

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
(Sherman Division)**

MEDSTRIVE, L.L.C.,

Plaintiff,

vs.

**XAVIER BECERRA, Secretary,
UNITED STATES
DEPARTMENT OF HEALTH
AND HUMAN SERVICES,**

Defendant.

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CIVIL ACTION NO. 4:21-cv-00665

**VERIFIED COMPLAINT
FOR INJUNCTIVE AND DECLARATORY RELIEF AND ATTORNEY FEES**

COMES NOW, Medstrive, L.L.C. (the “Plaintiff” or “Medstrive”), and files this its Verified Complaint for Injunctive and Declaratory Relief and Attorney Fees against Xavier Becerra, Secretary of the United States Department of Health and Human Services (the “Defendant”), and alleges and avers as follows:

INTRODUCTION

1. On March 17, 2020, HHS issued a Medicare payment suspension to withhold all earned payments for services rendered by Medstrive, a durable medical equipment prosthetics, orthotics, and supplies supplier ("DMEPOS" or “DME”). These payments will be applied toward a Medicare overpayment should one be subsequently determined by HHS. However, the government provided no appeal or right to hearing to dispute or contest the action. Accordingly, Plaintiff moves to temporarily enjoin HHS’s “suspension” of its Medicare payments during the COVID-19 emergency or until the government provides a hearing on the adverse action in conformance with Due Process of Law. The suspension will irreparably harm Plaintiff by

forcing it out of business and into bankruptcy, and it jeopardizes the health and safety of the provider's patients by disrupting their services and requiring that they obtain them elsewhere in the Houston area, a "hot spot" of the COVID-19 outbreak.

2. Medstrive is a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) that delivers durable medical equipment (DME) to patients in their homes in the greater-Denison area. To be covered, the DME must be necessary and reasonable for treating an illness or injury or improving the function of a malformed body member. For such medical equipment to be billed to Medicare, the supplier must receive a signed certificate of medical necessity (CMN) from the treating physician. In addition, the supplier must have a signed original, faxed, photocopied, or electronic CMN in its records before it can submit a claim for payment to Medicare. In addition to the CMN requirement, CMS has designated a list of certain covered items, referred to as Special Covered Items, that require a written order. They include, among others, any items of DME that appear on the durable medical equipment, prosthetics, orthotics, and supplies fee schedule with a price ceiling at or greater than \$1,000.

3. On April 9, 2021, Defendant noticed the imposition of a Medicare payment suspension of Plaintiff's Medicare payments. The suspension was brought under 42 C.F.R. § 405.371(a)(2) based upon a "credible allegation of fraud." CMS, the federal agency that administers the Medicare program, based its decision upon its mistaken belief that "Medstrive is in violation of Medicare DMEPOS Supplier Standard #11 by soliciting Medicare beneficiaries." According to CoventBridge, "Medstrive bills Medicare for orthotics that neither the beneficiaries nor their primary care physicians have requested and are medically unnecessary." In fact, CMS asserts that the DME supplier has committed fraud by providing orthotics devices under the guise of using "generic diagnoses" to provide multiple orthotics to every beneficiary for areas of

the body never treated by their physicians. Of course, this ignores that the product was prescribed by a treating practitioner and supported by information from the patients' medical records in all instances. As a result of the suspension action, *all* Medicare payments owed to the supplier are being withheld pending resolution of the ongoing investigation.

4. Like “the Sword of Damocles,” the government threatens prosecution for fraud, alleging Plaintiff has incorrectly reported diagnoses or procedures to maximize Medicare payments wrongly. However, Plaintiff has no right to an administrative appeal to challenge or otherwise dispute these allegations. Yet, its Medicare payments are “suspended” and may be interrupted for a year or longer. And even then, the provider may have no legal recourse to challenge the adverse action.

5. Unfortunately, the suspension action could not have come at a worse time. President Donald Trump declared a national emergency over the COVID-19 outbreak on March 13, 2020. Dr. Deborah Birx, White House Coronavirus Response Coordinator, reported that U.S. deaths caused by COVID-19 might be catastrophic. She said that Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, has predicted U.S. deaths could range from 1.6 to 2.2 million in a worst-case scenario and projected 100,000 to 200,000 in a best-case scenario. Thus far, the United States has reported 625,375 deaths through August 20, 2021.¹ In addition, the U.S. Department of Health and Human Services Secretary, Xavier Becerra, signed a renewal of determination that extended the current COVID-19 public health emergency by 90 days, effective July 20, 2021.² The virus has had a substantial impact on our nation's hospitals

¹ In at least 90% of these deaths, COVID-19 was listed as the underlying cause of death. For the remaining deaths, COVID-19 was listed as a contributing cause of death. https://covid.cdc.gov/covid-data-tracker/#trends_totaldeaths_totaldeathsp100k.

