ALPHA-1 FOUNDATION

3300 Ponce de Leon Blvd.
Coral Gables, Florida 33134
Toll Free: (877) 228-7321
Tel: (305) 567-9888
www.alpha1.org

April 27, 2020

The Honorable Seema Verma, M.P.H.
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency
CMS-1744-IFC

Dear Administrator Verma:

The Alpha-1 Foundation appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') Interim Final Rule entitled "Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (the IFC). In our outreach and education initiatives on the IFC, we describe the Administration's efforts to respond to the health care access challenges presented in the wake of this pandemic as "unprecedented." The Alpha-1 community appreciates CMS' efforts to promote flexibilities that enable health care providers to maximize resources and minimize the spread of the novel coronavirus.

Background

Alpha-1 Antitrypsin Deficiency (Alpha-1) is a genetic condition that can result in serious lung disease in adults and/or liver disease at any age. For patients with Alpha-1-related lung disease, weekly augmentation therapy with intravenous infusion of alpha-1 antitrypsin protein (AAT) is the standard of care. Treatment plans for individual patients may also include the appropriate use of antibiotics, an immunization program including viral hepatitis and influenza strains, reduction or elimination of environmental risk factors, appropriate inhaled medications, an exercise program, and in-home oxygen, as needed.

Prior to CMS' issuance of the IFC, Alpha-1 patients expressed a great deal of fear and uncertainty on whether and how the pandemic would impact their ability to continue treatment while maintaining the social distancing required to reduce the risk of exposure to COVID-19 disease. The Alpha-1 Foundation reached out to CMS' COVID-19 task force in mid-March to make the Agency aware of the significant challenges and concerns facing Alpha-1 patients during the public health emergency (PHE).

As we previously expressed to CMS, we were pleased to share our understanding of the IFC with Alpha-1 patients, and allay their understandable fear over having to choose between two high-risk paths (discontinuing treatment vs risking exposure to the novel coronavirus).

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The Alpha-1 Foundation appreciates the Agency's attention to the needs of Alpha-1 patients and others at high risk of severe COVID-19, and continue to believe that the flexibilities contained in the IFC will save lives and reduce the burden of this PHE on Medicare's most vulnerable patients. In our letter dated [insert date], a copy of which is attached, we also noted that patients expressed concerns that they might face a substantial increase in out-of-pocket costs if their in-home infusions were covered under Part D rather than Part B. Our comments reiterate this concern, and identify additional implementation issues and clarification needs that the patient and provider communities have brought to our attention to date.

The Alpha-1 Foundation urges CMS to ensure that patients for whom in-home infusions are the safest option do not face financial hardship accessing treatment

The Alpha-1 Foundation applauds CMS' thoughtful approach to making in-home administration of Part B treatments available for Medicare beneficiaries and agree with CMS' statement calling for system-wide changes to address the PHE:

> We believe that this increased risk produces an immediate change, not only in the circumstances under which services can safely occur, but also results in an immediate change to the business relationships between providers, suppliers, and practitioners.

Ideally, providers, suppliers, and practitioners would meet CMS' unprecedented set of Medicare program flexibilities by adapting their practices and business arrangements to the social-distancing realities of this PHE. We appreciate that the Agency created two pathways through which Medicare beneficiaries can receive their medications at home to account for divergent provider practice patterns, COVID-19-related nursing shortages, and other geographic-specific factors that could make it difficult for clinician practices to enter into arrangements for providing home administration of Part B treatments.

Alpha-1 patients have expressed concerns that the choice between stopping treatment or risking COVID-19 disease exposure could be replaced by the similarly difficult choice between a home infusion associated with a very high, immediate out-of-pocket cost, risking exposure to the virus in a clinic or infusion center setting, or foregoing treatment. Many, if not most of Medicare's Alpha-1 patients purchase a Medicare supplemental plan to ensure that the out-of-pocket costs that would be associated with augmentation therapy are covered. To the extent that business practices between suppliers and providers push the costs of Part B drugs administered in the home to the Part D benefit, the patient incurs a substantial cost while the supplemental plan they continue to pay for receives a substantial cost reduction. Our patients believe that this is unfair. More importantly, however, Alpha-1 patients are concerned that they will not be able to absorb this additional cost. We urge CMS to:

- Consider a mechanism that would continue cost-sharing support from supplemental plans beneficiaries have previously relied upon for their Part B

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copayments even if the drug administration does not fit precisely within the "incident to" requirements for Part B drug payment; or
- Temporarily permit beneficiaries to seek copayment assistance directly from the manufacturer until the catastrophic benefit is reached, without raising concerns about fraud and abuse violations.

The Alpha-1 Foundation similarly urges CMS to ensure that clinicians and providers understand the scope and breadth of the flexibilities contemplated in the IFC. For example, CMS' identification of home health agencies and home infusion suppliers as potential sources from which a clinician could augment their practice should not limit practices that may be able to contract with visiting nurse associations, enter into arrangements with specialty pharmacies with infusion capabilities, or engage in-house nursing staff for patients in long-term care facilities experiencing lockdown due to the PHE.

