How can pharmaceutical and life sciences companies comply with the increasing demands of government price reporting?

Various governmental regulatory and oversight organisations continue to scrutinise pharmaceutical companies’ government price reporting practices. Government investigations have led to negotiations and settlements with the Office of the Inspector General (OIG), requiring several pharmaceutical manufacturers to comply with the terms and conditions of a Corporate Integrity Agreement (CIA). CIAs, which can last from five to eight years, are costly, consume internal resources and are challenging to implement. The Deficit Reduction Act of 2005 (DRA) and Final Rule, published July 2007, poses new challenges to the pharmaceutical manufacturer as both updated the Medicaid rules around reporting frequency, calculation methodologies, treatment of authorised generics and other obligations. In addition to the ASP requirement, the Final Rule includes certifying the accuracy of the AMP and BP calculations by the manufacturer’s CEO, CFO, or an individual who reports directly to them and who has delegated authority to sign on their behalf. In addition, the calculation of Average Sales Price (ASP) through the enactment of the Medicare Prescription Drug, Improvement, and Modernisation Act of 2003 (MMA), coupled with the increased scrutiny placed on reporting to comply with Sarbanes-Oxley has brought a heightened level of attention to this area. These circumstances have forced pharmaceutical manufacturers to examine the policies, procedures and controls associated with government price reporting and the core transaction system used to calculate these reportable amounts. Companies need to assess whether discrepancies exist between policy and practice and between regulatory and legislative guidance and develop steps to remediate gaps.

How can PwC help your organisation?

PwC provides comprehensive government price reporting compliance services that assess the policies, procedures and systems which support the submission of pricing information to federal and state agencies. We understand the complexity surrounding the pharmaceutical industry’s underlying sales and marketing information systems, promotional and discounting programmes, and the issues that rise when applying them to complex and at times, unclear government reporting requirements. PwC brings the following experience to the table:

- We have reviewed policies, procedures, systems and controls that support government price-reporting and claims-processing requirements. We have helped clients develop new policies and implement process improvements identified during our review. Additionally, we have assess government price reporting calculations, focusing on the calculation methodologies for:
  - Medicare ASP
  - Medicaid Average Manufacturer Price (AMP) and Best Price (BP)
  - Public Health Service (PHS) pricing
  - Federal Supply Schedule (FSS), Non-federal Average Manufacturer Price (Non-FAMP) and Federal Ceiling Price (FCP)
  - Various other government agency price-reporting requirements
Working with senior management, internal and external counsel, and the government, we have assisted pharmaceutical manufacturers negotiate and implement CIAs and develop the Independent Review Organisation (IRO) workplan. In fact, PwC serves as the IRO for many CIAs currently in place within the pharmaceutical industry. This distinction attests to our extensive skill in developing and executing efficient and effective procedures to test compliance.

We have significant experience helping companies respond to US Department of Justice inquiries, evaluating concerns regarding historical government pricing practices and preparing refilings with the Centers for Medicare and Medicaid Services (CMS), the Veterans Administration (VA) or others. Related PwC services include:

- Leveraging technology to efficiently identify and retrieve finance, sales and accounting information necessary for government pricing calculations
- Calculations government pricing, including Medicaid rebate (i.e., AMP/BP), Medicare ASP, PHS, FSS and VA pricing
- Analysing potential financial exposure related to previously reported government pricing
- Helping corporate management assess ASP calculation accuracy before management’s quarterly certification and filing with CMS