² <https://aasm.org/hhs-extends-covid-19-public-health-emergency-january-2021/>.

and a cascading effect on ancillary providers and practitioners.³ Suffice it to say, DME suppliers face tremendous challenges as they attempt to treat an ever-growing patient base due to the COVID-19 infection.

6. The impact of the Medicare payment suspension threatens to force Plaintiff's closure and filing of bankruptcy. The DME supplier derives approximately 60% of its revenues from providing sick and elderly Medicare patients durable medical equipment. Obviously, if the provider is not paid for these supplies, it cannot pay its employees, who provide necessary treatment options, to these very needy patients.

7. If Plaintiff is forced to close, Plaintiff's patients will have to obtain their medical equipment elsewhere. Indeed, due to the COVID-19 outbreak, the ability to secure such services is limited. It is evident that the healthcare industry, including medical suppliers, in Texas is facing a crisis due to the pandemic. Plaintiff strives to maintain a balance between care for its employees and those patients who rely on Plaintiff's supplies during this unprecedented time. With the prospect of burgeoning coronavirus visits combined with the suppliers achieving this type of balance, it will undoubtedly result in a scramble on behalf of patients to obtain supplies because of COVID-19.

8. Had Defendant acted properly, it would not have imposed the suspension. Federal regulations provide that CMS may find good cause exists *not* to suspend a supplier's Medicare payments where it is determined that beneficiary access to items or services would be so jeopardized by a payment suspension in whole or in part as to cause a danger to life or health. 42 C.F.R. § 405.371(b)(1)(ii). It is a clear abuse of discretion for CMS not to find that good

³ The Trump Administration announced a wide array of temporary regulatory waivers and new rules to equip the American health care system, including DME Suppliers, with maximum flexibility to respond to the COVID-19 pandemic. These temporary regulatory waivers are still in effect during the Current Administration.

cause exists here when the COVID-19 pandemic and the surge of confirmed coronavirus cases is adversely affecting America's healthcare system, including DME suppliers.⁴ Not only will Plaintiff be forced to shut down, but the government's suspension action also places an even greater burden on the already overworked healthcare community.⁵

9. Notwithstanding the abuse of discretion, Medstrive has a constitutional property interest in payments for services rendered and is now *indefinitely* suspended during the investigation into the adequacy of its documentation. Defendant violates Due Process of Law by imposing the adverse action during the COVID-19 pandemic and national emergency when it fails to give notice and an opportunity for a hearing to contest the Medicare payment suspension. Indeed, the provider has no administrative appeal rights to contest the suspension. Clearly, there is a high risk that Plaintiff will be erroneously deprived of its property interest in earned Medicare payments withheld by suspension, pursuant to 42 C.F.R. § 405.371(a)(2), because the supplier is not entitled to an administrative appeal to dispute and contest the adverse action, HHS has abused its discretion and not found good cause not to impose the adverse action, and there is absolutely no established time frame for resolving the investigation of its documentation.

10. Moreover, patients at Medstrive have a constitutional Due Process right (consistent with principles of equal protection) to obtain safe and reliable medical equipment

⁴ Aside from the jeopardy to patients, the impact of the suspension is at odds with the coronavirus stimulus package. On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security (CARES) Act was enacted, an economic relief package in response to the COVID-19 pandemic. The CARES Act provides economic support at the federal level to the business sector, employees, individuals and families, and specific industries that have been impacted, including air transportation, healthcare, and education. Key provisions providing for loan forgiveness require that workers need to remain employed.

⁵ HHS's Office of Inspector General issued a message on minimizing burdens to providers on March 30, 2020. It stated that the OIG places a high priority on providing the health care community with the flexibility to provide needed care during this emergency. The delivery of patient care during this public health emergency must be the primary focus of the health care industry. For any conduct during this emergency that may be subject to OIG administrative enforcement, OIG will carefully consider the context and intent of the parties when assessing whether to proceed with any enforcement action. In view of the consequences, a review that is primarily focused on documentation that allegedly failed to support the complexity of claimed services does not warrant suspension of Medicare payments during the COVID-19 pandemic and national emergency.

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