## Bundled Payment

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Current quality measures for ESRD lack a strong evidence base, and Mehrotra said "there is a compelling need to identify additional metrics and determine whether they provide better information on patient risk and health, such as efficiency and patient centeredness of care." Comparative effectiveness research into how health care practices affect outcomes is needed because "there's virtually no data on whether implementing the bundle improves any of these other measures," he said.

The utilization of current metrics to assess performance in the QIP poses a threat to the individualization of patient care, Mehrotra said. "One size does not fit all, and this is particularly true with the management of a complex disease like ESRD." An example he points to is the proposed mineral metabolism measure, which will penalize facilities with a higher proportion of patients with calcium levels >10.2 mg/dL. "Yet the data that identifies calcium of 10.2 mg/dL as 'dangerous' or 'bad' is very weak, and a clinical trial that randomizes patients to different calcium levels is needed to determine whether it affects outcomes."

Just as the AHRQ review concluded, Mehrotra expects the use of bundled payments to expand, saying that "the perverse incentive of rewarding volume of care has to diminish, otherwise it is difficult to see how health care costs will come down." But he sees benefits in the current dialysis bundle in "the rapid growth of the home dialysis population, which I personally believe to be a good development and is in line with the goals of CMS."

**References**


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# Industry Spotlight

## Kidney cancer roundup

Pfizer Inc. says that its oral drug Inlyta (axitinib) has been granted European approval for use as a second-line therapy for kidney cancer patients, according to Reuters News. The drug, already approved in the United States, has been approved in Europe as a second-line treatment for patients who have not responded to initial chemotherapy.

The company announced that the approval was based on data from a clinical trial showing that the drug significantly extended progression-free survival in patients who did not respond to treatment with a different Pfizer drug, Sutent.

In January 2012, axitinib was approved in the United States for the same indication as the European approval. Axitinib works by inhibiting proteins that can influence tumor growth and cancer progression.

Renal cell carcinoma (RCC) affects 102,000 people in Europe every year, the company reported.

In other kidney cancer news, Seattle Genetics has embarked on a clinical trial to assess the safety of its monoclonal antibody–based therapy for advanced kidney cancer. The phase 1b trial will also measure the compound's ability to fight the tumors safely. The compound, called SGN-75, is taken in combination with a cancer drug called everolimus to treat kidney cancer. Everolimus is an oral prescription medication used to treat advanced RCC when certain other medicines, such as sunitinib or sorafenib, have not worked.

SGN-75 is an antibody-drug conjugate composed of an antibody attached to a synthetic cell-killing agent, using Seattle Genetics' proprietary technology, according to the website *Investor Report*.

"We are encouraged by the preliminary single-agent activity and tolerability demonstrated by SGN-75 in RCC patients and by our preclinical data suggesting synergy," with drugs like everolimus, called mTOR inhibitors, said Jonathan Drachman, MD, senior vice president of research and translational medicine at Seattle Genetics. He said that his company looks forward to learning whether the combination "can provide therapeutic benefit to patients who currently have limited treatment options."

According to Seattle Genetics, the study is expected to enroll up to 40 patients at several centers in the United States and is enrolling patients who have previously been treated with one or two tyrosine kinase inhibitor drugs.

## Fresenius still largest nephrology quality data registry

For the fourth consecutive year since a federal data registry program was launched in 2007, Fresenius' chronic kidney disease data registry has been the largest registry for nephrology. Fresenius and dozens of other registries have gained admittance as official registries in the federal program that requires physician quality-indicator reporting. That program, the Physicians Quality Reporting System (PQRS) is administered by the Centers for Medicare and Medicaid Services (CMS).

The Fresenius registry, known as Acumen PQRS, has been a qualified CMS data registry since 2009. In 2015, participation will be required of all eligible medical professionals who are eligible to report the work as described by the required indicators. The PQRS federal program was designed to enhance the quality of information reported by health care professionals.

"Acumen PQRS will continue to provide nephrologists with the best data registry for their practices," said Terry Ketchersid, MD, vice president and medical officer for Fresenius Medical Care, who directs the Acumen registry. "We are committed to maintaining our level of excellence."

The program uses both financial incentives and penalties to ensure high-quality reporting. The system pays physicians incentive bonuses for appropriate and correct use of registry reporting of quality measures. Beginning in 2015, eligible professionals who don't participate will face a payment adjustment.

The Acumen database added 700 new reporting members last year, Fresenius reported.

Each year, the measures can change in content. The Renal Physicians Association (RPA) has taken an active role in developing the nephrology measures used by the program. On September 4, the group wrote to Marilyn Tavenner, acting administrator for CMS, and asked for consideration of the same suggested quality measures submitted to CMS nearly a year ago, in October 2011. An example of a suggested quality measure would be percentage of calendar months within a 12-month period during which patients 18 years old and older with a diagnosis of ESRD who were receiving hemodialysis or peritoneal dialysis had a hemoglobin level below 10 g/dL.

The American Medical Association notes that "the CMS believes these quality initiatives aim to empower providers and consumers with information that would support the overall delivery and coordination of care, and ultimately would support new payment systems that provide more financial resources to provide improved quality care." Currently CMS reimburses for the volume of covered services.

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