## Bundled Payments and Rare Disease Ombudsman

**Today.** CMS uses bundled payments in 2-3 settings of care as a way to reduce costs and incentivize efficient care. Payment levels for the bundles are set by looking at large numbers of patients' care and averaging the cost of that care, looking across several conditions that are either clinically related or similar in cost. For ultra-rare conditions, 200 or more conditions can sometimes be grouped together due to bodily system primarily impacted, especially "inborn errors of metabolism"). Bundled payments are essentially based on averages.

**Ultra-Rare Circumstance.** Averages do not work for ultra-rare conditions. There are usually very few patients and the conditions are not similar or related enough to warrant comparison or averaging. CMS has "lumped together" a lot of very rare diseases into sweeping categories to avoid creating too many separate bundles. This may have worked reasonably well when few ultra-rare conditions had treatment options, but once any condition has a treatment option beyond monitoring and supportive care, the payment level is too low to support the disease-specific treatment. This problem is exacerbated by the fact that facilities rarely have the treatment in stock and must proactively order it on a patient-by-patient basis.

**Example.** Porphyria is a good example. The result has been insufficient payment for hospitals for very rare conditions. And hospitals have become extremely creative at avoiding treating patients with these very rare diseases. APF has a full set of patient horror stories that drive home the need to do things differently.

**Solutions.**

1. *Require CMS to create an "Extremely Low Claim Volume in Bundled Settings List ("ELCV")."*

- Distribute the list to all Medicare participating hospitals and remind hospitals that their conditions of participation are at risk if the patients with these conditions report inadequate care.
- Include a dedicated 1-800 number for patients and providers to be able to report care issues, as they occur, and achieve rapid resolution to avoid compromised patient outcomes.
- Require CMS to report to Congress annually on calls received, including the conditions, prevalence for each condition, diagnosis code, assigned MS-DRG, whether provider or patient reported, and resolution achieved. The report should also include trends and recommendations for additional Agency actions to address continuing and emerging access concerns.

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2. *Require that CMS apply New Technology Add-On Payment criteria for breakthrough drugs and biologicals in ultra-rare diseases that are similar to the newly-implemented review criteria CM applies to breakthrough medical devices.*

3. *Establish a rare and ultra-rare disease Ombudsman within HHS.*

- The mission of the Ombudsman would be to ensure that patients are not subject to barriers in accessing meaningful, quality coverage for their unique healthcare needs.
- This includes access to FDA-approved treatments using the same level of medical necessity inquiry that is applied to commonly-encountered conditions.

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