**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF TEXAS**

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| **SONAS MEDICAL SUPPLY, INC.,** | § | |
| | § | |
| **Plaintiff,** | § | |
| | § | |
| **vs.** | § | **CIVIL ACTION NO. 4:21-cv-529** |
| | § | |
| | § | |
| **XAVIER BECERRA, Secretary, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,** | § | |
| | § | |
| **Defendant.** | § | |

**COMPLAINT FOR JUDICIAL REVIEW, ATTORNEY FEES, AND EXEMPLARY DAMAGES**

SONAS MEDICAL SUPPLY, Inc. (hereinafter "Sonas," "Plaintiff," or the "Supplier"), by and through its attorneys, hereby files this its Complaint for Judicial Review, Attorney Fees, and Exemplary Damages against Defendant, Xavier Becerra, Secretary of the United States Department of Health and Human Services ("HHS" or the "Agency"), and alleges and avers as follows:

## INTRODUCTION AND FACTS

1. In this case, HHS seeks to collect from Plaintiff an alleged Medicare overpayment. On November 10, 2016, AdvanceMed, a Medicare contractor, sent a letter notifying Plaintiff of an extrapolated overpayment in the amount of $1,339,239.44. According to the contractor, the overpayment stemmed from a review of 45 claims with 59 claim lines submitted by Plaintiff to CMS from May 1, 2012 to July 20, 2015 for payment. AdvanceMed denied payment on all claims, calculating an "actual" overpayment which was then projected over a universe of all claims billed by Plaintiff from May 1, 2012 to July 20, 2015.

2. Plaintiff received denial information from AdvanceMed in an attachment which recounted service dates for each of the claims. In the attachment, the dates of service reviewed were included, as was a summary explanation for each denial. However, only cursory information was provided to Plaintiff as to the statistical sampling and extrapolation methodology utilized in projection of the overpayment.

3. On November 16, 2016, CGS, a Medicare contractor, issued a formal demand letter notifying Plaintiff of the alleged overpayment and extending appeal rights. The demand letter was received by Plaintiff on or about December 2, 2016.

4. Plaintiff submitted a request for redetermination pursuant to 42 C.F.R. § 405.940 *et seq*, and on February 17, 2017, CGS issued an unfavorable redetermination decision. Plaintiff then sought reconsideration in accordance with 42 C.F.R. § 405.968.

5. On August 7, 2017, CGS issued an unfavorable reconsideration decision. However, it was not until January 22, 2018, that Plaintiff received notice of the overpayment's recalculation, which finalized the reconsideration decision pursuant to Medicare regulations.

6. On March 7, 2018, Plaintiff's Former Counsel drafted a Request for ALJ Hearing on behalf of Plaintiff. However, the request was not mailed until the end of the month and was not received until April 2, 2018. The Honorable ALJ dismissed the request on September 30, 2020. Plaintiff received the notice of dismissal on or about October 8, 2020.

7. On or about December 4, 2020, Plaintiff filed its request for review of the ALJ decision by the Medicare Appeals Council ("Council" or "MAC"). On or about May 13, 2021, Plaintiff received a copy of the MAC's decision which denied the request for review as the Council upheld the ALJ decision which dismissed the request for hearing as it was deemed untimely. (Exhibit A).

8. Plaintiff now files this request for judicial review of the MAC's decision pursuant to 42 C.F.R. § 405.1136 within 60 days from the date of receipt.

**PARTIES**

9. Plaintiff, Sonas Medical Supply, Inc., is a corporation organized under the laws of the State of Texas, a durable medical equipment prosthetics, orthotics, and supplies ("DMEPOS") supplier participating in the Medicare program and is located in Collin County, TX.

10. Defendant, Xavier Becerra, is Secretary of the U.S. Department of Health and Human Services (hereinafter "HHS" or "Defendant"), an agency of the United States of America, and he may be served by delivering a copy of the summons and complaint to the United States Attorney for the Eastern District of Texas and by sending a copy of the summons and complaint by certified mail to the Attorney General of the United States in Washington, DC. The Secretary of HHS oversees the Medicare program, and he adopts and issues the final decision made by the Medicare Appeals Council such that the Secretary of HHS becomes the Defendant in appeals for judicial review pursuant to 42 C.F.R. § 405.1136(d).

