Regulatory Season is Over

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About the Authors

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The Centers for Medicare & Medicaid Services (CMS) issued its 2011 final rules for its Physician Fee Schedule (PFS) and Hospital Outpatient Prospective Payment System (HOPPS).[1] The PFS and HOPPS final rules were published in the November 24 and November 29, 2010, Federal Registers, respectively, and the comment periods for both rules closed on January 3, 2011. This column examines the impact of these final rules for the biopharmaceutical industry and, in particular, for specialty drugs.

The PFS Final Rule

The PFS Final Rule implements of key provisions related to specialty drugs enacted by the Affordable Care Act (ACA). These payment policy changes will apply to services furnished on or after January 1, 2011.

1. Payment for Biosimilar Biological Products

CMS adopted the reimbursement formula (ASP plus 6% of the innovator ASP) set forth in the ACA for biological products licensed by the FDA as biosimilar or interchangeable biological products (FOBs). The ACA created the framework for a new regulatory approval pathway within the FDA for biosimilar and interchangeable biological products, as well as market exclusivity for new biologics to incentivize innovation. The term "biosimilar" refers to an officially-approved subsequent version of an innovator biopharmaceutical product made by a different sponsor following patent and exclusivity expiry on the innovator product.

2. "Carry-Over" ASP

"Carry-over" ASP refers to CMS' use of previously reported ASP data for the next quarter if the agency does not receive the required pricing information in a timely manner from a manufacturer. In the final rule, CMS established a new methodology that would carry over the most recently reported ASP for purposes of calculating the Medicare payment rate when the reported ASP is unavailable.

CMS stated it will limit the use of the carry-over ASP to those cases where missing data results in a 10% or greater change in the ASP payment limit compared with the previous quarter. CMS also finalized its proposal with the limitation that the carryover policy applies to multiple source drugs only.

3. ASP "Overfill"

Overfill is the small quantity of medication that pharmaceutical manufacturers include in drug vials to help assure that appropriate doses of the drug can be withdrawn from the vial for administration. In recent years, however, it has been alleged that certain manufacturers include excess amounts of overfill as a marketing ploy.

CMS's final PFS rule updates its regulations to clearly state that Medicare ASP payment limits are based on the amount of product in the vial or container as reflected on the FDA-approved label. CMS also proposed to update its regulations to clearly state that payment for amounts of product in excess of the amount reflected on the FDA-approved label is prohibited.

Partial Quarter ASP Data

CMS will continue their policy of pricing new single source drugs at Wholesale Acquisition Cost (WAC), or the manufacturer's list price to drug to wholesalers or direct purchasers, for the drug's first quarter. CMS also stated that it will add National Drug Codes for new multiple source drugs and product line expansions of single source drugs to the ASP-based payment rate calculation for a quarter as soon as these products are reported.

The HOPPS Final Rule

1. Payment for Pass-through and Non-pass–through Drugs

CMS grants pass-through status to some new medications, which allows hospitals to receive additional reimbursement for the products. Pass-through status is effective for at least 2 years, but no more than 3 years. CMS's initial HOPPS rule proposed to pay for separately payable drugs and biologicals *without* pass-through status at ASP plus 6%. CMS noted that most commenters voiced support for CMS' proposed ASP plus 6%; however, the agency's final rule set payment at ASP plus 5%. CMS stated in its final rule that Pass-through drugs (a relatively small category of newer drugs) will continue to be paid at ASP plus 6%, which is unchanged from 2010.

2. Payment for Therapeutic Radiopharmaceuticals

The final HOPPS rule proposed to continue to reimburse all non-pass-through, separately payable therapeutic radiopharmaceuticals at the same rate as non-pass-through drugs and biologicals (ASP plus 6%) based on ASP information, if available, for a "patient ready" dose and updated on a quarterly basis for products for which manufacturers report ASP data. If ASP data are not available, CMS proposed to use CY 2009 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals. ***SPT***

References

1. PFS CY2011 Final Rule available at http://edocket.access.gpo.gov/2010/pdf/2010-27969.pdf; HOPPS CY2011 Final Rule available at http://edocket.access.gpo.gov/2010/pdf/2010-27926.pdf.