain the DME.

Neighbor Island medical center
"As you may or may not be aware Mr. A has been here 153 days. Since 7/31/13 he has been here solely due to the insurance plan's inability to procure a wheelchair. Once the CFO became involved we saw a little effort as the insurance plan did issue a "one time" contract with [a Maui DME supplier] to provide a wheelchair, but it turns out [a Maui DME supplier] is not licensed to issue the type of wheelchair our patient requires. As such we are now back at "square one" with a patient taking up an acute bed simply because he does not have a wheelchair. We have since lost his bed offer at [nursing facility], which is a source of great frustration for all parties involved. While this is an extreme example, it is indicative of our ongoing issues in working with the insurance plan and the DME providers and their inability to provide the services their members require"

Neighbor Island medical center: Delay in discharge and avoidable hospital stay
[Locally-based award vendor] wins the DME Competitive Bidding and signs an exclusive contract with a healthcare provider. The healthcare provider agreed on the exclusive contract with one DME Company because this DME Vendor agreed to coordinate the DME needs for all their patients. (the Case Manager will have to contact one DME Company). However, [locally-based award vendor] was unable to provide a specialty service that the patient needed. The patient needed Trach Supplies. [locally-based award vendor] was unable to provide Trach supplies without additional durable medical equipment ordered. The service had to be sent from an off island vendor causing an avoidable day in the hospital. Due to no Trach supply vendor on island, there is a problem with servicing the equipment and the ability to provide hands on representative to initiate help or problem solve on island.

Neighbor Island medical center: Competitive Bidding does not offer patient choice
A patient was being discharged from the hospital, and safety equipment was need for the home. After numerous phone calls to off island and Maui vendors, the oxygen was delivered to the patient and all expenses needed to be paid out of pocket for all oxygen supplies indefinitely. The patient recently moved to Maui from the mainland with oxygen use history. Patient was unable to have [local award vendor] or [locally-based award vendor] service due to prior authorization to mainland DME provider.

Oahu medical center: Numerous problems with [local award vendor] for DME equipment:
[Local award vendor] won the DME Competitive Bidding and signed an exclusive contract with certain healthcare providers. There is a monthly charge to the healthcare providers by [local award vendor] to be exclusive for all their DME needs. Our medical center did not facilitate an exclusive contract with them.

Calls were made to [local award vendor] to because they won the DME Competitive Bid for the DME needed at discharge.

[Local award vendor] response has been they service healthcare providers that signed a contract them first and they are too busy and cannot accommodate us.

We contacted the Medicare Hotline for DME issues many times to report these issues.

PALMETTO GBA
A CELERIAN GROUP COMPANY

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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

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

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.

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

Hawaii Association of Health Plans

March 19, 2014

The Honorable Angus L.K. McKelvey, Chair
The Honorable Derek S.K. Kawakami, Vice Chair

Committee on Consumer Protection and Commerce

Re: SB 2031, SD2, HD1 – Relating to Health

Dear Chair McKelvey, Vice Chair Kawakami, and Members of the Committee:

My name is Rick Jackson and I am Chairperson of the Hawaii Association of Health Plans ("HAHP") Public Policy Committee. HAHP is a non-profit organization consisting of nine (9) member organizations:

AlohaCare
Hawaii Medical Assurance Association
HMSA
Hawaii-Western Management Group, Inc.
Kaiser Permanente
MDX Hawai'i
'Ohana Health Plan
University Health Alliance
UnitedHealthcare

Our mission is to promote initiatives aimed at improving the overall health of Hawaii. We are also active participants in the legislative process. Before providing any testimony at a Legislative hearing, all HAHP member organizations must be in unanimous agreement of the statement or position.

HAHP appreciates the opportunity to provide testimony in opposition to SB 2031, SD2, HD1, which requires vendors who have been awarded contracts through the Centers for Medicare Services durable medical equipment, prosthetics, orthotics, and supplies bidding program to have a physical presence in Hawaii.

HAHP has concerns with this Bill as it would unnecessarily limit opportunities to contract with vendors. We are aware of the growing pressure that hospitals face with patients on waitlists for specialized equipment, and are concerned that we would lose much needed specialty vendors on the mainland.

Thank you for the opportunity to provide testimony.

