



## **H.R. 4438: The John W. Walsh Alpha-1 Home Infusion Act**

The Alpha-1 Foundation is working with Congress to find a solution to the patient access problem facing Medicare beneficiaries who are not able to obtain their needed home infusions due to the Medicare law. The legislation named after our legendary founder John W. Walsh will establish a permanent home infusion benefit in the Medicare Part program specifically for Alpha-1 patients. The lead sponsors of this legislative initiative is Representative Maria Salazar (R-FL) and Representative Chellie Pingree (D-ME)

Alpha-1 Antitrypsin Deficiency is a hereditary condition. Without treatment, this condition may result in serious lung disease in adults and/or liver disease in infants, children, and adults. Because Alpha-1 is genetic, Alpha-1 lung disease is sometimes called “genetic COPD”. Alpha-1 Antitrypsin Deficiency is treated by FDA approved augmentation therapies. Therapy slows but not reverses the progression of the lung destruction associated with the disorder. Alpha-1 patients need weekly infusions of their replacement therapy.

### **Background**

When the Medicare program was established, there was no Alpha-1 therapies nor was there the reliance home infusion. With the onset of COVID-19 pandemic, the Alpha-1 Foundation alerted the Centers for Medicare and Medicaid Services (CMS) about the need for Alpha-1 augmentation infusions to be administered in a safe of care and offer protection from exposure to this deadly virus. CMS agreed that there would be detrimental health effects on Alpha-1 patients for skipping infusions because the risk of possible exposure to COVID-19 when going to a hospital infusion suite or a physicians’ office. CMS responded rapidly with the flexibility within the billing and payment system for Alphas to receive home infusions under Medicare Part B or Medicare Part D. Because of the lack of CMS guidance on reimbursement for the treatment, items and services; the temporary benefit was not accessible for patients. The primary reason given by home health providers was that this was a temporary benefit that did not have rules and regulations established to assist with contracts and reimbursement of Alpha-1 Antitrypsin augmentation therapy.

### **Legislation**

The bill establishes a permanent benefit for Alpha-1 patients to receive augmentation therapy in the home setting through Medicare part B. Infusion at home is the standard of care for patients with commercial insurance coverage to receive augmentation infusion therapy. This bill will establish parity for Alphas who are Medicare

beneficiaries. The new Medicare Part B benefit would provide a reimbursement structure for augmentation therapy; intravenous administration kits and up to 2 hours of nursing services. An Alpha-1 patient who is on Medicare should not have to choose between skipping needed therapy or exposure to a potentially fatal virus which preys on those with pulmonary issues.

## **Potential Cost Savings of Legislation**

The Alpha-1 Foundation believes that the passage of HR 4438 will lead to cost savings for the Medicare Program. The standard of care for Alpha-1 Antitrypsin patients in commercial insurance is home infusion. If infusing at a physicians' office, hospital or clinic was the more cost-effective site of care, commercial carriers would mandate treatment at that site. The augmentation therapy will be reimbursed at the same amount in the home or at the infusion clinic. The therapy is the largest expense.

- According to the explanation of benefits that the Alpha-1 Foundation has received from patients the average cost that Medicare pays for the administration of augmentation therapy is \$182.37 per infusion/per week. Alpha-1 patients receive their infusion therapy on a weekly basis.
- According to the explanation of benefits received that the Alpha-1 Foundation has received from patients the average cost the Commercial insurance reimburses for the administration of augmentation is \$110.00 per infusion/per week.
- An average savings for home infusion administration in Medicare will be approximately \$70.00 per week/per patient.

This legislation makes receiving needed treatment in the home safer and more cost-effective. This analysis does not take into account any potential cost-savings from self-infusing the medication which a percentage of the Alpha-1 Community undertakes.

## **Who Was John W. Walsh**

John W. Walsh was the legendary founder of the Alpha-1 Foundation. John Walsh's leadership and passion helped to shape the Alpha-1 Foundation into a successful organization. By his perseverance and hard work. John Walsh improved the lives of every Alpha-1 patient in the United States and around the world.

**To co-sponsor The John W. Walsh Alpha-1 Home Infusion Act, please contact Mr. Sean Smith, Legislative Assistant with the Office of Congresswoman Maria Salazar at 202.225.3931 or at [Sean.Smith@mail.house.gov](mailto:Sean.Smith@mail.house.gov)**