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ESRD Bundling: Issue Background Summary

In June 2008, Congress passed the Medicare Improvements for Patients and Providers Act (MIPPA), which heralded several provisions of significant impact for the nephrology community. The legislation included measures to improve the efficiency and flexibility of the End Stage Renal Disease (ESRD) Program, including development of a case-mix adjusted bundled payment rate, a pay for performance (P4P) quality incentive, and an educational provision to help chronic kidney disease (CKD) patients manage their condition. Importantly, MIPPA contains the first major reform of ESRD payment policy in nearly 30 years; it was last modified by the introduction of the composite rate payment in 1983.

Since that time, Medicare has reimbursed each dialysis session with a fixed payment, known as the composite rate, intended to cover the cost of all services, supplies, equipment, and pharmaceuticals associated with the treatment. Over the years, costly yet effective new drugs—including erythropoietin, vitamin D, and iron—have become routine components of dialysis care. However, because these drugs and other items, including some lab services and certain supplies, were not in existence at the development of the original policy, they are not included in the current composite rate payment and are instead separately billed [2]. Due to an increase in their utilization in ESRD patient care, separately billed items now represent 40 percent of total Medicare spending for dialysis services [3]. In order to contain these growing costs and promote efficiency, MIPPA requires CMS to develop a new bundled payment that includes the separately billed drugs—as well as their equivalents and some additional lab services.

While MIPPA describes the basic scope of the ESRD bundle, it leaves many finer aspects of its components, implementation, and payments to be finalized by CMS [4]. The bundle described in MIPPA allows for the possibility of adjustments to the bundled rate based on case-mix adjustors such as patient weight, body mass index, duration of renal replacement therapy, and ethnicity—which impact patient response to, and need for, various drugs and services. Other factors may include “low-volume” facility status or “high cost outliers,” to account for variation in the type or amount of care individual patients require, including variation in ESA dosage.

In its forthcoming ESRD Bundling Proposed Rule, CMS is expected to adjust and clarify the components of the bundle and the case-mix payment adjustment factors; many aspects of CMS’ decision are the subject of substantial controversy in the nephrology community. The inclusion of ESAs in the bundle—as well as the potential inclusion of certain oral drugs for which there are no intravenous equivalents—is of particular interest, as it may push providers to use relatively smaller doses of those drugs or implement other changes in patient care in order to remain cost-effective. Certain patient populations—for instance, younger individuals and African Americans—that typically require higher doses of ESAs to manage anemia than others may potentially be disadvantaged by the bundled payment system [4].

Also controversial is the prospect that providers may seek to avoid patient populations with adverse case-mix factors altogether, cherry-picking those most likely to require a relatively low-cost treatment [4]. The extent to which access to, and quality of, care for these and other vulnerable patient populations may be compromised under bundled ESRD payments hinges largely on CMS' final definition of case-mix adjustment factors such as geographic location, rural service areas, and "high cost outliers."

Additionally, concern exists regarding the opportunity for dialysis organizations, government organizations, and other interested parties to limit the number and type of drugs on formularies to less costly alternatives, or create onerous approval processes for use of certain types, to constrain costs in the new reimbursement environment. Given that in many regions of the country just one or two providers offer dialysis services, this may effectively eliminate access to certain drugs for many ESRD patients. Furthermore, this could potentially impede upon nephrologists' autonomy to prescribe the most appropriate therapies for their patients, thereby inhibiting innovation in patient care and slowing the progress of independent research to the bedside.

Despite the challenges surrounding implementation, considerable opportunity for bundled payments to elevate the quality of care for patients exists as well. The bundled rate payment system is almost certain to render savings in dialysis care and to urge providers to optimize treatment plans to attain the greatest possible value and efficiency. Furthermore, potential reduction in ESA utilization may be a benefit for some patient populations, as research suggests current dosing levels may not provide the advantages scientists once thought, and Medicare funding currently used for their purchase could thus be reallocated toward more effective therapies [5].

References:

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