Holy OPPS!

BY LEAH RALPH

On July 13, 2017, the Centers for Medicare & Medicaid Services (CMS) released its CY 2018 proposed Hospital Outpatient Prospective Payment System (OPPS) and Physician Fee Schedule (PFS) rules. The proposed OPPS rule was the big news this year, signaling major changes may be in store for hospital reimbursement in 2018. The agency is proposing significant reduction in payment for drugs purchased under the 340B Drug Pricing Program and further reimbursement reductions for new off-campus provider-based departments (PBDs).

While the 340B Program has grown, and reform has been widely debated by policymakers over the past decade, CMS' rule proposes to fundamentally alter the program (notably a program that is not within CMS' purview). The agency is proposing to reduce Medicare reimbursement for separately payable drugs without pass-through status purchased through the 340B Program from average sale price (ASP) plus 6 percent to ASP minus 22.5 percent. Because CMS cannot currently identify 340B drugs in Medicare OPPS claims data, to better understand the breadth of the program, the agency also proposes to require that hospitals submitting claims for separately payable drugs *not* acquired through the 340B Program use a modifier on the claim in order to be reimbursed at ASP plus 6 percent. Significantly, as written, the agency's proposal would put the onus on all hospitals—340B *and* non-340B—to identify when drug claims should *not* be reimbursed at the reduced rate. ACCC continues to work through the details of the proposal and meet with policymakers and other stakeholders to put forward meaningful, workable solutions for reforming the 340B Program. Join us at our National Oncology Conference, Oct. 18-20, in Nashville, Tenn., to learn more about CMS' proposal and ACCC's advocacy efforts around this issue.

CMS also proposes to double down on its site-neutral payment policy from last year and further reduce reimbursement for non-excepted PBDs. In general, these are entities that began billing Medicare as an off-campus PBD after November 2015. For these non-excepted PBDs, the agency is proposing to decrease payment from 50 to 25 percent of OPPS rates. CMS expressed concern that paying 50 percent of the OPPS rate might result in payments for items and services that are greater than would otherwise be paid to physician offices under the PFS. Early analysis by ACCC, however, shows that reimbursement at 25 percent of OPPS will be well below PFS rates for certain services.

Another significant change proposed relates to packaging of drug administration services. Currently, CMS excludes packaging of drug administration services (i.e., those costing less than or equal to $100) from the ancillary services packaging policy. The agency is proposing to change that policy by packaging Level 1 and 2 drug administration services when these services are performed with another separately payable service, but paying for them separately when performed alone. CMS believes that conditional packaging of drug administration services will promote equitable payment between physician offices and hospital outpatient departments. ACCC disagrees with the agency's rationale and will be urging CMS not to finalize this policy.

CMS is also soliciting comments on the "14-Day Rule," a policy that determines when a hospital may bill Medicare for a clinical diagnostic laboratory test versus when the laboratory performing the test may bill Medicare directly. CMS is considering potential modifications to the "14-Day Rule" that would allow labs to bill Medicare directly for molecular pathology tests and advanced diagnostic laboratory tests. ACCC played an active role in requesting that this policy be reopened for public comment.

With respect to payment for biosimilars, in the PFS rule, CMS is continuing its approach from 2016. Despite the expanding biosimilars market and promise of lower costs, the agency is maintaining its stance that biosimilars will generally share a single HCPCS code and that these products will be grouped into the same payment calculation for the purposes of determining a single ASP payment limit.

CMS is taking comments on both the OPPS and PFS CY 2018 proposed rules through Sept. 11, 2017, and seeking open-ended comments from the public on policies that would maintain flexibility and efficiencies in the Medicare program while reducing unnecessary burdens for clinicians and patients. ACCC is busy drafting its comments and we want to hear from *you*. Please contact Leah Ralph, Health Policy Director, at lralph@accc-cancer.org with your input. We also encourage you to submit comments directly to CMS at regulations.gov. OI

Leah Ralph is ACCC Director of Health Policy.