**JURISDICTION AND VENUE**

11. This action arises under the Medicare Act, a part of the Social Security Act at 42 U.S.C. §§ 1395 *et seq.* Plaintiff appeals a decision of the MAC issued on March 22, 2018 and a final decision of the Secretary of Health and Human Services. *See* 42 C.F.R. § 405.1130. Additionally, the Court has supplemental jurisdiction under 28 U.S.C. § 1367 over a certain number of Plaintiff's other claims because they are so related to the claims within the Court's original jurisdiction that they form part of the same case or controversy under Article 3 of the U.S. Constitution. Plaintiff received the final decision of the MAC on or about May 13, 2021. Plaintiff now timely files its original complaint for judicial review in federal district court in the judicial

district in which Plaintiff resides on or before the expiration of sixty days (60) from receipt of the final decision. *See* 42 U.S.C. § 1395ff(b).

12. Plaintiff's principal office is located in Dennison, Texas, therefore, venue is proper in the Eastern District of Texas. *See* 42 U.S.C. §§ 405(g) and 1395ff(b).

## APPLICABLE MEDICARE LAW

### The Medicare Program

13. As part of the Social Security Amendments of 1965, Congress established the Medicare program: a national health insurance plan to cover the cost of medical care for the elderly and disabled. *See* 42 U.S.C. § 1395 *et seq*. Officially known as "Health Insurance Benefits for the Aged and Disabled," it provides basic protection against the costs of inpatient hospital and other institutional care. It also covers the costs of physician and other healthcare practitioner services and items not covered under the basic program. In 1997, beneficiaries were extended the option of choosing a managed care plan. More recently, in 2006, the program was expanded further to include a prescription drug benefit.

### Durable Medical Equipment

14. Medicare covers durable medical equipment furnished to beneficiaries by suppliers participating in the program. *See* 42 U.S.C. § 139x(s)(6); 42 C.F.R. §§ 410(h), 410.38(a). To be reimbursed for such medical equipment, a supplier must receive a signed certificate of medical necessity ("CMN") from the treating physician. A supplier must have a signed original, faxed, photocopied, or electronic CMN in its records before it can submit a claim for payment to Medicare. Also, it must maintain the supporting documentation and make them available to CMS upon request for seven years from the date of service. *See* 42 C.F.R. §§ 410.38(g)(5) and 424.516(f).

**Payment and Audit Functions**

15. Medicare's payment and audit functions are performed by various federal contractors. For instance, the payment of durable medical equipment at issue in this case was made by AdvancedMed. Various other contractors, like Qlarant., a Unified Program Integrity Contractor (or "UPIC"), investigate instances of suspected fraud, waste, and abuse as well as identify any improper payments that are to be collected by administrative contractors.

**Statistical Sampling and Extrapolation of Overpayments**

16. Congress authorized HHS to "use extrapolation to determine overpayment amounts" if the Secretary determines that "there is a sustained or high level of payment error." 42 U.S.C. § 1395ddd(f)(3)(A); 42 C.F.R. § 405.926(p). Thus, the law allows extrapolation to be used to derive an overpayment from a statistically valid random sample of sampling units applied across the frame of sampling units. *See Chaves County Home Health Servs. v. Sullivan*, 931 F.2d 914 (D. C. Cir. 1991). Based on the legislature's instruction, the Secretary promulgated policy and rules on the framework for extrapolation, as permitted by statute. The Secretary's policy is encapsulated in CMS Rules 86-1-9 and 86-1-10. The Secretary's guidance, found in the Medicare Program Integrity Manual ("MPIM"), Pub. 100-08, Chap. 3, (eff. 5-10-04, now at MPIM Chap. 8, eff. 06-28-11), provides instructions to ensure that a "statistically valid sample is drawn and that statistically valid methods are used" to project an overpayment from the sample to the audit frame. The MPIM, which is not a statistics text, includes references upon which the theory of sampling and extrapolation are based. However, for an overpayment estimate to be valid, the laws and assumptions of probability and statistics must be met. *See* Robert D. Messer, M.D. & Assoc., Docket No. M-11-2534, Medicare Appeals Council (Dec. 11, 2011). In other words, the

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