The Alpha-1 Foundation appreciates CMS' reduction in paperwork burden for providers prescribing in-home oxygen and other durable medical equipment supplies in the patient's home.

For Alpha-1 patients with lung disease, in-home oxygen therapy can be an important part of the overall treatment plan. For patients receiving new or revised prescription for in-home oxygen, the significant steps CMS has taken to reduce the burden on clinicians should enable timely access to this important benefit. As CMS is likely aware, the COVID-19 PHE could greatly increase the demand for in-home oxygen, both in patients seeking to address COVID-19 disease within their homes and those released from an inpatient facility with an ongoing need for in-home oxygen. We believe that CMS' IFC initiative will improve care for these patients as well as Alpha-1 patients and support:

- The temporary relaxation of the face-to-face or in-person encounter requirement for evaluating and/or certifying a patient's in-home oxygen needs; and
- CMS decision not to enforce the clinical indications for coverage across respiratory, home anticoagulation management and infusion pump national and local coverage decisions.

We urge CMS to consider the potential challenges associated with increased demand for in-home oxygen, particularly in light of the difficulties patients have experienced receiving prescribed oxygen equipment and necessary supplies and maintenance prior to the PHE. The Alpha-1 Foundation is concerned that the combined effects of the PHE and the competitive bidding gap period may exacerbate access issues that cannot be addressed through reduced clinician burden. We urge CMS to explore mechanisms to ensure a sufficient in-home oxygen supply by either moving to a non-reduced fee schedule payment or utilizing the Federal Supply Schedule vendors for in-home oxygen and any other durable medical equipment supplies that may face increased demand. At a minimum, we suggest that CMS identify an access pathway that beneficiaries can use in the event that they experience delays in access to particular items during the PHE.

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The Alpha-1 stakeholder community has identified several questions with implementation of the IFC.

As you may be aware, the Alpha-1 Foundation has maintained a continuing dialogue with our stakeholder community as well as with CMS staff. Our patient and provider outreach efforts have included a Fact Sheet and Webinar, and we have sought and received comments and questions on both.

1. Who decides which option an Alpha-1 patient will use for infusion therapy?

The Alpha-1 Foundation has encouraged patients to take an active, if not guiding, role in determining where to receive augmentation therapy. We strongly believe that a patient expressing concerns that receiving treatment within a provider setting is too risky should not have their concerns dismissed with assurances that a particular setting is sufficiently "safe."

Similarly, we have encouraged providers and patients to have an open discussion about the options and the associated costs of each.

Unfortunately, we have heard from some patients that their concerns about risk of COVID-19 exposure are not sufficiently grounded to warrant in-home infusion. We hope that CMS will strongly encourage providers and clinicians to take a patient-centric approach and make every effort to accommodate the expressed needs of their Alpha-1 patients.

2. How long will this exception for home infusions be in place? Will it be state by state as they open back up or will a block of time, say 6 months, be instituted? (Will it be predicated by the arrival of a new vaccine?)

We have heard from stakeholders expressing the belief that the PHE presents a short-lived inconvenience and a marginal risk to patients. Although there are ongoing discussions about "re-opening" the nation, individual states, or regions, the Alpha-1 Foundation does not anticipate that the danger of COVID-19 exposure will dissipate sufficiently in the short-term to justify eliminating social-distancing recommendations for Alpha-1 patients and other high-risk individuals. In fact, we expect that the need for a home infusion option could, and probably should, extend beyond the point at which the general public starts to move toward "normalcy."

The Alpha-1 Foundation asks that CMS reinforce to the provider community the need for vulnerable patients to maintain social distancing while continuing their treatments. We believe that providers will be more likely to adapt their business practices and arrangements if they are not expecting that the changes will be nullified by CMS in the near future.

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3. Is there a number to call or a person to whom we can direct questions if we run in to any roadblocks?

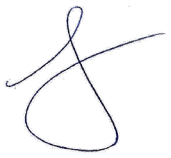
The Alpha-1 Foundation remains committed to its role as an informational resource and clearinghouse for questions and concerns. We would, however, appreciate any guidance CMS could give on identifying the appropriate contact person for specific issues with accessing in-home Part B drug administration and receiving care through telemedicine, as well as to address concerns associated with unexpected increases in out-of-pocket costs for treatment.

Conclusion

Once again, the Alpha-1 Foundation appreciates CMS' leadership in addressing patient-centered care during the COVID-19 PHE. The PHE presents unprecedented challenges for patients, providers, payers, and policy makers. We believe CMS' IFC represents a strong step toward addressing those challenges and look forward to continuing to work with the Agency as it continues to refine and adapt the Medicare and Medicaid programs to respond to the PHE.

If you have any questions or would like to discuss the issues raised in our comments, please contact me at 202-246-1231 (cellular) or maoday@alpha1.org.

Best regards,



Miriam O'Day
President & CEO
Alpha-1 Foundation
3300 Ponce de Leon Blvd.
Coral Gables, FL 33134
maoday@alpha1.org
202-246-1231 (Cellular)