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Exploring government pricing and reimbursement policy challenges associated with biosimilars

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The Biologics Price Competition and Innovation Act (BPCIA) were signed into law on March 23, 2010 as part of the Patient Protection and Affordable Care Act (PPACA). BPCIA's announcement of a new Food and Drug Administration (FDA) regulatory pathway for the approval of bio-similar products has created several government pricing and reimbursement policy challenges. The proposed presentation will discuss the coverage, reimbursement and related strategy questions from the perspective of both an experienced reimbursement counsel and a reference product manufacturer. Reimbursement issues discussed during this joint presentation will include the impact of Average Sales Price (ASP) and non-ASP reimbursement systems and the crucial distinction between the bio-similar and inter-changeability standards. The potential for National Coverage Determinations, Local Coverage Determinations and innovation reimbursement reforms will also be discussed, as will value-based contracting approaches.

Biography

William A Sarraille is a senior member of the Healthcare Practice group and a nationally-recognized lawyer in healthcare law. He concentrates on a variety of healthcare matters, including Medicare and Medicaid reimbursement, coverage and coding, pharmaceutical price reporting, issues related to the marketing and promotion of pharmaceuticals and medical devices, internal investigations, clinical research issues, Stark and Anti-Kickback Law analyses, Medicare and Medicaid audits, healthcare acquisitions and due diligence, compliance program audits, managed care matters, healthcare contracts, administrative litigation, legislative matters, coverage for new devices and services, the representation of witnesses and companies before Congressional Committees and the defense of healthcare criminal and False Claims Act matters.

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