Sincerely,

Rick Jackson
Chair, Public Policy Committee

To: Representative Angus McKelvey, Chair, Representative Derek Kawakami, Vice Chair
Members of Consumer Protection and Commerce Committee

Hrg: Wednesday, March 19 @ 2:10pm, Conference Room 325

Re: **Testimony in STRONG SUPPORT of SB2031, SD2, HD2**

By: Valerie Chang, JD, Executive Director
Hawaii COPD Coalition, www.hawaiicopd.org
733 Bishop Street, Suite 1550, Honolulu, HI 96813
(808)699-9839
copd.hawaii@yahoo.com

I thank you for this opportunity in STRONG SUPPORT of SB2031, SD2, HD2, which improves access to medical supplies and equipment for patients by requiring vendors or suppliers who have been awarded contracts through the Centers for Medicare and Medicaid Services Durable Medical Equipment to have a physical presence in Hawaii.

My name is Valerie Chang. I am Executive Director of the Hawaii COPD Coalition. Our organization provides services and support to Hawaii's people affected by Chronic Obstructive Pulmonary Disease, more commonly known as emphysema and chronic bronchitis. COPD is now the third leading cause of death in the US and second leading cause of disability. Over 30,800 people in Hawaii have already been diagnosed with COPD and it is estimated that at least 30,800 more people may suffer from COPD but remain undiagnosed. Many of these COPD patients were seduced by tobacco when they were very young and unable to quit the addiction for decades, causing irreparable harm. There are over $55 million in COPD hospital charges in Hawaii each year.

This CPC Committee is well aware of the many problems faced by Hawaii patients due to our unique and isolated location, especially in acquiring durable medical equipment like supplemental oxygen. Stories throughout the nation and in Hawaii keep repeating the problems that patients and their families are facing in acquiring supplemental oxygen and servicing of the same in a timely manner. This is literally a matter of life and death of our patients who need supplemental oxygen to keep healthy and out of the hospital and emergency rooms.

Supplemental oxygen reimbursement rates have been cut repeatedly resulting in suppliers offering fewer and fewer options for patients to have for their oxygen use. There are no longer **any** Hawaii suppliers which offer liquid oxygen, which is one of the lightest and most portable forms of supplemental oxygen and allow patients to continue working and remaining active, contributing members of the community. ***Nearly 70% of the 24 million people in the US with COPD are 65 or younger, and in their prime working years.***

It can currently take several days or up to a week or longer to get a portable oxygen concentrator, nebulizer compressor or other equipment from the mainland US to Hawaii. I and other COPD patients have had to send equipment for repair and servicing. It is vitally important that there be a Hawaii presence for patients and families to work with while their equipment is being serviced and maintained. Having reliable means of getting their equipment promptly will allow COPD patients to remain active, productive contributing employees and community members and keep them out of the hospitals and emergency rooms.

The requirements of a full time employee, available during normal working hours within the State of Hawaii are very minimal, but should help improve access and service to Hawaii patients and their healthcare providers. It is very challenging to deal across geographic and time zones for Hawaii's medically fragile people. It would be even better if successful bidders doing business in Hawaii are required to supply and service needed durable medical equipment within a set, reasonable amount of time so that patients, healthcare systems and providers are not held hostage, waiting for the equipment to arrive and be properly serviced in Hawaii. This would require an additional amendment to add this further requirement, due to Hawaii's geographic isolation.

Thanks for the opportunity to testify about this issue that is so vital to the health of Hawaii and our nation. This issue is very important to our state and our Hawaii COPD Coalition is very glad that this committee has taken a leadership role in addressing this important matter. Please pass this bill, **SB2031, SD2, HD2**. Thank you.

THE QUEEN'S HEALTH SYSTEMS

1301 Punchbowl Street • Honolulu, Hawaii 96813 • Phone (808) 691-5900

S.B. 2031, S.D. 2, H.D.1
Relating to Health
House Committee on Consumer Protection and Commerce
March 19, 2013; 2:10 p.m.

Thank you for the opportunity to provide testimony in **support** of SB 2031, SD2, HD1, Relating to Health.

Section 302 of the Medicare Modernization Act of 2003 established requirements for a new competitive bidding program for certain durable medical equipment, prosthetics, orthotics, and supplies. Under the program, suppliers compete to become Medicare contract suppliers by submitting bids to furnish certain items in competitive bidding areas, and the Centers for Medicare and Medicaid Services awards contracts to finite number of suppliers meant to meet the supply demand. The majority of the award winners are located 5,000-10,000 miles away. SB 2031, which requires awarded vendors to have a physical presence in Hawaii, is needed as the new process has resulted in various challenges for Hawaii's system of care, including but not limited to:

1) The time difference makes it difficult to contact vendors to obtain needed equipment. Not available on Sundays or afterhours (last delivery is 3:30 p.m.).
2) Case Managers ask for the vendor to provide an order in a certain timeframe because the patient has a flight home to a neighbor island and the vendor does not respond
3) At times, the contracted vendors experience difficulty in fulfilling the order demands and delivery requirements in a timely manner. These have led to QMC staff faxing, sometimes for hours, to get the order to go through to the company.
4) There is no "choice" when it comes to the purchase of certain items that are only available through a certain vendor. There have been situations when vendors are not able to service a patient, so the order is redirected by the vendor to be filled, but without coordinating with the hospital. This is very frustrating and impedes communication, coordination, and limits patient choice.
5) Vendor wants to actually speak to a patient to ensure the patient is able to make co-payment prior to discharge
6) With so many challenges and complications, patients are not being discharged to appropriate settings in a timely manner, which drives costs up.

7) Not having needed equipment can also have a negative impact on the patient's well-being and improvement.
8) Some patients have been purchasing the equipment on their own because it takes too long to obtain it through a designated Medicare DME provider.

Given the complexity and implications of the accurate and prompt fulfillment of these orders, QMC suggests requiring the vendors to maintain a local, physical presence is reasonable and could resolve many of these ongoing concerns.

kawakami3-Benigno

From: Vi Cabellaarnobit <violeta.acemedhi@gmail.com>
Sent: Tuesday, March 18, 2014 11:58 PM
To: CPCtestimony
Subject: Testimony SB2031 SD2
Attachments: Impact of Competitive Bidding Program.wps

Categories: Might Be Important for Later

Aloha,

Here enclosed is my written testimony and would really appreciate all your support on this concerns requiring vendors who have been awarded contracts through the Centers for Medicare and Medicaid Services durable medical equipment, prosthetics, orthotics, and supplies bidding program to have a physical presence in Hawaii. Definitely it has increased health care cost to our state and kupuna, with no access on safety medical device our elderly population have frequent ER visits, hospitalization or rehabilitation secondary to fall injury or compromised medical conditions.

We cannot afford to continue denying access on needed medical equipment and supplies otherwise we are not providing quality of life and cost effectiveness in caring family members in the comfort of their own home environment.

Should you have ant further questions or concerns please do not hesitate to call or email for further testimony.

Sincerely,
VIoleta Arnobit, BSN,RN
CEO and Clinical Administrator
Ace Medical,Inc.

kawakami3-Benigno

From: mailinglist@capitol.hawaii.gov
Sent: Tuesday, March 18, 2014 9:04 PM
To: CPCtestimony
Cc: paulakomarajr@yahoo.com
Subject: *Submitted testimony for SB2031 on Mar 19, 2014 14:10PM*

SB2031
Submitted on: 3/18/2014
Testimony for CPC on Mar 19, 2014 14:10PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing
Paul A. komara, Jr.	Individual	Oppose	No

Comments:

Please note that testimony submitted less than 24 hours prior to the hearing, improperly identified, or directed to the incorrect office, may not be posted online or distributed to the committee prior to the convening of the public hearing.

Do not reply to this email. This inbox is not monitored. For assistance please email webmaster@capitol.hawaii.gov

LATE

HMSA

Blue Cross Blue Shield of Hawaii

An Independent Licensee of the Blue Cross and Blue Shield Association

March 19, 2014

The Honorable Angus L. K. McKelvey, Chair
The Honorable Derek S. K. Kawakami, Vice Chair
House Committee on Consumer Protection and Commerce

Re: SB 2031, SD2, Proposed HD2 – Relating to Health

Dear Chair McKelvey, Vice Chair Kawakami, and Members of the Committee:

The Hawaii Medical Service Association (HMSA) appreciates the opportunity to testify on SB 2031, SD2, Proposed HD2. HMSA opposes this Bill.

It has long been HMSA's mission to improve the health and well-being of our members and for all the people of Hawai`i. But, we also are cognizant of the need to provide services and products our members demand, in the most efficient way. We need to do our part to contain the cost of Hawaii's health care system.

To that end, we believe in the importance of ensuring cost-effective access to quality durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) from suppliers that members can trust. The Center for Medicare and Medicaid Services (CMS) competitive bid program for DMEPOS is designed to do just that. During its first year of the procurement program's implementation, it saved the Medicare program over $202 million, a 42 percent drop in expenditures in the nine participating markets.

HMSA has concerns with this Bill because it undermines the goal of that efficient CMS procurement process – it will reduce competition and drive up costs for Medicare recipients.

Under the original Medicare program, purchases of DMEPOS must be made exclusively from the list of vendors secured under the CMS DMEPOS procurement contract. This Bill will require the licensure of DMEPOS vendors requiring all DMEPOS to have a physical local presence. This legislation will:

- reduce competition
- in some cases, effectively create monopolies; and
- worst of all, potentially eliminate the availability of any vendor a particular DMEPOS.

Simply put, this Bill is not consumer friendly, and it is detrimental to the welfare of Honolulu's Medicare recipients.